

ARENA PHARMACEUTICALS INC

Form 10-Q

November 06, 2014

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2014**

**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)**

<p><b>Delaware</b> (State or other jurisdiction of incorporation or organization)</p> <p><b>6154 Nancy Ridge Drive, San Diego, CA</b> (Address of principal executive offices)</p>	<p><b>23-2908305</b> (I.R.S. Employer Identification No.)</p> <p><b>92121</b> (Zip Code)</p> <p><b>858.453.7200</b>  (Registrant's telephone number, including area code)</p>
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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 November 3, 2014:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	220,114,995



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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 the finished drug product containing the active pharmaceutical ingredient lorcaserin hydrochloride, or lorcaserin, that is marketed for chronic weight management in the United States. Lorcaserin may in the future be marketed in the United States or in other countries as BELVIQ or under a different trade name for chronic weight management, for a different indication, in a different formulation or in combination with another drug. In this report, we use BELVIQ to refer to the finished drug product containing lorcaserin and/or, depending on the context, the active pharmaceutical ingredient lorcaserin, and without regard to the current or potential indication, formulation or combination.

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.****ARENA PHARMACEUTICALS, INC.****Condensed Consolidated Balance Sheets****(In thousands)**

	<b>September 30, 2014 (Unaudited)</b>	<b>December 31, 2013<sup>1</sup></b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 188,328	\$ 221,878
Accounts receivable	2,914	10,602
Inventory	11,861	12,759
Prepaid expenses and other current assets	5,974	3,571
<b>Total current assets</b>	<b>209,077</b>	<b>248,810</b>
Land, property and equipment, net	75,489	77,388
Intangibles, net	8,977	10,182
Other non-current assets	3,129	3,427
<b>Total assets</b>	<b>\$ 296,672</b>	<b>\$ 339,807</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 4,159	\$ 6,000
Accrued clinical and preclinical study fees	4,486	1,317
Accrued compensation	4,699	4,205
Payable to Eisai	19,051	19,305
Current portion of deferred revenues	19,869	37,861
Derivative liabilities	1,403	0
Current portion of lease financing obligations	2,379	2,056
<b>Total current liabilities</b>	<b>56,046</b>	<b>70,744</b>
Deferred rent	340	247
Deferred revenues, less current portion	95,092	101,329
Derivative liabilities	0	4,892
Lease financing obligations, less current portion	68,908	70,738
Commitments and contingencies		
Stockholders equity:		

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Common stock	22	22
Additional paid-in capital	1,308,735	1,293,840
Accumulated other comprehensive income	3,709	5,728
Accumulated deficit	(1,236,180)	(1,207,733)
Total stockholders' equity	76,286	91,857
Total liabilities and stockholders' equity	\$ 296,672	\$ 339,807

<sup>1</sup> The balance sheet data at December 31, 2013, has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by US generally accepted accounting principles for complete financial statements.

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****ARENA PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)****(In thousands, except per share data)****(Unaudited)**

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
<b>Revenues:</b>				
Net product sales	\$ 5,726	\$ 2,011	\$ 12,137	\$ 3,330
Other Eisai collaborative revenue	2,133	973	14,034	68,933
Manufacturing services	158	443	1,184	2,181
Other collaborative revenue	147	151	424	434
Total revenues	8,164	3,578	27,779	74,878
<b>Operating Costs and Expenses:</b>				
Cost of product sales	1,755	460	4,049	1,514
Cost of manufacturing services	81	632	1,124	3,286
Research and development	24,508	14,592	72,521	47,428
General and administrative	8,029	7,760	25,198	23,614
Total operating costs and expenses	34,373	23,444	102,892	75,842
Loss from operations	(26,209)	(19,866)	(75,113)	(964)
<b>Interest and Other Income (Expense):</b>				
Interest income	16	28	69	68
Interest expense	(1,723)	(1,768)	(5,205)	(5,333)
Gain from valuation of derivative liabilities	2,593	4,100	3,489	10,101
Gain on sale of available-for-sale securities	16,276	0	49,553	0
Other	(1,625)	306	(1,240)	152
Total interest and other income, net	15,537	2,666	46,666	4,988
Net income (loss)	\$ (10,672)	\$ (17,200)	\$ (28,447)	\$ 4,024
Net income (loss) per share:				
Basic	\$ (0.05)	\$ (0.08)	\$ (0.13)	\$ 0.02
Diluted	\$ (0.05)	\$ (0.08)	\$ (0.13)	\$ 0.02
Shares used in calculating net income (loss) per share:				
Basic	219,866	218,316	219,592	217,923

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Diluted	219,866	218,316	219,592	224,354
<b>Comprehensive Income (Loss):</b>				
Net income (loss)	\$ (10,672)	\$ (17,200)	\$ (28,447)	\$ 4,024
Foreign currency translation gain (loss)	(1,626)	1,303	(2,019)	104
Unrealized loss on available-for-sale securities	(18,313)	0	0	0
Comprehensive income (loss)	\$ (30,611)	\$ (15,897)	\$ (30,466)	\$ 4,128

See accompanying notes to unaudited condensed consolidated financial statements.



