

ARENA PHARMACEUTICALS INC  
Form 10-Q  
August 05, 2013

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

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended June 30, 2013

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

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>23-2908305</b> (I.R.S. Employer Identification No.)
<b>6154 Nancy Ridge Drive, San Diego, CA</b> (Address of principal executive offices)	<b>92121</b> (Zip Code)
<b>858.453.7200</b> (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 <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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 July 30, 2013:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	218,253,685

**ARENA PHARMACEUTICALS, INC.**

**INDEX**

**PART I FINANCIAL INFORMATION**

Item 1.	<u>Financial Statements</u>	1
	<u>Condensed Consolidated Balance Sheets As of June 30, 2013, and December 31, 2012</u>	1
	<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) Three and Six Months Ended June 30, 2013, and 2012</u>	2
	<u>Condensed Consolidated Cash Flow Statements Six Months Ended June 30, 2013, and 2012</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>	13
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4.	<u>Controls and Procedures</u>	22

**PART II OTHER INFORMATION**

Item 1.	<u>Legal Proceedings</u>	23
Item 1A.	<u>Risk Factors</u>	23
Item 6.	<u>Exhibits</u>	46

	<u>Signatures</u>	47
--	-------------------	----

In this Quarterly Report on Form 10-Q, Arena Pharmaceuticals, Arena, we, us and our refer to Arena Pharmaceuticals, Inc., and our wholly owned subsidiaries on a consolidated basis, unless the context otherwise provides. APD is an abbreviation for Arena Pharmaceuticals Development.

Arena Pharmaceuticals®, Arena® and our corporate logo are registered 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.

BELVIQ (pronounced BEL-VEEK) is the trade name for lorcaserin hydrochloride in the United States. While lorcaserin hydrochloride 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.

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

	<b>June 30, 2013 (Unaudited)</b>	<b>December 31, 2012<sup>1</sup></b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 178,905	\$ 156,091
Accounts receivable	1,096	5,556
Inventory	7,245	6,058
Prepaid expenses and other current assets	3,174	3,454
Total current assets	190,420	171,159
Land, property and equipment, net	73,898	75,417
Acquired technology and other intangibles, net	9,939	10,611
Other non-current assets	3,697	4,019
Total assets	\$ 277,954	\$ 261,206
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 13,293	\$ 7,123
Accrued compensation	3,639	3,087
Current portion of deferred revenues	7,801	15,453
Current portion of derivative liabilities	0	2,587
Current portion of lease financing obligations	1,855	1,664
Total current liabilities	26,588	29,914
Deferred rent	180	122
Deferred revenues, less current portion	45,382	47,282
Derivative liabilities, less current portion	9,041	12,455
Lease financing obligations, less current portion	71,821	72,794
Commitments and contingencies		
Stockholders' equity:		
Common stock	22	22
Additional paid-in capital	1,287,704	1,281,426
Accumulated other comprehensive income	4,290	5,489
Accumulated deficit	(1,167,074)	(1,188,298)
Total stockholders' equity	124,942	98,639
Total liabilities and stockholders' equity	\$ 277,954	\$ 261,206

- <sup>1</sup> The balance sheet data at December 31, 2012, 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.

## Arena Pharmaceuticals, Inc.

## Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except per share data)

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
<b>Revenues:</b>				
Net product sales	\$ 1,319	\$ 0	\$ 1,319	\$ 0
Eisai collaborative revenue	66,465	20,919	67,960	21,778
Manufacturing services	973	1,029	1,738	2,321
Other collaborative revenue	170	29	283	67
Total revenues	68,927	21,977	71,300	24,166
<b>Operating Costs and Expenses:</b>				
Cost of product sales	581	0	1,054	0
Cost of manufacturing services	1,009	652	2,654	1,443
Research and development	18,828	14,076	32,836	28,546
General and administrative	8,603	5,216	15,854	11,571
Amortization of acquired technology and other intangibles	0	173	0	349
Total operating costs and expenses	29,021	20,117	52,398	41,909
Income (Loss) from operations	39,906	1,860	18,902	(17,743)
<b>Interest and Other Income (Expense):</b>				
Interest income	16	25	40	40
Interest expense	(1,778)	(2,489)	(3,565)	(5,520)
Gain (Loss) from valuation of derivative liabilities	2,142	(16,770)	6,001	(19,145)
Loss on extinguishment of debt	0	(4,668)	0	(6,338)
Other	(186)	(57)	(154)	30
Total interest and other income (expense), net	194	(23,959)	2,322	(30,933)
Net income (loss)	40,100	(22,099)	21,224	(48,676)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	0	0	0	(2,824)
Net income (loss) allocable to common stockholders	\$ 40,100	\$ (22,099)	\$ 21,224	\$ (51,500)
<b>Net income (loss) per share allocable to common stockholders:</b>				
Basic	\$ 0.18	\$ (0.12)	\$ 0.10	\$ (0.29)
Diluted	\$ 0.18	\$ (0.12)	\$ 0.09	\$ (0.29)
<b>Shares used in calculating net income (loss) per share allocable to common stockholders:</b>				
Basic	217,940	190,272	217,723	177,243
Diluted	224,528	190,272	224,551	177,243
<b>Comprehensive Income (Loss):</b>				

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

Net income (loss)	\$ 40,100	\$ (22,099)	\$ 21,224	\$ (48,676)
Foreign currency translation gain (loss)	389	(2,234)	(1,199)	(547)
Comprehensive income (loss)	\$ 40,489	\$ (24,333)	\$ 20,025	\$ (49,223)

See accompanying notes to unaudited condensed consolidated financial statements.

## Arena Pharmaceuticals, Inc.

## Condensed Consolidated Cash Flow Statements

(In thousands)

(Unaudited)

	Six months ended June 30,	
	2013	2012
<b>Operating Activities</b>		
Net income (loss)	\$ 21,224	\$ (48,676)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	3,877	4,724
Amortization of acquired technology and other intangibles	194	349
Share-based compensation	4,223	2,361
(Gain) Loss from valuation of derivative liabilities	(6,001)	19,145
Amortization of prepaid financing costs	68	224
Loss on disposal or sale of equipment	6	0
Accretion of note payable to Deerfield	0	1,225
Loss on extinguishment of debt	0	6,338
Changes in assets and liabilities:		
Accounts receivable	4,404	(19,907)
Inventory	(1,225)	0
Prepaid expenses and other assets	264	(940)
Accounts payable and accrued liabilities	1,578	(2,498)
Deferred revenues	(3,189)	3,231
Deferred rent	58	(61)
Net cash provided by (used in) operating activities	25,481	(34,485)
<b>Investing Activities</b>		
Purchases of land, property and equipment	(3,150)	(636)
Proceeds from sale of equipment	32	0
Other non-current assets	257	37
Net cash used in investing activities	(2,861)	(599)
<b>Financing Activities</b>		
Principal payments on lease financing obligations	(782)	(612)
Principal payments on note payable to Deerfield	0	(22,261)
Proceeds from issuance of common stock	2,011	127,612
Proceeds from issuance of preferred stock	0	16,463
Net cash provided by financing activities	1,229	121,202
Effect of exchange rate changes on cash	(1,035)	61
Net increase in cash and cash equivalents	22,814	86,179
Cash and cash equivalents at beginning of period	156,091	57,632
Cash and cash equivalents at end of period	\$ 178,905	\$ 143,811
<b>Supplemental Disclosure Of Non-Cash Investing and Financing Information:</b>		
Conversion of preferred stock into common stock	\$ 0	\$ 14,561
Retirement of treasury stock	\$ 0	\$ 23,070



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

Deemed dividend related to beneficial conversion feature of convertible preferred stock	\$	0	\$	2,824
---	----	---	----	-------

See accompanying notes to unaudited condensed consolidated financial statements.

## Notes to Unaudited Condensed Consolidated Financial Statements

### 1. Basis of Presentation and BELVIQ Launch

#### *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, 2012, as filed with the Securities and Exchange Commission, or SEC, from which we derived our balance sheet as of December 31, 2012. 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 February 2013, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2013-02, Comprehensive Income (Topic 220) Clarifying Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. Under ASU No. 2013-02, companies are required to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, companies are required to present, either on the face of the financial statements or in the accompanying notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, companies are required to cross-reference to other disclosures that provide additional detail on those amounts. ASU No. 2013-02 is effective prospectively for reporting periods beginning after December 15, 2012. ASU No. 2013-02 did not impact our disclosures because the balance included in accumulated other comprehensive income related only to foreign currency translation, for which there were no reclassifications in any periods reported.

In March 2013, the FASB issued ASU No. 2013-05, Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity, which requires the release of any related cumulative translation adjustment into net income when a parent ceases to have a controlling financial interest in a subsidiary or group of assets that is a business within a foreign entity. ASU No. 2013-05 is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. We do not expect the adoption of ASU No. 2013-05 to have a material impact on our consolidated financial statements.

The preparation of financial statements in accordance with GAAP requires our management to make estimates and assumptions that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. The amounts reported could differ under different estimates and assumptions.

#### *BELVIQ Launch*

In June 2013, BELVIQ, our internally discovered drug for chronic weight management in adults who are overweight with a comorbidity or obese, was made available to patients by prescription in the United States. Eisai Inc., or Eisai, is responsible for the marketing and distribution of BELVIQ under the Amended and Restated Marketing and Supply Agreement, or Eisai BELVIQ Agreement, between Eisai and our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH. (See Note 6.)

### 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 -

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

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.