**Table of Contents****ARENA PHARMACEUTICALS, INC.****Condensed Consolidated Cash Flow Statements****(In thousands)****(Unaudited)**

	<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Operating Activities</b>		
Net income (loss)	\$ (28,447)	\$ 4,024
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	6,434	5,763
Amortization of intangibles	394	305
Share-based compensation	9,941	6,542
Gain from valuation of derivative liabilities	(3,489)	(10,101)
Gain on sale of available-for-sale securities	(49,553)	0
Amortization of prepaid financing costs	102	102
(Gain) loss on sale of equipment	172	(21)
Changes in assets and liabilities:		
Accounts receivable	7,279	(6,330)
Inventory	211	(3,520)
Prepaid expenses and other assets	(2,551)	37
Accounts payable, payable to Eisai and accrued liabilities	3,420	17,823
Deferred revenues	(22,998)	12,565
Deferred rent	93	91
Net cash provided by (used in) operating activities	(78,992)	27,280
<b>Investing Activities</b>		
Proceeds from sale of available-for-sale securities	49,553	0
Purchases of property and equipment	(6,444)	(4,600)
Proceeds from sale of equipment	47	60
Other non-current assets	209	467
Net cash provided by (used in) investing activities	43,365	(4,073)
<b>Financing Activities</b>		
Principal payments on lease financing obligations	(1,507)	(1,216)
Proceeds from issuance of common stock	4,892	2,685
Net cash provided by financing activities	3,385	1,469
Effect of exchange rate changes on cash	(1,308)	(64)
Net increase (decrease) in cash and cash equivalents	(33,550)	24,612

Cash and cash equivalents at beginning of period	221,878	156,091
Cash and cash equivalents at end of period	\$ 188,328	\$ 180,703

See accompanying notes to unaudited condensed consolidated financial statements.

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**ARENA PHARMACEUTICALS, INC.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of Arena Pharmaceuticals, Inc., which include our wholly owned subsidiaries, should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission, or SEC, from which we derived our balance sheet as of December 31, 2013. 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 May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers. ASU No. 2014-09 outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. ASU No. 2014-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016. ASU No. 2014-09 allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying ASU No. 2014-09 is recognized as an adjustment to the fiscal 2017 opening retained earnings balance. We have not yet selected an adoption method as we are currently evaluating the impact of ASU No. 2014-09 on our consolidated financial statements.

In August 2014, FASB issued ASU No. 2014-15, Presentation of Financial Statements – Going Concern: Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. Under GAAP, continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity’s liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. If and when an entity’s liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting. Even when an entity’s liquidation is not imminent, there may be conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern. In those situations, financial statements should continue to be prepared under the going concern basis of accounting, but the amendments in ASU No. 2014-15 should be followed to determine whether to disclose information about the relevant conditions and events. The amendments in ASU No. 2014-15 are effective for the annual reporting period ending after December 15, 2016, and for annual and interim periods thereafter. We do not expect the adoption of ASU No. 2014-15 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.

**2. Fair Value Disclosures**

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

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

- Level 1 - Observable inputs such as unadjusted quoted prices in active markets for identical instruments.
- Level 2 - Quoted prices for similar instruments in active markets or inputs that are observable for the asset or liability, either directly or indirectly.
- Level 3 - Significant unobservable inputs based on our assumptions.

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The following tables present our valuation hierarchy for our financial assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2014, and December 31, 2013, in thousands:

<b>Fair Value Measurements at September 30, 2014</b>				
	<b>Balance</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<i>Assets:</i>				
Money market funds <sup>1</sup>	\$ 163,900	\$ 163,900	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrant derivative liabilities	\$ 1,403	\$ 0	\$ 1,403	\$ 0

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

<b>Fair Value Measurements at December 31, 2013</b>				
	<b>Balance</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<i>Assets:</i>				
Money market funds <sup>1</sup>	\$ 208,833	\$ 208,833	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrant derivative liabilities	\$ 4,892	\$ 0	\$ 4,892	\$ 0

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

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

We held an investment in TaiGen Biotechnology Co., Ltd., or TaiGen, that from December 31, 2011, to January 17, 2014, had a cost basis of zero due to prior impairment charges. On January 17, 2014, TaiGen completed an initial public offering and its common stock began to trade on the GreTai Securities Listed Market, under the name TaiGen Biopharmaceuticals Holding Limited. Such market is deemed to be comparable to a US over-the-counter market such that the fair value of our investment in TaiGen, which previously had been accounted for as a cost method investment with a cost basis of zero, became readily determinable. Accordingly, on January 17, 2014, we recorded our investment in TaiGen of 29.6 million shares based on its fair value of approximately \$49.1 million, with the unrealized gain of \$49.1 million recorded as a component of accumulated other comprehensive income (loss) in the stockholders' equity section of our March 31, 2014, condensed consolidated balance sheet. We began recording our investment in TaiGen at fair value based on the trading price of TaiGen's common stock, and the remaining investment was revalued on each balance sheet date, with any unrealized gains or losses recorded as a component of accumulated other comprehensive income (loss) in the stockholders' equity section of our condensed consolidated balance sheets.