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

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 June 30, 2013, and December 31, 2012, in thousands:

	Fair Value Measurements at June 30, 2013			
	Balance at June 30, 2013	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>	\$ 108,786	\$ 108,786	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrants	\$ 9,041	\$ 0	\$ 0	\$ 9,041

	Fair Value Measurements at December 31, 2012			
	Balance at December 31, 2012	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>	\$ 143,747	\$ 143,747	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrants	\$ 15,042	\$ 0	\$ 0	\$ 15,042

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

The following table presents the activity for our derivative liabilities, which are classified as Level 3 in our valuation hierarchy, during the three and six months ended June 30, 2013, in thousands:

	Three months ended June 30, 2013	Six months ended June 30, 2013
Beginning balance	\$ 11,183	\$ 15,042
Gain from valuation of derivative liabilities	(2,142)	(6,001)
Balance at June 30, 2013	\$ 9,041	\$ 9,041

## 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, which is stated at the lower of cost (using a first-in, first-out basis) or market, relates to BELVIQ. The costs of manufacturing BELVIQ associated with deferred revenues are recorded as deferred costs, which are included in finished goods inventory until such time as the related deferred revenue is recognized. Our inventory consisted of the following as of June 30, 2013, and December 31, 2012, in thousands:

	June 30, 2013	December 31, 2012
Raw materials	\$ 405	\$ 423
Work in process	1,995	4,184
Finished goods	4,845	1,451

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

Total inventory	\$ 7,245	\$ 6,058
-----------------	----------	----------

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

Accounts payable and other accrued liabilities consisted of the following as of June 30, 2013, and December 31, 2012, in thousands:

	June 30, 2013	December 31, 2012
Payable to collaborators (See Note 6)	\$ 6,348	\$ 0
Accounts payable	2,525	3,884
Accrued expenses	2,789	2,006
Accrued clinical and preclinical study fees	1,254	566
Loss provision	315	482
Other accrued liabilities	62	185
<b>Total accounts payable and other accrued liabilities</b>	<b>\$ 13,293</b>	<b>\$ 7,123</b>

#### 5. 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. As a result of the warrant's anti-dilution provision and certain subsequent equity issuances at prices below the adjustment price of \$6.72 defined in the Series B Warrants, the number of shares issuable upon exercise of the warrants increased and the exercise price decreased. In June 2013, a portion of the June 2006 Series B Warrant was exercised to purchase 10,000 shares of our common stock, resulting in net proceeds to us of \$0.1 million, and the remaining portion of the June 2006 Series B Warrant to purchase 1,457,405 shares of common stock expired pursuant to its terms in June 2013. As of June 30, 2013, the number of shares issuable upon exercise of the outstanding August 2008 Series B Warrant was 1,965,418 at an exercise price of \$4.34 per share. The outstanding August 2008 Series B Warrant is recorded as a derivative liability on our condensed consolidated balance sheets.

Our derivative liabilities consisted of the following as of June 30, 2013, and December 31, 2012, in thousands:

	June 30, 2013	December 31, 2012
Series B Warrants - current portion	\$ 0	\$ 2,587
Series B Warrants, less current portion	9,041	12,455
<b>Total derivative liabilities</b>	<b>\$ 9,041</b>	<b>\$ 15,042</b>

Our outstanding warrants are revalued on each balance sheet date, with changes in the fair value between reporting periods recorded as other income or expense. At June 30, 2013, and December 31, 2012, the outstanding Series B Warrants were valued using the Black-Scholes option pricing model and the following assumptions:

	June 30, 2013	December 31, 2012	
	August 2008 Series B Warrant	June 2006 Series B Warrant	August 2008 Series B Warrant
Risk-free interest rate	0.4%	0.1%	0.3%
Dividend yield	0%	0%	0%
Expected volatility	79%	66%	93%
Expected life (years)	2.12	0.50	2.62



The change in the fair value of our derivative liabilities between reporting periods is recorded in the interest and other income (expense) section of our condensed consolidated statements of operations and comprehensive income (loss). We recognized the following gain (loss) in the three and six months ended June 30, 2013, and 2012, in thousands:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Series B Warrants	\$ 2,142	\$ (16,770)	\$ 6,001	\$ (19,200)
Deerfield acceleration right	0	0	0	55
<b>Total gain (loss) from valuation of derivative liabilities</b>	<b>\$ 2,142</b>	<b>\$ (16,770)</b>	<b>\$ 6,001</b>	<b>\$ (19,145)</b>

The Deerfield acceleration right, which we previously recorded as a derivative liability, related to a formerly outstanding right to require us to accelerate principal payments under our formerly outstanding loan from certain Deerfield entities. Until this right was terminated in May 2012, such right was revalued on each balance sheet date.

## 6. Marketing and Supply Agreement with Eisai Inc.

In May 2012, Arena GmbH and Eisai entered into the Eisai BELVIQ 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 Mexico, Canada and Brazil, subject to applicable regulatory approval in the additional territories. Under this agreement, we provide services related to development and regulatory activities, and we also manufacture and sell BELVIQ to Eisai. We are also entitled to receive upfront payments, milestone payments based on the achievement of regulatory filings and approvals, one-time purchase price adjustment payments and other payments, and payments from sales of BELVIQ.

The following table summarizes the revenues we have recognized under the Eisai BELVIQ Agreement in the three and six months ended June 30, 2013, and 2012, in thousands:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Net product sales	\$ 1,319	\$ 0	\$ 1,319	\$ 0
Milestone payments	65,500	20,000	66,000	20,000
Amortization of upfront payments	861	919	1,723	1,778
Reimbursements of development and patent expenses	104	0	237	0
<b>Total</b>	<b>\$ 67,784</b>	<b>\$ 20,919</b>	<b>\$ 69,279</b>	<b>\$ 21,778</b>

We manufacture and sell BELVIQ to Eisai for marketing and distribution in the United States and, subject to applicable regulatory approval, in the additional territories under our 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 BELVIQ Agreement that are estimated by Eisai based on their experience, including deductions for certain taxes, credits, allowances, discounts, rebates, chargebacks, returns and other items), or the Product Purchase Price, in all of such territories on an aggregate basis. The Product 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 product sales exceeding \$750.0 million, subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country. The Eisai BELVIQ 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 Mexico, Canada or Brazil. In addition, we are eligible to receive up to an aggregate of \$1.19 billion in one-time purchase price adjustment payments and other payments based on Eisai's annual net product 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 product 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 product 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 product 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.



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

In November 2012, we received \$11.6 million for BELVIQ product supply delivered to Eisai pursuant to an initial order under the Eisai BELVIQ Agreement, which was recorded as deferred revenues. The amount received for such product supply was based on Eisai's estimated price at the time the order was placed, which did not include deductions for certain items related to product launch. The price that Eisai pays us for BELVIQ product supply is Eisai's estimate of the actual Product Purchase Price,

and is subject to change on April 1 and October 1 of each year. At the end of Eisai's fiscal year (March 31), the estimated price paid to us for product that Eisai sold to their distributors is compared to the actual Product Purchase Price of such product, and the difference is either refunded back to Eisai (for overpayments) or paid to us (for underpayments). On a monthly basis, Eisai provides us the total amount of net sales for the month, the detailed total deductions from gross sales to net sales and the sales in units. We recognize our revenues monthly based on our percentage of Eisai's monthly net sales figures. When the revenues we recognize differ from the estimated price Eisai paid us for such product, the difference is reclassified from deferred revenues to a receivable or payable account, as appropriate. We also adjust the deferred revenue balance for the product supply held at Eisai based on the most current net product sales figures provided to us, with the difference reclassified from deferred revenues to a receivable or payable account. At March 31 of each year, the amount recorded as receivable or payable will be settled by the applicable party.

In June 2013, BELVIQ was made available to patients by prescription in the United States. We recognize revenues from net product sales when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. We recognize revenue when Eisai ships BELVIQ to their distributors. Eisai's estimated deductions used to determine net sales are subject to revision, and could result in material adjustments to our recognized revenues if actual deductions differ materially from Eisai's original estimates.

We recognized \$1.3 million of revenues from net product sales in the three months ended June 30, 2013. The estimated price of the product supply sold in the quarter was lower than the estimated price that Eisai paid us for the initial product supply, which did not include deductions for certain items related to product launch. The difference of \$6.3 million between the estimated price that Eisai paid us for the product supply and the estimated price the product was sold at during the quarter, for both the amounts sold in the quarter and the product supply remaining in Eisai's inventory at June 30, 2013, was reclassified from deferred revenues to payable to collaborators (see Note 4) at June 30, 2013.

Revenues from the upfront payments we received of \$50.0 million when we entered into the original agreement and \$5.0 million when we entered into the amended agreement were deferred, as we determined that the exclusive rights did not have standalone value without our ongoing development and regulatory activities. These payments are being recognized ratably as revenue over the periods in which we expect the services to be rendered, which are approximately 16 years and 13 years, respectively.

In the three months ended June 30, 2013, we recognized \$65.0 million in milestones earned upon the final scheduling designation of the US Drug Enforcement Administration, or DEA, for BELVIQ and a \$0.5 million milestone earned upon Eisai filing for regulatory approval of BELVIQ in Canada. In the three months ended March 31, 2013, we recognized a \$0.5 million milestone earned upon Eisai filing for regulatory approval of BELVIQ in Mexico. We are also entitled to receive from Eisai up to \$53.5 million of additional non-refundable milestone payments based on achievement of regulatory filings and approvals. Under the milestone method of revenue recognition, we recognize revenue for the amount payable to us for achieving each substantive milestone payment, if any, in the period the milestone is achieved.