Gains and losses on the sale of available-for-sale securities are determined using the specific-identification method. During the three and nine months ended September 30, 2014, we sold 10.6 million and 29.6 million shares of TaiGen, respectively, and recorded gains of \$16.3 million and \$49.6 million, respectively, which were reclassified out of accumulated other comprehensive income. The following table summarizes the components of the unrealized gain (loss) on available-for-sale securities we recognized related to our investment in TaiGen in the three and nine months ended September 30, 2014, in thousands:

	<b>Three months ended September 30, 2014</b>	<b>Nine months ended September 30, 2014</b>
Reclassification adjustment for realized gain on sale of available-for-sale securities	\$ (16,276)	\$ (49,553)
Unrealized holding gain (loss) on available-for-sale securities	(2,037)	49,553
Unrealized loss on available-for-sale securities	\$ (18,313)	\$ 0

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As of September 30, 2014, we had sold the remaining equity we held in TaiGen and had no remaining amount recorded in accumulated other comprehensive income related to our former investment in TaiGen.

**4. Inventory**

All of our inventory relates to BELVIQ, and consisted of the following as of September 30, 2014, and December 31, 2013, in thousands:

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Raw materials	\$ 579	\$ 657
Work in process	3,069	4,104
Finished goods at Arena GmbH	4,597	0
Finished goods at Eisai	3,616	7,998
<b>Total inventory</b>	<b>\$ 11,861</b>	<b>\$ 12,759</b>

**5. Land, Property and Equipment**

Land, property and equipment consisted of the following as of September 30, 2014, and December 31, 2013, in thousands:

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Cost	\$ 166,015	\$ 165,373
Less accumulated depreciation and amortization	(90,526)	(87,985)
<b>Land, property and equipment, net</b>	<b>\$ 75,489</b>	<b>\$ 77,388</b>

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

Accounts payable and other accrued liabilities consisted of the following as of September 30, 2014, and December 31, 2013, in thousands:

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Accounts payable	\$ 2,579	\$ 3,721
Accrued expenses	1,391	1,477
Loss provision	82	567
Other accrued liabilities	107	235
	<b>\$ 4,159</b>	<b>\$ 6,000</b>

Total accounts payable and other accrued liabilities

## 7. Derivative Liabilities

In August 2008, we issued a warrant to purchase 1,106,344 shares of our common stock at an exercise price of \$7.71 per share that expires on August 14, 2015. 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 warrant agreement, the number of shares issuable upon exercise of the warrant increased and the exercise price decreased. At September 30, 2014, the number of shares issuable upon exercise of the outstanding warrant was 1,965,418 at an exercise price of \$4.34 per share. At September 30, 2014, the outstanding warrant was valued at \$1.4 million and recorded as a current derivative liability on our condensed consolidated balance sheet. At December 31, 2013, the outstanding warrant was valued at \$4.9 million and recorded as a long-term derivative liability on our condensed consolidated balance sheet.

Our outstanding warrant is revalued on each balance sheet date, with changes in the fair value between reporting periods recorded in the interest and other income (expense) section of our condensed consolidated statements of operations and comprehensive income (loss).



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In November 2013, our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, and Eisai Inc. and Eisai Co., Ltd. (collectively with Eisai Inc., Eisai) entered into the Second Amended and Restated Marketing and Supply Agreement, or Eisai Agreement. The Eisai Agreement amended and restated the previous agreement and expanded Eisai's exclusive commercialization rights for BELVIQ to all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. BELVIQ is approved in the United States for chronic weight management in adults who are overweight with a comorbidity or obese, and was made available to patients by prescription in the United States by Eisai in June 2013. In addition to providing commercialization rights, which are subject to applicable regulatory approval, we provide Eisai with services related to development and regulatory activities, and manufacture and sell BELVIQ to Eisai. Under the Eisai Agreement, we have received an upfront payment and payments from sales of BELVIQ, and are entitled to receive payments from future sales of BELVIQ, milestone payments based on the achievement of regulatory filings and approvals, one-time purchase price adjustment payments and other payments.

Prior to entering into the Eisai Agreement, Arena GmbH and Eisai Inc. entered into the original marketing and supply agreement in July 2010, under which we granted Eisai Inc. exclusive commercialization rights for BELVIQ solely in the United States and its territories and possessions. In May 2012, Arena GmbH and Eisai Inc. amended and restated such agreement by entering into the first amended agreement, which expanded Eisai Inc.'s exclusive commercialization rights to include most of North and South America.