The following table summarizes the deferred revenues attributable to Eisai as of June 30, 2013, and December 31, 2012, in thousands:

	June 30, 2013	December 31, 2012
Upfront payments	\$ 44,417	\$ 46,140
Product sales	3,932	11,594
<b>Total deferred revenues attributable to Eisai</b>	<b>48,349</b>	<b>57,734</b>
Less current portion	(7,378)	(15,040)
<b>Deferred revenues attributable to Eisai, less current portion</b>	<b>\$ 40,971</b>	<b>\$ 42,694</b>

With respect to the post-marketing studies Eisai and we committed to conduct as part of the FDA approval of BELVIQ, Eisai and we will be responsible for 90% and 10%, respectively, of the expenses for the cardiovascular outcomes trial, and we will share equally with Eisai the expenses 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 and we will be responsible for 90% and 10%, respectively, of the expenses for such work, with the exception of the expenses for stability testing, which we will share equally with Eisai. In addition, with respect to any non-FDA required development work we may conduct 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.

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

Eisai will indemnify Arena GmbH for losses resulting from certain third-party claims, including for (a) Eisai's negligence, willful misconduct or violation of law, (b) Eisai's breach of the Eisai BELVIQ Agreement or related agreements, (c) certain uses or misuses of BELVIQ, (d) certain governmental investigations of Eisai related to BELVIQ, and (e) infringement relating to Eisai's use

of certain trademarks related to BELVIQ. Arena GmbH will indemnify Eisai for losses resulting from certain US product liability claims and third-party claims, including for (i) Arena GmbH's negligence, willful misconduct, failure to comply with law, breach of any agreement with a third party with respect to product development prior to the effective date of the original agreement with Eisai, (ii) Arena GmbH's negligence or willful misconduct with respect to certain uses or misuses of BELVIQ outside of the agreement, (iii) certain uses or misuses of BELVIQ after the term of the agreement or in any territory no longer under the agreement, (iv) Arena GmbH's negligence, willful misconduct or violation of law, (v) Arena GmbH's breach of the Eisai BELVIQ Agreement or related agreements; (vi) certain infringement of intellectual rights of a third party; and (vii) infringement relating to Eisai's use of certain trademarks related to BELVIQ. In addition, each of Arena GmbH and Eisai will share equally in losses resulting from third-party product liability claims in the territories added with the Eisai BELVIQ Agreement, except to the extent caused by one party's negligence, willful misconduct, violation of law or breach or default of the Eisai BELVIQ Agreement or certain other agreements between the parties. We are unable to predict the maximum potential amount of any future payment for such product liability indemnification provisions. As of June 30, 2013, we have not incurred any significant costs under these indemnification provisions.

Eisai may terminate the Eisai BELVIQ Agreement with respect to the United States or any country in the additional territories following the later of the expiration of all issued BELVIQ patents in such country and 12 years after the first commercial sale of BELVIQ in such country. Either party has the right to terminate the Eisai BELVIQ Agreement early in certain circumstances, including (a) if the other party is in material breach, (b) for commercialization concerns, and (c) for certain intellectual property infringement. Eisai also has the right to terminate the Eisai BELVIQ Agreement early in its entirety or with respect to each country in certain circumstances, including (i) termination in a country if sales of generic equivalents of BELVIQ in such country exceed sales of BELVIQ in that country (based on volume), and (ii) if Eisai is acquired by a company that has a product that competes with BELVIQ. In addition, we can terminate the Eisai BELVIQ Agreement early in its entirety or with respect to each country in the additional territories in certain circumstances, including termination in each country if Eisai does not satisfy certain regulatory filing and commercialization diligence requirements in such country.

## 7. Stockholders' Equity

### *Equity Compensation Plan*

On June 10, 2013, our stockholders approved our 2013 Long-Term Incentive Plan, or 2013 LTIP. Upon such approval, our 2012 Long-Term Incentive Plan, or 2012 LTIP, was terminated. However, notwithstanding such termination or the previous termination of our 2009 Long-Term Incentive Plan, 2006 Long-Term Incentive Plan, as amended, 2002 Equity Compensation Plan, Amended and Restated 2000 Equity Compensation Plan, and Amended and Restated 1998 Equity Compensation Plan (together with the 2012 LTIP, the "Prior Plans"), all outstanding awards under the Prior Plans will continue to be governed under the terms of the Prior Plans. The number of shares of common stock authorized for issuance under the 2013 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 2013 LTIP.

The 2013 LTIP provides for the grant of a total of 30 million shares of our common stock (subject to adjustment for certain corporate events), as (i) decreased for grants made under the Prior Plans between December 31, 2012, and the approval of the 2013 LTIP and (ii) increased by the number of shares subject to any stock awards under the Prior Plans that, between December 31, 2012, and the approval of the 2013 LTIP, are forfeited, expire or settled for cash and as otherwise provided in the 2013 LTIP. When approved by our stockholders, there were 26,720,370 shares of common stock available for issuance under the 2013 LTIP. As of June 30, 2013, there were 26,581,647 shares of common stock available for issuance under the 2013 LTIP.

Shares under the 2013 LTIP may be granted as incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards. Subject to certain limited exceptions, stock options and stock appreciation rights granted under the 2013 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 2013 LTIP reduce the available number of shares by 1.25 shares for every share issued. In addition, shares that are released from awards granted under the Prior Plans or the 2013 LTIP because the awards expire, are forfeited or are settled for cash will increase the number of shares available under the 2013 LTIP by one share for each share released from a stock option or stock appreciation right and by 1.25 shares for each share released from a restricted stock award or restricted stock unit award.

Stock options granted under the 2013 LTIP generally vest 25% a year for four years and are exercisable for up to seven 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. Restricted stock unit awards generally vest over one or four years from the date of grant. 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 2013 LTIP prohibits option and stock appreciation right repricings (other than to reflect stock splits, spin-offs or certain other corporate events) without stockholder approval.



### Issuances of Common Stock

In the six months ended June 30, 2013, we issued a total of 552,730 shares of our common stock pursuant to stock option exercises and a total of 196,029 shares of our common stock under our employee stock purchase plan, resulting in net proceeds to us of \$1.6 million and \$0.3 million, respectively. In addition, in June 2013, we issued 10,000 shares of our common stock pursuant to the exercise of a portion of the then-outstanding June 2006 Series B Warrant to purchase shares of our common stock at \$8.76 per share, resulting in net proceeds to us of \$0.1 million.

### Share-based Compensation

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

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Cost of product sales	\$ 0	\$ 0	\$ 17	\$ 0
Research and development	1,134	540	1,858	707
General and administrative	1,305	414	2,348	1,654
Total share-based compensation expense	\$ 2,439	\$ 954	\$ 4,223	\$ 2,361

Upon receiving FDA approval for BELVIQ in June 2012, we began to capitalize into inventory share-based compensation related to awards granted to BELVIQ manufacturing employees. Such compensation will subsequently be recognized as cost of product sales when the related inventory is sold. A total of \$0.1 million of share-based compensation was capitalized as of June 30, 2013.

### Share-based Award Activity

The following table summarizes our stock option activity during the six months ended June 30, 2013, in thousands (except per share data):

	Options	Weighted-Average Exercise Price
Outstanding at January 1, 2013	13,842	\$ 4.44
Granted	1,436	8.52
Exercised	(553)	2.88
Forfeited/cancelled/expired	(161)	6.35
Outstanding at June 30, 2013	14,564	\$ 4.88

The following table summarizes activity with respect to our restricted stock unit awards, or RSUs, which have a service condition, during the six months ended June 30, 2013, in thousands (except per share data):

	RSUs	Weighted-Average Grant-Date Fair Value
Outstanding at January 1, 2013	165	\$ 8.87
Granted	131	8.81
Vested	0	
Forfeited/cancelled	0	

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

Outstanding at June 30, 2013	296	\$	8.84
------------------------------	-----	----	------

In March 2013, we granted our executive officers Total Stockholder Return, or TSR, performance restricted stock unit, or PRSU, awards. The PRSUs may be earned and converted into outstanding shares of our common stock based on the TSR of our common stock relative to the TSR over a three-year performance period beginning March 1, 2013, of the NASDAQ Biotech Index. In the aggregate, the target number of shares of common stock that may be earned under the PRSUs is 780,000; however, the actual number of shares that may be earned ranges from 0% to 200% of such amount. As these awards contain a market condition, we used a Monte Carlo simulation model to estimate the grant-date fair value of the PRSUs, and determined related share-based compensation expense. The table below sets forth the assumptions used to value the awards at the date of grant and the estimated grant-date fair value:

Risk-free interest rate	0.4%
Dividend yield	0%
Expected volatility	89%
Remaining performance period (years)	2.99
Estimated fair value per share of PRSUs granted	\$ 7.50

## 8. Concentration of Credit Risk and Major Customers

Financial instruments, which potentially subject us to concentrations of credit risk, consist primarily of cash and cash equivalents. We limit our exposure to credit loss by holding our cash primarily in US dollars or, from time to time, 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 the exclusive distributor and our only customer for BELVIQ in most of North and South America, and BELVIQ has only received marketing approval in the United States. We also produce drug products for Siegfried AG, or 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:

Source of Revenue	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Eisai BELVIQ Agreement	98.3%	95.2%	97.2%	90.1%
Manufacturing services agreement with Siegfried	1.4%	4.7%	2.4%	9.6%
Other collaborative agreements	0.3%	0.1%	0.4%	0.3%
Total percentage of revenues	100.0%	100.0%	100.0%	100.0%

## 9. Net Income (Loss) Per Share

We calculate basic and diluted net income (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 outstanding subject to repurchase or forfeiture for the three and six months ended June 30, 2013, or 2012.