The following table summarizes the revenues we recognized under our collaboration with Eisai in the three and nine months ended September 30, 2014, and 2013, in thousands:

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net product sales	\$ 5,726	\$ 2,011	\$ 12,137	\$ 3,330
Amortization of upfront payments	1,885	861	5,745	2,584
Reimbursement of research and development expenses	143	16	7,456	26
Milestone payments	0	0	500	66,000
Reimbursements of patent and trademark expenses	105	96	333	323
Subtotal other Eisai collaborative revenue	2,133	973	14,034	68,933
<b>Total</b>	<b>\$ 7,859</b>	<b>\$ 2,984</b>	<b>\$ 26,171</b>	<b>\$ 72,263</b>

The following table summarizes the deferred revenues under our collaboration with Eisai as of September 30, 2014, and December 31, 2013, in thousands:

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Upfront payments	\$ 96,359	\$ 102,104

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Net product sales	11,707	30,299
Total deferred revenues attributable to Eisai	108,066	132,403
Less current portion	(19,247)	(37,301)
Deferred revenues attributable to Eisai, less current portion	\$ 88,819	\$ 95,102

Upfront and Milestone Payments

In connection with entering into the Eisai Agreement, we received from Eisai an upfront payment of \$60.0 million. This payment is in addition to the \$50.0 million and \$5.0 million in upfront payments we received from Eisai in connection with entering into the original agreement and the first amended agreement, respectively. Revenues from these upfront payments were deferred, as we determined that the exclusive rights did not have standalone value without our ongoing development and regulatory activities. Accordingly, these payments are recognized ratably as revenue over the periods in which we expect the services to be rendered, which are approximately 15 years for the Eisai Agreement and first amended agreement and 16 years for the original agreement. In addition to the upfront payments, we have received from Eisai a total of \$86.5 million in milestones payments, and we are eligible to receive up to an aggregate of \$176.0 million in additional regulatory and development milestone payments.

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**Table of Contents****Product Purchase Price and Purchase Price Adjustment Payments**

We manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Eisai for Eisai's commercialization in the United States and, subject to applicable regulatory approval, in the other territories under the Eisai Agreement (other than Europe, China and Japan) for a purchase price starting at 31.5% and 30.75%, respectively (and starting at 27.5% in Europe, China and Japan), of Eisai's aggregate annual net product sales (which are the gross invoiced sales less certain deductions described in the Eisai Agreement), or the Product Purchase Price, in the respective territory. The Product Purchase Price will increase on a tiered basis in the United States and the other territories (other than Europe, China and Japan) to as high as 36.5% and 35.75%, respectively, on the portion of Eisai's annual aggregate net product sales exceeding \$750.0 million in all territories other than Europe, China and Japan. The Product Purchase Price will increase to 35% in Europe, China and Japan on the portion of Eisai's annual aggregate net product sales exceeding \$500.0 million in such territories. The Product Purchase Price is subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country. The revenue we recognize for BELVIQ product revenue related to redemption of vouchers is based on our cost of goods sold.

In addition to payments for purchases of BELVIQ, we are eligible to receive up to an aggregate of \$1.56 billion in one-time purchase price adjustment payments and other payments. These payments include up to an aggregate of \$1.19 billion that are based on Eisai's annual net product sales of BELVIQ in all of the territories under the Eisai 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. The \$1.56 billion also includes \$370.0 million in one-time purchase price adjustment payments we are eligible to receive based on annual net product sales in the non-US territories, comprised of \$185.0 million based on Eisai's annual net product sales in the non-US territories in North and South America and \$185.0 million based on Eisai's annual net product sales in the territories outside of North and South America. The first and last amounts are payable upon first achievement of annual net product sales of \$100.0 million and \$1.0 billion, respectively, with respect to each of the following areas: (i) the non-US territories in North and South America and (ii) the territories outside of North and South America. In addition, we are also eligible to receive certain payments by Eisai if certain annual minimum sales requirements in Mexico, Canada and Brazil are not met during the first ten years after initial commercial sale in such territories.

The amount that Eisai pays us for BELVIQ product supply is based on Eisai's estimated price at the time the order is shipped, which is Eisai's estimate of the Product Purchase Price, and is subject to change on April 1 and October 1 of each year. Eisai's estimate of the Product Purchase Price was changed as of October 1, 2013, and there was no further change as of April 1, 2014. 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 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 product sales for the month, details of the total deductions from gross to net product sales and the sales in units. We recognize our revenues monthly based on our percentage of Eisai's monthly net product sales figures. When the revenues we recognize differ from the estimated price that 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 revenues 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.