When we are in a net loss position, we exclude outstanding stock options, RSUs and PRSUs, all of which are subject to forfeiture, as well as warrants and 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 for such periods. When we report net income, the weighted-average number of shares used to calculate our diluted net income per share includes the potential diluted effect of in-the-money securities, using the treasury stock method.

The table below reconciles the number of shares used to calculate basic and diluted net income (loss) per share for the periods presented, in thousands.

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Weighted-average shares outstanding	217,940	190,272	217,723	177,243
Potentially dilutive common shares outstanding:				
Stock options	5,603		5,815	
Warrants	920		951	
RSUs and unvested restricted stock	65		62	
Weighted-average shares used to calculate diluted net income (loss) per share	224,528	190,272	224,551	177,243



The table below presents the potentially dilutive securities that would have been included in the above calculation of diluted net income (loss) per share allocable to common stockholders if they were not antidilutive for the periods presented, in thousands.

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Stock options	4,057	4,085	3,204	1,747
Warrants	0	8,106	0	6,006
RSUs	30	0	0	0
Unvested restricted stock	0	79	0	79
<b>Total</b>	<b>4,087</b>	<b>12,270</b>	<b>3,204</b>	<b>7,832</b>

Because the market condition for the PRSUs was not satisfied at June 30, 2013, such securities are excluded from the tables above.

## 10. 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. On March 28, 2013, the Court granted our motion to dismiss the consolidated amended complaint without prejudice. On May 13, 2013, the plaintiff filed a new consolidated amended complaint. On June 14, 2013, we filed a motion to dismiss the new consolidated amended complaint. On July 15, 2013, the plaintiff filed an opposition to our motion to dismiss. On July 29, 2013, we filed our reply. 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. On March 29, 2013, the Court granted our motion to dismiss, in part without prejudice. On May 13, 2013, the plaintiff filed a new amended complaint. On June 14, 2013, we filed a motion to dismiss the new amended complaint. On July 10, 2013, the plaintiff filed an opposition to our motion to dismiss. On July 29, 2013, we filed our reply. Due to the stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

**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, 2012, or 2012 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 lorcaserin hydrochloride 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 target G protein-coupled receptors to address unmet medical needs. Our US operations are located in San Diego, California, and our operations outside of the United States, including our commercial manufacturing facility, are located in Zofingen, Switzerland.

In June 2013, BELVIQ, our internally discovered drug for chronic weight management in adults who are overweight with a comorbidity or obese, was made available to patients by prescription in the United States. Eisai Inc., or Eisai, is responsible for the marketing and distribution of BELVIQ under the Amended and Restated Marketing and Supply Agreement, or Eisai BELVIQ Agreement, between Eisai and our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH.

Under the Eisai BELVIQ Agreement, Eisai has the marketing and distribution rights for BELVIQ in most of North and South America, including the United States, Mexico, Canada and Brazil. Arena GmbH also has marketing and supply agreements with Ildong Pharmaceutical Co., Ltd., or Ildong, for BELVIQ in South Korea, which we refer to as the Ildong BELVIQ Agreement, and with CY Biotech Company Ltd., or CYB, in Taiwan, which we refer to as the CYB BELVIQ Agreement. We continue to own rights to market and distribute BELVIQ outside of these territories. The marketing of BELVIQ is subject to regulatory approval for the particular territory.

Our collaborators are responsible for filing applications for regulatory approval of BELVIQ in the territories covered under the respective agreement. Eisai filed applications for regulatory approval of BELVIQ in Mexico and Canada in March and June of 2013, respectively, and we expect that Eisai will also submit an application for regulatory approval of BELVIQ in Brazil in the near term. In addition, as part of its planned submission for regulatory approval of BELVIQ in South Korea, Ildong initiated a pharmacokinetic study for BELVIQ in South Korea, and we expect Ildong to submit an application for approval of BELVIQ in the near term.

In June 2013, in connection with the final scheduling designation of BELVIQ by the US Drug Enforcement Administration, or DEA, we received \$65.0 million in milestone payments from Eisai. In connection with the applications for regulatory approval filed in Mexico and Canada, we received milestone payments of \$0.5 million each from Eisai. We also expect to receive additional payments from Eisai in 2013 from sales of BELVIQ. In addition, we received a net upfront payment of \$2.0 million in connection with entry into the CYB BELVIQ Agreement.

We intend to seek regulatory approval of BELVIQ in additional territories that are not currently under collaboration. Outside of our collaborations, we have a pending marketing authorization application, or MAA, for regulatory approval of BELVIQ in Switzerland. In February 2013, Swissmedic provided feedback to our MAA in the form of a list of questions with major objections. We responded to the list of questions in writing, and we subsequently received a preliminary determination from Swissmedic that those concerns have not been satisfied. We expect to continue discussions with the intent of addressing Swissmedic's concerns.



We previously filed an MAA for regulatory approval of BELVIQ in the European Union. We did not believe we could resolve the major objections identified by the European Medicines Agency's Committee for Medicinal Products for Human Use, or CHMP, prior to the time we expected the CHMP to issue its final opinion, and, therefore, decided to withdraw the BELVIQ MAA for the European Union. We are evaluating submitting in Europe at a later date.

In addition to commercializing BELVIQ as a monotherapy for chronic weight management, we intend to explore BELVIQ's therapeutic potential in combination with other drugs and for other indications. We recently completed dosing in a study to evaluate the safety, tolerability and pharmacokinetic properties of the co-administration of BELVIQ and phentermine, and we are in the process of analyzing the results. In addition, we expect Eisai to initiate a pilot study to evaluate the safety of co-administration of BELVIQ and phentermine over 12 weeks. We expect that results from these combination studies will help us evaluate options for possible further development of BELVIQ in combination.

We also intend to utilize our GPCR-focused discovery and development approach to selectively advance other of our internally discovered, oral drug candidates, which include (i) APD811, an agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension, for which dosing has been completed in a Phase 1 trial; (ii) temanogrel, an inverse agonist of the serotonin 2A receptor intended for the treatment of thrombotic diseases, which has completed single- and multiple-ascending dose Phase 1 trials and is expected to complete an additional Phase 1 trial in healthy volunteers and potentially a Phase 2a proof-of-concept trial in patients under our Co-Development and License Agreement with Ildong; (iii) APD334, an agonist of the sphingosine 1-phosphate subtype 1, or S1P<sub>1</sub>, receptor intended for the treatment of a number of conditions related to autoimmune diseases, for which dosing has been completed in a Phase 1 trial; and (iv) APD371, an agonist of the cannabinoid receptor 2 intended for the treatment of pain, which is in preclinical development. Our research and development pipeline also includes GPR119 agonists intended for the treatment of type 2 diabetes. With respect to APD334, preliminary results show a reduction in blood lymphocyte count, the desired benefit, and a slowing of heart rate, an undesirable adverse event seen with other drugs targeting the S1P<sub>1</sub> receptor. Further evaluation of the data is ongoing.

Developing marketed drugs is a long, uncertain and expensive process, and our ability to achieve our goals, including furthering the commercialization of BELVIQ, obtaining regulatory approval of, and commercializing, BELVIQ in additional territories, conducting required post-marketing and other 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 generated limited revenues from sales of BELVIQ, which is our first and only drug approved by any regulatory authority. Even though we recorded net income in the three and six months ended June 30, 2013, we may 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 our existing collaborative agreements, 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.

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

## 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 June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Net product sales	\$ 1.3	\$ 0.0	\$ 1.3	\$ 0.0
Milestone payments from Eisai	65.5	20.0	66.0	20.0
Manufacturing services agreement with Siegfried	1.0	1.1	1.7	2.3
Amortization of upfront payments from Eisai	0.9	0.9	1.7	1.8
Reimbursements of development and patent expenses from Eisai	0.1	0.0	0.3	0.0
Other collaborative agreements	0.1	0.0	0.3	0.1
<b>Total revenues</b>	<b>\$ 68.9</b>	<b>\$ 22.0</b>	<b>\$ 71.3</b>	<b>\$ 24.2</b>

### Research and development expenses

Type of expense	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 6.9	\$ 5.3	\$ 13.7	\$ 10.9
External clinical and preclinical study fees and expenses (including non-commercial manufacturing costs)	6.3	4.2	8.4	8.7
Facility and equipment costs	2.6	2.8	5.1	5.6
Research supplies	1.2	0.7	2.5	1.4
Non-cash share-based compensation	1.1	0.5	1.8	0.7
Other	0.7	0.6	1.3	1.2
<b>Total research and development expenses</b>	<b>\$ 18.8</b>	<b>\$ 14.1</b>	<b>\$ 32.8</b>	<b>\$ 28.5</b>

**General and administrative expenses**

Type of expense	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 2.9	\$ 2.1	\$ 5.4	\$ 4.2
Legal, accounting and other professional fees	2.4	1.3	4.4	3.0
Facility and equipment costs	1.2	1.0	2.3	2.0
Non-cash share-based compensation	1.3	0.4	2.4	1.6
Other	0.8	0.4	1.4	0.8
Total general and administrative expenses	\$ 8.6	\$ 5.2	\$ 15.9	\$ 11.6

**THREE MONTHS ENDED JUNE 30, 2013, AND 2012**

**Revenues.** We recognized revenues of \$68.9 million for the three months ended June 30, 2013, compared to \$22.0 million for the three months ended June 30, 2012. This increase was primarily due to (i) \$65.0 million of non-refundable milestone payments from Eisai that we earned in connection with the DEA's final scheduling designation of BELVIQ, (ii) \$1.3 million from net product sales of BELVIQ and (iii) a \$0.5 million non-refundable milestone payment that we earned in connection with Eisai filing an application for regulatory approval of BELVIQ in Canada. The revenue recognized for the three months ended June 30, 2012, included a \$20.0 million non-refundable milestone payment from Eisai that we earned in connection with approval of BELVIQ by the US Food and Drug Administration, or FDA.