In the three months ended September 30, 2014, we recognized total revenues from net product sales of BELVIQ of \$5.7 million, of which \$5.2 million related to sales at the Product Purchase Price and \$0.5 million related to redemptions of vouchers. In the nine months ended September 30, 2014, we recognized total revenues from net product sales of BELVIQ of \$12.1 million, of which \$11.0 million related to sales at the Product Purchase Price and \$1.1 million related to redemptions of vouchers. The Product Purchase Price for the product Eisai has sold to date was

lower than the initial estimated price that Eisai paid us for such product, primarily because the price that Eisai paid us did not include deductions for the use of vouchers and savings cards or for certain items related to product launch. In September 2014, Eisai determined to include product sampling as part of its commercialization efforts and they allocated certain bottles of BELVIQ for the initial product sampling. Eisai initiated product sampling in October 2014. Under the Eisai Agreement, Eisai will pay us our cost of goods for these product samples. The allocation of BELVIQ bottles for product sampling reduced our deferred revenues and increased our payable to Eisai by \$6.0 million at September 30, 2014. These excess payments related to the above deductions and product sampling, which reflect both the amounts Eisai has sold to date and the product supply remaining in Eisai's inventory at September 30, 2014, are included in the \$19.1 million classified as Payable to Eisai on our condensed consolidated balance sheet. On a quarterly basis, subsequent to the end of each calendar quarter, we will refund to Eisai the portion of these excess payments related to product sampling for product shipped to physicians during the quarter. On an annual basis, subsequent to the end of Eisai's fiscal year, we will refund to Eisai the portion of these excess payments related to product sold by Eisai to their distributors through March 31.

*Development Payments*

In connection with the US approval of BELVIQ, the US Food and Drug Administration, or FDA, is requiring (i) an evaluation as part of the cardiovascular outcomes trial, or CVOT, of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors and (ii) the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese

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pediatric patients. In addition to the FDA-required studies, we and Eisai are prioritizing the development areas of smoking cessation, a once-daily formulation, co-administration with phentermine, as well as potentially exploring, including as part of the CVOT, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

The chart below summarizes the general agreement regarding cost sharing between Eisai and us for significant development activities under the Eisai Agreement. In addition, Eisai or we may from time to time conduct approved development of BELVIQ at such party's own expense. For example, Eisai is responsible for the expenses of the pilot study of 12-week duration to preliminarily assess BELVIQ and phentermine when co-administered.

**Eisai Second Amended and Restated Marketing and Supply Agreement: Cost Sharing for Development**

		<b>Rest of</b>	
	<b>United States</b>	<b>North and South America</b>	<b>Remaining Territories</b>
<b>BELVIQ for weight management</b>	Not Applicable	<b>General</b>	Up to total of \$100.0 million -
<i>- Pre-approval*</i>		Eisai: 90%; Arena: 10%	Eisai: 50%; Arena: 50%
		<b>Certain stability work</b>	Thereafter, Eisai: 100%
		Eisai: 50%; Arena: 50%	
<b>BELVIQ for weight management</b>	<b>General</b> Eisai: 90%; Arena 10%	<b>General</b>	Up to total of \$50.0 million -
<i>- Post-approval*</i>		Eisai: 90%; Arena: 10%	Eisai: 50%; Arena: 50%
	<b>Non-FDA required portion of CVOT</b>	<b>Certain stability work</b>	Thereafter, Eisai: 90%;
	Up to \$80.0 million -	Eisai: 50%; Arena: 50%	Arena: 10%
	Eisai: 50%; Arena: 50%		
	Thereafter, Eisai: 100%		
	<b>Certain pediatric studies</b>		
<b>Products other than BELVIQ for weight management</b>	Eisai: 50%; Arena: 50%		
	Up to a total of \$250.0 million (as reduced by up to \$80.0 million for non-FDA required portion of CVOT) -		

**management** Eisai: 50%; Arena: 50%

***- Pre-approval***

**Products other than BELVIQ for weight management** Up to a total of \$100.0 million in the aggregate across all additional products -

Eisai: 50%; Arena: 50%

***- Post-approval***

Thereafter, Eisai: 90%; Arena: 10%

\* Development required by a regulatory authority, with the exception of the non-FDA required portions of the CVOT.

**Certain Other Terms**

Please refer to our Annual Report on Form 10-K for the year ended December 31, 2013, for additional information regarding termination, indemnification, product liability, certain limitations and other provisions included in the Eisai Agreement.

**Table of Contents****9. Share-based Activity****Share-based Compensation**

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Cost of product sales	\$ 0	\$ 0	\$ 0	\$ 17
Research and development	1,753	1,188	5,276	3,047
General and administrative	1,645	1,131	4,665	3,478
Total share-based compensation expense	\$ 3,398	\$ 2,319	\$ 9,941	\$ 6,542
Total share-based compensation expense capitalized into inventory	\$ 22	\$ 35	\$ 61	\$ 79

**Share-based Award Activity**

The following table summarizes our stock option activity during the nine months ended September 30, 2014, in thousands (except per share data):

	Options	Weighted-Average Exercise Price
Outstanding at January 1, 2014	14,681	\$ 4.99
Granted	2,126	\$ 6.78
Exercised	(1,070)	\$ 3.72
Forfeited/cancelled/expired	(230)	\$ 6.28
Outstanding at September 30, 2014	15,507	\$ 5.30

The following table summarizes activity with respect to our time-based restricted stock unit awards, or RSUs, during the nine months ended September 30, 2014, in thousands (except per share data):

RSUs	Weighted-Average Grant-Date Fair Value
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Unvested at January 1, 2014	369	\$	7.23
Granted	178	\$	6.50
Vested	(110)	\$	7.88
Forfeited/cancelled	0		
Unvested at September 30, 2014	437	\$	6.77



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In March 2014, 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, 2014, of the NASDAQ Biotechnology Index. In the aggregate, the target number of shares of common stock that may be earned under the PRSUs is 695,000; however, the actual number of shares that may be earned ranges from 0% to 200% of such amount. In addition, there is a cap on the number of shares that can be earned under the PRSUs equal to six times the grant-date fair value of the award, and funding is capped at 100% if the absolute 3-year TSR is negative even if performance is above the median. As these awards contain a market condition, we used a Monte Carlo simulation model to estimate the grant-date fair value, which totaled \$5.0 million and will be recognized over the performance period. The table below sets forth the assumptions used to value the PRSUs granted in 2014 and the estimated grant-date fair value:

Risk-free interest rate	0.7%
Dividend yield	0%
Expected volatility	78%
Remaining performance period (years)	2.99
Estimated fair value per share of PRSUs granted	\$ 7.16

All of the PRSUs granted to date were unvested at September 30, 2014.

**10. 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 the United States, which is the only jurisdiction for which BELVIQ has received regulatory approval for marketing. 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:

	Three months ended		Nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Eisai marketing and supply agreement	96.3%	83.4%	94.2%	96.5%
Manufacturing services agreement with Siegfried	1.9%	12.4%	4.3%	2.9%
Other collaborative agreements	1.8%	4.2%	1.5%	0.6%
Total percentage of revenues	100.0%	100.0%	100.0%	100.0%



**Table of Contents****11. Net Loss Per Share**

We calculate basic and diluted net loss per share using the weighted-average number of shares of common stock outstanding during the period.

When we are in a net loss position, we exclude from our calculation of diluted net loss per share all potentially dilutive (i) stock options, (ii) RSUs, (iii) PRSUs, (iv) unvested restricted stock in our deferred compensation plan and (v) warrants, and our diluted net loss per share is the same as our basic net loss per share for such periods. When we are in a net income position, the weighted-average number of shares used to calculate our diluted net income per share includes the potential dilutive effect of in-the-money securities, as determined 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.

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Weighted-average shares outstanding	219,866	218,316	219,592	217,923
Potentially dilutive common shares outstanding:				
Stock options	0	0	0	5,489
Warrants	0	0	0	876
RSUs and unvested restricted stock	0	0	0	66
Weighted-average shares used to calculate diluted net income (loss) per share	219,866	218,316	219,592	224,354

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

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Stock options	11,614	4,796	12,185	3,757
Warrants	55	694	490	0
RSUs, PRSUs, and unvested restricted stock	508	79	214	0
Total	12,177	5,569	12,889	3,757

**12. 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 were 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 sought unspecified monetary damages and other relief. 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 March 28, 2013, the Court dismissed the consolidated amended complaint without prejudice. On May 13, 2013, the lead plaintiff filed a second consolidated amended complaint. On November 5, 2013, the Court dismissed the second consolidated amended complaint without prejudice as to all parties except for Robert E. Hoffman, who was dismissed from the action with prejudice. On November 27, 2013, the lead plaintiff filed a motion for leave to amend the second consolidated amended complaint. On March 20, 2014, the Court denied plaintiff's motion and dismissed the second consolidated amended complaint with prejudice. On April 18, 2014, the lead plaintiff filed a notice of appeal, and on August 27, 2014, the lead plaintiff filed his appellate brief in the US Court of Appeals for the Ninth Circuit. On October 24, 2014, we filed our answering brief in response to the lead plaintiff's appeal. 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.

In addition to the class actions, a complaint involving similar legal and factual issues had been brought by an individual stockholder. On March 29, 2013, the Court dismissed the matter, in part without prejudice. On May 13, 2013, the individual

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stockholder filed a new amended complaint. On March 20, 2014, the Court dismissed the matter in part, and remanded the remaining claims to state court. On May 5, 2014, we and the individual stockholder agreed to resolve this dispute, and the state court dismissed the complaint with prejudice on May 16, 2014.

**13. Commitment to Acquire Real Property**

In January 2008, under an asset purchase agreement, we acquired from Siegfried certain drug product facility and real estate assets in Zofingen, Switzerland, including approximately 67,000 square feet of space in a building that consists of approximately 134,000 square feet of space. These assets are being used to manufacture BELVIQ as well as certain drug products for Siegfried. Under such agreement, we had the option to purchase the remaining portion of the building we are occupying at a price of CHF 15.0 million, plus an inflation adjustment. Siegfried also had the option to sell us such remaining portion of the building at a price of CHF 8.0 million, plus an inflation adjustment.