When collaborators pay us before revenues are earned, we record such payments as deferred revenues until earned. As of June 30, 2013, we had a total of \$53.2 million in deferred revenues. Of such amount, \$44.4 million is attributable to upfront payments we received under the Eisai BELVIQ Agreement, \$3.9 million is attributable to the BELVIQ product supply delivered to Eisai in October 2012 and \$4.8 million is attributable to the upfront payment we received under the Ildong BELVIQ Agreement.

Absent any new collaborations, we expect our 2013 revenues will primarily consist of the \$66.0 million of milestone payments from Eisai earned to date in 2013 and net product revenues from sales of BELVIQ. We also expect to recognize revenues in 2013 from amortization of the upfront payments we received from Eisai, Ildong and CYB, as well as manufacturing services revenues from Siegfried.

Revenues for milestones that may be achieved in the future and from sales of BELVIQ are difficult to predict, and our revenues will likely vary significantly from quarter to quarter and year to year. We expect that this will particularly be the case in 2013 as we transition from a research and development company to a company with a marketed drug.

With respect to the United States, Eisai made BELVIQ available to patients in June 2013. We expect that Eisai's sales of BELVIQ will increase, but, due to the early stage of commercialization, it is difficult to predict the amount of such sales or the related revenues we will generate. Future sales of BELVIQ will depend on, among other factors, the availability and use of BELVIQ, changes to Eisai's marketing program and insurance coverage. Revenues we generate from Eisai's sales of BELVIQ depend on Eisai's net sales of BELVIQ, which are the gross invoiced sales less certain deductions, including deductions for certain taxes, credits, allowances, discounts, rebates, chargebacks, returns and other items. Deductions from gross sales to net sales may vary from period to period, particularly in the near term, depending on the amount and extent of such deductions, which include deductions for vouchers, coupons or other promotions for free or discounted product.

In addition to revenues from the commercialization of BELVIQ in the United States, we expect that any significant revenues in the short term will depend on 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.

**Cost of product sales.** Cost of product sales consists primarily of direct and indirect costs related to manufacturing BELVIQ, including, among other costs, salaries, share-based compensation and other personnel costs, machinery depreciation costs and amortization expense related to our manufacturing facility production licenses. Upon receiving FDA approval of BELVIQ in June 2012, we began to capitalize inventory costs for BELVIQ, which will be subsequently recognized as cost of product sales when the related inventory is sold. We recognized cost of product sales of \$0.6 million for the three months ended June 30, 2013. We did not record any such cost for the three months ended June 30, 2012, which was prior to FDA approval of BELVIQ.

**Cost of manufacturing services.** Cost of manufacturing services consists primarily of direct and indirect costs associated with manufacturing drug products for Siegfried under our amended manufacturing services agreement, including related salaries, other personnel costs, machinery

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

depreciation costs and amortization expense related to our manufacturing facility production licenses. Cost of manufacturing services increased by \$0.3 million to \$1.0 million for the three months ended June 30, 2013, from \$0.7 million for the three months ended June 30, 2012. This increase was primarily related to our contract loss provision for these services, which is the result of providing the services at sales prices that are less than our costs.

**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 increased by \$4.7 million to \$18.8 million for the three months ended June 30, 2013, from \$14.1 million for the three months ended June 30, 2012. This was primarily due to increases of (i) \$2.1 million in external clinical and preclinical study fees and expenses, (ii) \$1.6 million in salary and other personnel costs, primarily as a result of increases in headcount post FDA approval of BELVIQ, and (iii) \$0.6 million in non-cash share-based compensation expense. We expect to continue to incur substantial research and development expenses in 2013, which may include non-FDA required development work relating to BELVIQ that may be significant depending on whether, and to what extent, a collaborator shares the expenses. We expect our research and development expenses in 2013 will be substantially higher than in 2012.

Included in the \$6.3 million of total external clinical and preclinical study fees and expenses noted in the table above for the three months ended June 30, 2013, was \$3.2 million related to non-commercial manufacturing and other development costs related to BELVIQ, \$1.3 million related to APD811, \$1.1 million related to APD334 and \$0.6 million related to APD371. Included in the \$4.2 million total external clinical and preclinical study fees and expenses noted in the table above for the three months ended June 30, 2012, was \$3.4 million related to non-commercial manufacturing and other development costs related to BELVIQ and \$0.8 million related to APD371.

**General and administrative expenses.** General and administrative expenses increased by \$3.4 million to \$8.6 million for the three months ended June 30, 2013, from \$5.2 million for the three months ended June 30, 2012. This was primarily due to increases of (i) \$0.9 million in non-cash share-based compensation expense, (ii) \$0.8 million in patent fees and (iii) \$0.8 million in salary and other personnel costs. We expect that our 2013 general and administrative expenses will be higher than in 2012.

**Amortization of acquired technology and other intangibles.** We recognized \$0.2 million for amortization of acquired technology and other intangibles related to our manufacturing facility production licenses for the three months ended June 30, 2012. Subsequent to the FDA approval of BELVIQ in June 2012, amortization expense is included in manufacturing overhead costs and is, therefore, recognized as cost of product sales when product sales are recorded, or as cost of manufacturing services related to manufacturing drug products for Siegfried under our amended manufacturing services agreement.

**Interest and other income (expense), net.** Interest and other income (expense), net, increased to income of \$0.2 million for the three months ended June 30, 2013, from an expense of \$24.0 million for the three months ended June 30, 2012. This \$24.2 million increase was primarily due to (i) a \$2.1 million non-cash gain from revaluation of our derivative liabilities for the three months ended June 30, 2013, compared to a \$16.8 million loss for the three months ended June 30, 2012, (ii) a \$4.7 million non-cash loss on extinguishment of debt recognized for the three months ended June 30, 2012, and (iii) a \$0.7 million decrease in interest expense due to the May 2012 payoff of our then outstanding loan from certain Deerfield entities.

## SIX MONTHS ENDED JUNE 30, 2013, AND 2012

**Revenues.** We recognized revenues of \$71.3 million for the six months ended June 30, 2013, compared to \$24.2 million for the six months ended June 30, 2012. This increase was primarily due to (i) \$65.0 million of non-refundable milestone payments from Eisai that we earned in connection with the DEA's final scheduling designation of BELVIQ, (ii) \$1.3 million from net product sales of BELVIQ and (iii) two non-refundable milestone payments of \$0.5 million each that we earned in connection with Eisai filing applications for regulatory approval of BELVIQ in Mexico and Canada. The revenue recognized for the six months ended June 30, 2012, included a \$20.0 million non-refundable milestone payment from Eisai that we earned in connection with approval of BELVIQ by the FDA.

**Cost of product sales.** We recognized cost of product sales of \$1.1 million for the six months ended June 30, 2013, which included unused capacity costs totaling \$0.5 million for one month in which no BELVIQ manufacturing was performed. We did not record any such cost for the six months ended June 30, 2012.

**Cost of manufacturing services.** Cost of manufacturing services increased by \$1.3 million to \$2.7 million for the six months ended June 30, 2013, from \$1.4 million for the six months ended June 30, 2012. This increase was primarily related to our contract loss provision for these services, which is the result of providing the services at sales prices that are less than our costs.

**Research and development expenses.** Research and development expenses increased by \$4.3 million to \$32.8 million for the six months ended June 30, 2013, from \$28.5 million for the six months ended June 30, 2012. This was primarily due to increases of (i) \$2.8 million in salary and



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

other personnel costs, (ii) \$1.1 million in research supplies and (iii) \$1.1 million in non-cash share-based compensation expense. Included in the \$8.4 million of total external clinical and preclinical study fees and expenses noted in the table above for the six months ended June 30, 2013, was \$4.7 million related to non-commercial manufacturing and other development costs related to BELVIQ, \$1.6 million related to APD811, \$1.2 million related to APD334 and \$0.6 million related to APD371. Included in the \$8.7 million of total external clinical and preclinical study fees and expenses for the six months ended June 30, 2012, was \$7.7 million related to non-commercial manufacturing and other development costs related to BELVIQ and \$0.9 million related to APD371.

**General and administrative expenses.** General and administrative expenses increased by \$4.3 million to \$15.9 million for the six months ended June 30, 2013, from \$11.6 million for the six months ended June 30, 2012. This was primarily due to increases of (i) \$1.2 million in salary and other personnel costs, (ii) \$1.0 million in patent fees and (iii) \$0.8 million in non-cash share-based compensation expense.

**Amortization of acquired technology and other intangibles.** We recognized \$0.3 million for amortization of acquired technology and other intangibles related to our manufacturing facility production licenses for the six months ended June 30, 2012, and none for the six months ended June 30, 2013.

**Interest and other income (expense), net.** Interest and other income (expense), net, increased to income of \$2.3 million for the six months ended June 30, 2013, from an expense of \$30.9 million for the six months ended June 30, 2012. This \$33.2 million increase was primarily due to (i) a \$6.0 million non-cash gain from revaluation of our derivative liabilities for the six months ended June 30, 2013, compared to a \$19.1 million loss for the six months ended June 30, 2012, (ii) a \$6.3 million non-cash loss on extinguishment of debt recognized for the six months ended June 30, 2012, and (iii) a \$2.0 million decrease in interest expense.

**Deemed dividend related to beneficial conversion feature of convertible preferred stock.** We recorded a deemed dividend of \$2.8 million in the six months ended June 30, 2012, upon the issuance of our formerly outstanding Series D Convertible Preferred Stock. We did not record any such dividend in the six months ended June 30, 2013.

## 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 recent US launch of BELVIQ and related payments received and expected from our collaborators, we may incur substantial losses for at least the short term as a result of manufacturing and commercializing BELVIQ, conducting required post-marketing and other 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 June 30, 2013, we had \$178.9 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. We expect that our 2013 operating expenses will be substantial as we continue to fund BELVIQ-related activities, and, at the same time, selectively advance certain of our research and development programs.

In addition to payments expected from Eisai based on net product sales of BELVIQ, other potential sources of liquidity in the short term include (i) payments from Eisai upon achievement of additional milestones, (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 and (iii) the sale or lease of facilities or other assets we own.

We 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 BELVIQ 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 BELVIQ Agreement that are estimated by Eisai based on their experience, including deductions for certain taxes, credits, allowances, discounts, rebates, chargebacks, returns 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), including in the event of generic competition in the applicable country.

As part of the FDA's approval of BELVIQ, 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 patients 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 and we will be responsible for 90% and 10%, respectively, of the expenses for the cardiovascular outcomes trial, and we will share equally with Eisai the expenses of certain pediatric studies. In addition, with respect to any non-FDA required development work we may conduct 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 BELVIQ 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 and we will be responsible for 90% and 10%, respectively, of the expenses for such work, with the exception of the expenses for stability testing, which we will share equally with Eisai. In addition, Ildong and CYT are responsible for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in South Korea and Taiwan, respectively, including related development costs and other expenses.

To date, we have obtained cash and funded our operations primarily through equity financings, payments from collaborators, the issuance of debt and related financial instruments and sale leaseback transactions. Although we expect that payments related to the commercialization of BELVIQ may be substantial in the short term, we expect to 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.

#### *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 existing collaborations, 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 post-marketing and other studies. As described above under short term, we will be responsible for a portion of the expenses for BELVIQ development work required by regulatory agencies. In addition, with respect to any non-FDA required development work we may conduct 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.

Subject to applicable regulatory approval, we expect Eisai to commercialize BELVIQ in additional territories in North and South America. The Eisai BELVIQ 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 Mexico, Canada or Brazil. In addition, we are eligible to receive up to an aggregate of \$1.19 billion in one-time purchase price adjustment payments and other payments based on Eisai's annual net product 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 product 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 product 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 product 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 additional milestone payments totaling \$53.5 million based on achievement of regulatory filings and approvals.

Under the Ildong BELVIQ Agreement and CYB BELVIQ Agreement, we are eligible to receive additional payments upon regulatory approval, as well as payments from sales of BELVIQ. We will manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Ildong and CYB. 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 potential payments from Eisai and other collaborators, as well as funds from public and private financial markets, potential sources of liquidity in the long term include (i) upfront, milestone, 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 of \$25.5 million was provided by operating activities in the six months ended June 30, 2013, compared to net cash of \$34.5 million used in operating activities in the six months ended June 30, 2012. This change was primarily the result of the \$65.5 million of milestone payments received in the six months ended June 30, 2013.

Net cash used in investing activities increased by \$2.3 million to \$2.9 million in the six months ended June 30, 2013, compared to \$0.6 million in the six months ended June 30, 2012. 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 2013 capital expenditures will increase significantly over the 2012 amount due to deferrals of capital spending in previous years.

Net cash of \$1.2 million was provided by financing activities in the six months ended June 30, 2013, as a result of net proceeds of \$1.9 million from stock option exercises and purchases under our employee stock purchase plan, and \$0.1 million from the exercise of a portion of the then-outstanding June 2006 Series B Warrants to purchase 10,000 shares of our common stock. Such proceeds were partially offset by \$0.8 million for payments on our lease financing obligations. Net cash of \$121.2 million was provided by financing activities in the six months ended June 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) \$27.9 million, after prepayment of \$5.0 million of loan principal, from the sale 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) to certain Deerfield entities, (iii) \$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., and (iv) \$12.8 million from Deerfield's exercise of warrants to purchase 7,642,179 shares of our common stock using cash. Such proceeds were partially offset by principal repayments to Deerfield totaling \$22.3 million.

#### **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, to a lesser extent, 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, milestone payments and net product sales. We recognize revenue when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Any advance payments we receive in excess of amounts earned are classified as deferred revenues until earned or as payable to collaborators on our consolidated balance sheets.

We manufacture and sell BELVIQ to Eisai for marketing and distribution in the United States and, subject to applicable regulatory approval, in the additional territories. The net sales price Eisai pays us for product supply for sales in the United States starts at 31.5% of their gross sales price, less their estimated deductions, including for certain taxes, credits, allowances, discounts, rebates, chargebacks, returns and other items. We defer recognition of revenue at the time we sell BELVIQ to Eisai because we presently do not have the ability to estimate product that may be returned to us. Instead, we recognize net product sales when Eisai ships BELVIQ to their distributors. Eisai's estimated deductions used to determine net sales are subject to revision, and could result in material adjustments to our recognized revenues if actual deductions differ materially from Eisai's original estimates.

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 deliverable represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer. Items are considered to have standalone value if they could be sold separately by any vendor or if the customer could resell the item on a standalone basis. If these criteria are not met, we combine the deliverable with the applicable undelivered elements, 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, have 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 income (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 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.

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 income (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 are revalued on each subsequent balance sheet date until such instruments are exercised or expire, with 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 use the Black-Scholes option pricing model to estimate the grant-date fair value for stock options and options to purchase



stock granted under our employee stock purchase plan that vest based on a service condition, and a Monte Carlo simulation model for awards with market conditions. These models are affected by our stock price on the date of grant, as well as assumptions regarding other subjective variables that 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. A Monte Carlo simulation model also takes into account the effect of applicable market conditions and the possibility that the condition may not be satisfied. Changes in the assumptions used could have a material impact on the compensation expense we recognize. The grant-date fair value of restricted stock unit awards is based on the closing price of our common stock on the date of grant.

We recognize compensation expense for all of our outstanding share-based awards ratably on a straight-line basis over the requisite service period. For awards with market conditions, we recognize compensation expense ratably on a straight-line basis over the requisite service period regardless of whether the market condition is satisfied, provided that the requisite service period has been met.

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 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 2012 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.*

#### **New Accounting Guidance**

In February 2013, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2013-02, Comprehensive Income (Topic 220) Clarifying Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. Under ASU No. 2013-02, companies are required to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, companies are required to present, either on the face of the financial statements or in the accompanying notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, companies are required to cross-reference to other disclosures that provide additional detail on those amounts. ASU No. 2013-02 is effective prospectively for reporting periods beginning after December 15, 2012. ASU No. 2013-02 did not impact our disclosures because the balance included in accumulated other comprehensive income related only to foreign currency translation, for which there were no reclassifications in any periods reported.

In March 2013, the FASB issued ASU No. 2013-05, Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity, which requires the release of any related cumulative translation adjustment into net income when a parent ceases to have a controlling financial interest in a subsidiary or group of assets that is a business within a foreign entity. ASU No. 2013-05 is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. We do not expect the adoption of ASU No. 2013-05 to have a material impact on our consolidated financial statements.

#### **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, 2012.

#### **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.





## 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. On March 28, 2013, the Court granted our motion to dismiss the consolidated amended complaint without prejudice. On May 13, 2013, the plaintiff filed a new consolidated amended complaint. On June 14, 2013, we filed a motion to dismiss the new consolidated amended complaint. On July 15, 2013, the plaintiff filed an opposition to our motion to dismiss. On July 29, 2013, we filed our reply. 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. On March 29, 2013, the Court granted our motion to dismiss, in part without prejudice. On May 13, 2013, the plaintiff filed a new amended complaint. On June 14, 2013, we filed a motion to dismiss the new amended complaint. On July 10, 2013, the plaintiff filed an opposition to our motion to dismiss. On July 29, 2013, we filed our reply. Due to the stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

### 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 risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our Annual Report on Form 10-K for the year ended December 31, 2012, 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 is the trade name for lorcaserin hydrochloride in the United States. While lorcaserin hydrochloride 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.*

#### *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 may be materially adversely affected and the price of our common stock may decline.**

We are focusing a significant portion of our activities and resources on BELVIQ, which is our first and only drug approved by the US Food and Drug Administration, or FDA. 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 identified in other risk factors, and BELVIQ may not receive marketing approval from any other regulatory agency. If the results or timing of regulatory filings, the regulatory process, regulatory developments, commercialization, clinical trials or preclinical studies, or other activities, actions or decisions related to BELVIQ do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

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

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 June 2013, BELVIQ became available to patients in the United States by prescription, and is being marketed in the United States by Eisai Inc., or Eisai, under a marketing and supply agreement, or Eisai BELVIQ Agreement, between Eisai and our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH. Under the Eisai BELVIQ Agreement, we also granted Eisai exclusive rights to market and distribute BELVIQ in most of the other territories in North and South America. In addition, Arena GmbH has entered into marketing and supply agreements with Ildong Pharmaceutical Co., or Ildong, for South Korea and with CY Biotech Company Ltd., or CYB, for Taiwan, granting them exclusive rights to market and distribute BELVIQ in the respective territories for weight loss or weight management in obese and overweight patients, subject to applicable regulatory approval. We refer collectively to all of these marketing and supply agreements as the BELVIQ Agreements.