In July 2014, Siegfried provided us notice of its exercise of the option to sell us the remaining portion of the building we are occupying at a price of CHF 8.0 million, plus an inflation adjustment. Under our agreement, we are required to purchase such remaining portion of the building in July 2015.

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### **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, 2013, or 2013 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 that involve a number of risks, uncertainties and assumptions. 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, continue, likely, or opportunity, the negative of these words or other similar words. Similarly, 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® (pronounced BEL-VEEK ) is the trade name for the finished drug product containing the active pharmaceutical ingredient lorcaserin hydrochloride, or lorcaserin, that is marketed for chronic weight management in the United States. Lorcaserin may in the future be marketed in the United States or in other countries as BELVIQ or under a different trade name for chronic weight management, for a different indication, in a different formulation or in combination with another drug. In this report, we use BELVIQ to refer to the finished drug product containing lorcaserin and/or, depending on the context, the active pharmaceutical ingredient lorcaserin, and without regard to the current or potential indication, formulation or combination.

## **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.

Our internally discovered drug, BELVIQ, is approved by the US Food and Drug Administration, or FDA, for marketing in the United States for chronic weight management, and Eisai made BELVIQ available by prescription in June 2013 to adults who are overweight with a comorbidity or obese. Eisai is responsible for marketing and distributing BELVIQ in the United States and, as described below, potentially in other territories under the Second Amended and Restated Marketing and Supply Agreement, or Eisai Agreement, which is among our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, Eisai Inc. and Eisai Co., Ltd., which we refer to collectively with Eisai Inc. as Eisai.

With respect to commercializing BELVIQ in the United States, Eisai is focused on physician awareness and education efforts, reimbursement coverage, and patient awareness and access. In July 2014, Eisai completed an increase of more than 200 new contract sales representatives in its Metabolic Business Unit, increasing the sales force for BELVIQ by 50% to approximately 600. Eisai expects this expanded sales force will enable Eisai to increase their reach to approximately 92,000 physicians in the United States. Eisai previously announced that its continued work to expand reimbursement has resulted in additional insurance coverage for BELVIQ. In addition, in April 2014, Eisai launched a national television advertising campaign for BELVIQ as part of its patient awareness and support campaign that is intended to complement its physician awareness efforts. Eisai is also continuing its efforts to promote the use of BELVIQ by providing patient access to discounted or free product, which has included vouchers for a 15-day supply of BELVIQ at no patient cost, free product samples and savings cards for discounted product.

Under the Eisai Agreement, Arena GmbH also granted Eisai exclusive commercialization rights for BELVIQ in all of the other countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. Arena GmbH has marketing and supply

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agreements with Ildong Pharmaceutical Co., Ltd., or Ildong, for BELVIQ in South Korea, which we refer to as the Ildong BELVIQ Agreement; with CY Biotech Company Limited, or CYB, in Taiwan, which we refer to as the CYB Agreement; and with Teva Pharmaceuticals Ltd.'s Israeli subsidiary, Abic Marketing Limited, or Teva, in Israel, which we refer to as the Teva Agreement.

The marketing of BELVIQ is subject to applicable regulatory approval, and it has not been approved for marketing outside of the United States. Our collaborators are responsible for regulatory activities related to obtaining marketing approval of BELVIQ in the territories covered under the respective agreement. Outside of the United States, our collaborators have pending applications for the potential marketing of BELVIQ in certain of the territories under our agreements, and we have had prior applications in other territories that were withdrawn or rejected. There is no assurance of whether, where or when BELVIQ will be approved for marketing outside of the United States.

In addition to commercializing BELVIQ as a monotherapy for chronic weight management, we intend to investigate, with our collaborators or independently, BELVIQ's therapeutic potential for other indications, using different formulations, and in combination with other drugs. If any such investigation results in a potential product, the product would need to be approved by the applicable regulatory authority before it could be marketed.

Under the Eisai Agreement, we and Eisai have initially prioritized the development areas of smoking cessation, a once-daily formulation, and co-administration with phentermine, as well as potentially exploring, including as part of the FDA-required cardiovascular outcomes trial, or CVOT, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes:

In November 2013, Eisai initiated dosing in a pilot study to preliminarily assess as the primary outcome the short-term safety and tolerability of lorcaserin and phentermine when co-administered, and we recently announced top-line results. In the 12-week trial, 238 patients were randomized to receive lorcaserin 10 mg twice daily (BID) alone, lorcaserin 10 mg BID with phentermine 15 mg once daily (QD), or lorcaserin 10 mg BID with phentermine 15 mg BID in a 1:1:1 ratio. Eisai was responsible for 100% of the expenses for the trial.