We expect that revenues under the Eisai BELVIQ Agreement (and, to a lesser extent, the marketing and supply agreements with Ildong and CYB) 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 future BELVIQ product sales or achievement of any other milestones under these agreements.

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 BELVIQ Agreements. In addition to pending regulatory applications, we plan to seek, independently or under collaboration, regulatory approval for BELVIQ in other territories. There is no assurance that any pending or future regulatory applications will be approved. For example, we decided to withdraw our Marketing Authorization Application, or MAA, for BELVIQ in the European Union. 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 risks identified in other risk factors:

the successful commercial introduction (or 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);

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, including related decisions by any such entity or individual;

incidence and severity of any side effects, including as a result of off-label use or in combination with one or more drugs;

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;

the current or future scheduling designation for BELVIQ by the US Drug Enforcement Administration, or DEA;

Eisai's 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 (including discounting or other promotions) and perceived cost-effectiveness;

the ability of patients and physicians and other providers to obtain and maintain sufficient coverage or 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;

introduction of counterfeit or unauthorized versions of BELVIQ;

to the extent BELVIQ is approved and marketed in a jurisdiction with a significantly lower price than in another jurisdiction, the impact of the lower pricing in the higher-priced territory, including on the pricing of reimbursement, if available, and by the diversion of low-priced BELVIQ into the higher-priced territory; 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, including due to the limitations for use in the product label, which may be more restrictive in different territories. 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 we may not be profitable.

**\*Data generated or analyzed with respect to product use in the market or required post-marketing or other studies 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. With respect to BELVIQ, Eisai, we and others will assess and monitor the safety of BELVIQ in the marketplace, and we will receive reports of adverse safety events. 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. From time to time, we or others may conduct additional studies, clinical trials or analyses of BELVIQ, including in connection with seeking regulatory approval of BELVIQ outside of the United States, in combination with other drugs, for other indications or using different formulations.

New data relating to BELVIQ, including from adverse event reports, required post-marketing and other 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, may adversely affect sales or result in withdrawal of BELVIQ from the market and may adversely affect prospects of developing or commercializing BELVIQ in combination with other drugs, for other indications or using different formulations. 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 greater restrictions on sales. Such guidelines or recommendations may lead to lower sales of BELVIQ.

**\*Forecasting of BELVIQ sales will be difficult, and if BELVIQ 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 for BELVIQ despite numerous uncertainties, which may be increased because we rely to at least some extent on our collaborators, particularly Eisai, providing us accurate and timely information. Actual results may deviate materially from projected results for various reasons, including the following, as well as risks identified in other risk factors:

the rate of adoption in the United States;

uncertainty related to pricing (including discounting or other promotions), reimbursement, product returns or recalls, competition, labeling, DEA scheduling, adverse events and others items that may impact commercialization;

lack of patient and physician familiarity with BELVIQ;

lack of patient use and physician prescribing history;

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

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

actual sales to patients may significantly differ from expectations based on sales to wholesalers;

our collaborators under the BELVIQ Agreements control the commercialization of BELVIQ in most of North and South America, South Korea and Taiwan, including related strategy and their allocation of resources, and we expect that any future collaborators for BELVIQ will similarly control the commercialization in the applicable territory; and

uncertainty relating to when BELVIQ may become commercially available to patients and rate of adoption in other territories.

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, increased difficulty in operational planning and higher than desired expenditures. Revenue shortfalls would have a negative impact on our cash flow and on our business in general. We expect that our revenues from BELVIQ will continue to be based in part on estimates, judgment and accounting policies, and incorrect estimates or regulators' or others' disagreement regarding such estimates or accounting policies may result in changes to guidance or previously reported results. For example, with respect to the commercialization of BELVIQ in the United States, our revenues are based on information we receive from Eisai, including their estimates of deductions for certain items, such as taxes, credits, allowances, discounts, rebates, chargebacks and returns, which are subject to significant judgment. We expect to continue to recognize revenues upon Eisai's sales to wholesalers. As BELVIQ is sold through to patients, if the actual level of deductions differ materially from Eisai's estimates, this could have a material impact on our revenues. In addition, expected and actual product sales and quarterly and other 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 not be 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 will continue to be substantial for at least the short term.

The revenues we may generate from sales of BELVIQ are uncertain and difficult to forecast. 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. We also intend to explore BELVIQ's therapeutic potential in combination with other drugs, for other indications or using different formulations. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical compound or drug candidate into a marketed drug, and our efforts may not result in marketed drugs.

We cannot assure you that any additional payments we may receive under the BELVIQ Agreements will be sufficient to fund our planned research and development and other activities. We will need to enter into marketing and supply agreements or other arrangements with one or more pharmaceutical companies, or obtain additional funds, to 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 market 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.

We cannot assure you that we will be profitable or, if we are profitable for any particular time period, that we will be profitable in the future. In addition, 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 and dilute your ownership in our company.



---

**\*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 may be materially adversely affected and our stock price may decline.**

In July 2012, we filed an MAA for BELVIQ in Switzerland with the Swiss health authority, Swissmedic, in March 2013, Eisai filed an MAA for BELVIQ in Mexico with the Federal Commission for the Protection Against Sanitary Risk, or COFEPRIS, and, in June 2013, Eisai Limited, a subsidiary of Eisai, filed a New Drug Submission for BELVIQ in Canada. We expect our collaborators will seek regulatory approval for the marketing of BELVIQ in additional territories under the BELVIQ 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 we or any of our collaborators will file for regulatory approval in additional territories, any other regulatory authority will grant marketing approval for BELVIQ or the expected timeframe of any such approval. For example, as described below, we decided to withdraw our MAA for BELVIQ in the European Union. As another example, VIVUS, Inc., announced in October 2012 that, despite the FDA's approval of its drug candidate for the treatment of obesity, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, 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 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, in January 2013, we received the Day 180 List of Outstanding Issues from the EMA's CHMP. The Day 180 List of Outstanding Issues identified major objections related to nonclinical and clinical issues, including tumors in rats, valvulopathy and psychiatric events, and the CHMP requested that we further justify BELVIQ's overall benefit-risk balance taking these issues into consideration. The major objections needed to be addressed before the CHMP could have recommended BELVIQ for marketing approval in the European Union. In accordance with the CHMP's process, we were asked to respond in writing, we were invited by the CHMP to provide an oral explanation, and we expected the CHMP to reach its final opinion at nominal Day 210, which, accounting for anticipated clock stoppages during the regulatory process, we expected to occur in the first half of 2013. Following our written response to the Day 180 List of Outstanding Issues and our April 2013 oral explanation, the CHMP's view was that certain major objections remained outstanding that precluded a recommendation for approval of the BELVIQ MAA at such time. We did not believe we could resolve the major objections related to the results of nonclinical studies prior to the time we expected the CHMP to issue its final opinion, and, therefore, we decided to withdraw the BELVIQ MAA for the European Union. We are evaluating submitting in Europe at a later date, but we may not submit for approval when expected or ever.

With respect to Switzerland, Swissmedic provided feedback to our MAA in the form of a list of questions with major objections, which include objections that are similar to those identified with respect to our MAA for the European Union. We responded to the list of questions in writing, and we subsequently received a preliminary determination from Swissmedic that those concerns have not been satisfied. While we intend to continue discussions to address Swissmedic's concerns, we may not be successful when expected or ever.

We cannot assure you that our collaborator's or our past or any future responses or submissions will be sufficient to the applicable regulatory authority or others, that the applicable regulatory authority or others will consider our BELVIQ program or data, including with regard to BELVIQ's efficacy or safety, as sufficient, or that any other regulatory authority 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 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.

As a condition to obtaining FDA approval of BELVIQ, Eisai and we 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 being profitable.

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

We are subject to a number of other risks associated with our dependence on the BELVIQ Agreements, including:

our collaborators 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 or outside of the agreements; or

our collaborators 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 our collaborators have the right to terminate the BELVIQ Agreements in certain circumstances. We could also agree with a collaborator to amend the terms of our agreement, and we or others, including investors and analysts, may not view any amendments as favorable. If any of the BELVIQ Agreements 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 BELVIQ under the BELVIQ Agreements, including for commercial sale. We rely to an extent on other companies, including third-party manufacturers and sole-source suppliers, and we or such other companies may encounter failures or difficulties or not receive or provide adequate supply, which could adversely affect the commercial production of BELVIQ or the clinical development or regulatory approval of our drug candidates.**

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

Under each of the BELVIQ Agreements, we are the exclusive supplier of BELVIQ. We own and operate a drug product manufacturing facility in Switzerland that will produce finished drug product of BELVIQ and potentially of one or more of our drug candidates. Such facility 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 or acquire such facilities or rely on third-party manufacturers for such production, which, in either case, would likely require substantial time and funds. With respect to BELVIQ, we estimate that it would take two years or longer and a substantial amount of financial and other resources to secure another source for finished drug product.

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 collectively in this document 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.

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;

capacity of our facilities or those of our contract manufacturers;

facility contamination by microorganisms or viruses or cross contamination;

compliance with regulatory requirements, including inspectional notices of violation 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, regulations 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, we have contracted with Siegfried to provide to us

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

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. We intend to reduce or eliminate our dependence on Siegfried for such technical and business services, and any changes may result in increased cost, additional risk or otherwise negatively impact our operations. If we or one of our manufacturers fail to maintain compliance or otherwise experience setbacks, 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 funding from collaborators or the financial markets, and creates other financial risks for us.**

Negative conditions in the US or global economy, including financial markets, may adversely affect our business and the business of our current and prospective distributors, licensees and collaborators, which we sometimes refer to generally as our collaborators, and others with which we do or may conduct business. The duration and severity of these conditions is uncertain. If

negative economic conditions persist or worsen, we may be unable to secure 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.

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 or product 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, Eisai and we 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 patients 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 being profitable.





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.

**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 the BELVIQ Agreements 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 or acquire 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 marketing and supply agreement, 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, including inspections at Arena GmbH by the FDA 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 a separate process that can delay when a drug may become available to patients beyond an NDA approval date, and the timing and outcome of such DEA process is uncertain. For example, the FDA approved the NDA for BELVIQ in June 2012, but conditioned the commercial sale of BELVIQ on DEA scheduling. The DEA's final rule placing BELVIQ into Schedule IV of the Controlled Substances Act was not effective until June 2013. The scheduling designation can also change after it has been finalized. DEA scheduling ranges from I to V, with I being the most tightly controlled category. If BELVIQ were to be rescheduled into 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;

- 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. With respect to our BELVIQ collaborations, our collaborators are responsible for regulatory filings, and we will depend on their capabilities, plans and diligence in obtaining regulatory approval.

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

With respect to our previously filed MAA for BELVIQ in the European Union, we did not believe we could resolve the major objections identified by the CHMP prior to the time we expected the CHMP to issue its final opinion, and we decided to withdraw the MAA. We are evaluating submitting an application for regulatory approval in Europe at a later date. If we do submit such an application, the regulatory authority could determine that our application and data from our BELVIQ studies and trials is not sufficient for approval in such territory. 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. Also, with respect our previously filed MAA for BELVIQ in the European Union, the EMA raised questions regarding the dropout rate in our clinical trials and how this affects the analysis of efficacy in those trials.

We have also submitted an MAA with Swissmedic for the marketing approval of BELVIQ in Switzerland. In February 2013, Swissmedic provided feedback to our MAA in the form of a list of questions with major objections, which include objections that are similar to those identified with respect to the MAA we previously submitted for the European Union. We responded to the list of questions in writing, and we subsequently received a preliminary determination from Swissmedic that those concerns have not been satisfied. While we intend to continue discussions to address Swissmedic's concerns, we may not be successful when expected or ever. In addition, Eisai filed regulatory applications for marketing approval of BELVIQ in Mexico and Canada, and we expect that we or our collaborators will submit applications for regulatory approval of BELVIQ in additional territories in the future.

We cannot assure you that our collaborator's or our past or any future responses or submissions will be sufficient to the applicable regulatory authority or others, that the applicable regulatory authority or others will consider our BELVIQ program or data, including with regard to BELVIQ's efficacy or safety, as sufficient, or that any other regulatory authority will ever approve BELVIQ.

Regulatory approval of a drug in one territory does not ensure additional regulatory approval in such territory (such as approval of the drug in combination with other drugs, for other indications or using different formulations) or regulatory approval in another territory, but a failure or delay in obtaining regulatory approval may negatively impact other regulatory processes. Failure to obtain regulatory approval in a territory, 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 candidates in other territories, 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.

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. Along with being costly and time consuming, unfavorable results from these trials 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 for weight management, for other indications, in combination with other drugs or using different formulations; and preclude us from being profitable.

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.

The DEA has placed BELVIQ into Schedule IV of the Controlled Substances Act, which subjects us to the DEA's regulations. The scheduling designation can change after finalization. If BELVIQ were to be rescheduled into 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 inspectional notices of violation or Warning Letters by any regulatory agency;

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 any regulatory agency 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.

**\*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.**

BELVIQ or any of our drug candidates that may be approved for marketing 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 and alternative treatments;

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 be profitable.

**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 studies of BELVIQ, and we or others may conduct additional studies or trials of BELVIQ alone or in combination with other drugs. 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;

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 and cost more 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;

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;

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

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 expect to experience additional setbacks from time to time 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 be 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 may 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; a program to be abandoned; or negatively impact a related marketed drug.

**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.

**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 create potential liabilities, 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 drugs or 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 the United States and other territories. 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. 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 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,

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

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 rights and obligations under our agreements, the interpretation of preclinical or clinical data, the achievement of milestone or other payments, the ownership of intellectual property, or research and development, regulatory, commercialization or other 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, obtain approval for 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;

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, regulatory, commercialization, pharmacovigilance or other activities or to permit public disclosure of the results of those activities;

slowing or cessation of a collaborator's research, development, regulatory 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 (also referred to as "Obamacare"), 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.

**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 timing and risk associated with research, development and commercialization, the regulatory process, 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 any approved drugs, such as BELVIQ. In addition, under the Eisai BELVIQ 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 will have limited product liability insurance that covers our clinical trials and products. 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.

We expect that Arena GmbH will manufacture BELVIQ from time to time for commercialization as well as for clinical trials or other studies. Arena GmbH also manufactures drug products for Siegfried. Arena GmbH is subject to liability for non-performance, product recalls and breaches of the agreements with Siegfried and our collaborators under the BELVIQ Agreements.

**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;

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. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties and prosecution.**

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

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

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 aspects of 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, 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, development or manufacturing efforts;

injury to our employees and others;

environmental damage resulting in costly clean up; and

liabilities under domestic or foreign 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 manufacturing facility in Zofingen, Switzerland, and we expect that, at least for the near-term, 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, disruption in transportation networks or delivery services, 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.**

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

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.

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 marketing, 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

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

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 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. For example, a third party has told us that it believes one of its issued US patents includes patent claims that cover BELVIQ or its use. We do not believe such patent claims are valid or, even if they are valid, that they cover BELVIQ or its use. If we fail to obtain any required licenses or make any necessary changes to our technologies, we may become involved in expensive and time-consuming litigation or 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 countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our drug candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***Risks Relating to Our Securities***

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

Our stock price has fluctuated historically. From January 1, 2011, to July 30, 2013, 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 decisions of regulatory authorities relating to BELVIQ, or other drugs or drug candidates, including those of our competitors;

the commercial availability and success or failure of BELVIQ (including perceptions of prescription information) 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;

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

fluctuation in quarterly results (including with respect to revenue recognition) or inaccurate sales or cash forecasting;

accounting restatements and changes;

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;

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; and

capital market conditions.

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 July 30, 2013, we had outstanding 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 warrant was adjusted as a result of certain equity sales following its issuance to decrease the exercise price and increase the number of shares issuable upon exercise of the warrant. Certain future equity issuances below the pre-defined warrant adjustment price may result in additional adjustments to such warrant to the extent then outstanding.

Along with our outstanding warrant, as of July 30, 2013, there were (i) options to purchase 14,546,845 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$4.89 per share, (ii) 296,096 restricted stock unit awards outstanding under our equity incentive plans, (iii) performance restricted stock unit awards outstanding under our 2012 Long-Term Incentive Plan, targeted at 780,000 shares (however, the actual number of shares that may be awarded ranges from 0% to 200% of such amount), (iv) 26,580,147 additional shares of common stock remaining issuable under our 2013 Long-Term Incentive Plan, (v) 1,038,990 shares of common stock remaining issuable under our 2009 Employee Stock Purchase Plan, as amended, and (vi) 79,169 shares of common stock remaining issuable under our Deferred Compensation Plan.

Once issued, the shares described above 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 July 30, 2013, there were 218,253,685 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

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

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. From time to time, there is a large short interest in our stock. These holders of such stock or positions may seek control of us, support transactions that we or you do not believe are favorable, 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 in 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, involve settlements, the terms of which may not be favorable to us, or result in other negative consequences to our business.

**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 provision in the Eisai BELVIQ Agreement, and we may enter into agreements with similar provisions. 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 provisions or 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 6. Exhibits.**

**EXHIBIT**

<b>NO.</b>	<b>DESCRIPTION</b>
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	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)
4.1	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)
10.1*	Arena's 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.1 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 10, 2013, Commission File No. 333-189213)
10.2*	Form of Stock Option Grant Agreement for Employees or Consultants under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.3*	Form of Incentive Stock Option Grant Agreement for Employees under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.3 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.4*	Form of Restricted Stock Unit Grant Agreement (other than for non-employee directors) under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.4 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.5*	Form of Restricted Stock Unit Grant Agreement for Non-Employee Directors under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.5 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
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

\* Management contract or compensatory plan or arrangement.

**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: August 2, 2013

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)

**EXHIBIT INDEX**

**EXHIBIT**

<b>NO.</b>	<b>DESCRIPTION</b>
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	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)
4.1	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)
10.1*	Arena's 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.1 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 10, 2013, Commission File No. 333-189213)
10.2*	Form of Stock Option Grant Agreement for Employees or Consultants under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.3*	Form of Incentive Stock Option Grant Agreement for Employees under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.3 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.4*	Form of Restricted Stock Unit Grant Agreement (other than for non-employee directors) under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.4 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.5*	Form of Restricted Stock Unit Grant Agreement for Non-Employee Directors under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.5 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
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

\* Management contract or compensatory plan or arrangement.