In March 2014, we and Eisai initiated dosing in a Phase 2 clinical trial to evaluate the potential of lorcaserin as an aid to smoking cessation, and we recently announced top-line results. In the 12-week trial, 603 active smokers were randomized to receive lorcaserin 10 mg QD, lorcaserin 10 mg BID or placebo in a 1:1:1 ratio. We and Eisai shared equally the expenses for the trial.

After completing an initial study to evaluate the safety, tolerability and pharmacokinetic properties of different formulations of lorcaserin 20 mg extended release tablets, we selected a once-daily formulation for further development. We recently completed dosing in two Phase 1 clinical studies evaluating such extended release tablet. We and Eisai will share equally the expenses related to the once-daily formulation.

In January 2014, Eisai initiated enrollment in the CVOT required by the FDA as one of the postmarketing commitments. The CVOT is also referred to as CAMELLIA (Cardiovascular And Metabolic Effects of Lorcaserin In Overweight And Obese Patients). The FDA required portion of CAMELLIA is designed to evaluate BELVIQ's effect on the incidence of MACE (non-fatal myocardial infarction, non-fatal stroke and



cardiovascular death) compared to placebo, with a non-inferiority margin for the hazard ratio of 1.4. We and Eisai will be responsible for 10% and 90%, respectively, of the expenses for this portion of such trial. As part of the non-FDA required portion of the trial, CAMELLIA is expected to also evaluate whether BELVIQ reduces the incidence of conversion to type 2 diabetes in patients without type 2 diabetes at baseline and the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure, or any coronary revascularization), both as compared to placebo. We and Eisai will share equally the expenses for this non-FDA required portion of the trial for up to \$40.0 million each, and Eisai will be responsible for 100% of such expenses thereafter. CAMELLIA is expected to run approximately five years.

We also intend to utilize our discovery and development approach focused on G protein-coupled receptors, or GPCRs, to advance other of our internally discovered drug candidates, which include the following clinical-stage, orally available candidates:

Ralinepag (formerly known as APD811), an agonist of the prostacyclin receptor intended for the treatment of vascular diseases, including potentially pulmonary arterial hypertension, has completed single- and multiple-ascending dose Phase 1 trials and is expected to begin a Phase 2 trial later in 2014. In September 2014, the US Food and Drug Administration granted ralinepag orphan drug status by for the treatment of pulmonary arterial hypertension.

Temanogrel, an inverse agonist of the serotonin 2A receptor intended for the treatment of thrombotic diseases, has completed single- and multiple-ascending dose Phase 1 trials. Under our Co-Development and License Agreement with Ildong, we expect Ildong to fund and complete an additional Phase 1 trial in healthy volunteers and potentially a Phase 2a proof-of-concept trial in patients. Ildong initiated a Phase 1 trial in the first quarter of 2014 to evaluate the safety of co-administration of temanogrel with aspirin and clopidogrel.

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APD334, an agonist of the sphingosine 1-phosphate subtype 1, or S1P<sub>1</sub>, receptor intended for the treatment of a number of autoimmune diseases, has completed a Phase 1 single-ascending dose trial. In May 2014, we initiated a Phase 1 multiple-ascending dose trial of APD334.

APD371, an agonist of the cannabinoid-2 receptor intended for the treatment of pain, is in a Phase 1 program we initiated in December 2013.

Developing drugs and obtaining marketing approval is a long, uncertain and expensive process, and our ability to achieve our goals, including furthering our collaborators' efforts to obtain regulatory approval of, and commercialize, BELVIQ, conducting required postmarketing 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 maintain our operations long enough to achieve sustained profitability.

It will require 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. We may continue to incur substantial losses, and do not expect to generate consistent positive operating cash flows for at least the short term. We will need to receive additional funds under our existing collaborative agreements, under any collaborative agreements we may enter into in the future (including for one or more of our drug candidates or programs), or by raising additional funds through equity, debt or other 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		Nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Net product sales	\$ 5.7	\$ 2.0	\$ 12.1	\$ 3.3
Reimbursements of development and patent expenses from Eisai	0.3	0.1	7.9	0.4
Amortization of upfront payments from Eisai	1.8	0.9	5.7	2.6
Manufacturing services agreement with Siegfried	0.2	0.4	1.2	2.2
Other collaborative agreements	0.2	0.2	0.4	0.4
Milestone payments from Eisai	0.0	0.0	0.5	66.0
<b>Total revenues</b>	<b>\$ 8.2</b>	<b>\$ 3.6</b>	<b>\$ 27.8</b>	<b>\$ 74.9</b>

**Research and development expenses**

Type of expense	Three months ended		Nine months ended	
	September 30, 2014	2013	September 30, 2014	2013
External clinical and preclinical study fees and internal non-commercial manufacturing costs	\$ 10.5	\$ 2.0	\$ 30.8	\$ 10.4
Salary and other personnel costs (excluding non-cash share-based compensation)	7.5	6.9	22.8	20.6
Facility and equipment costs	2.7	2.5	7.6	7.6
Non-cash share-based compensation	1.8	1.2	5.3	3.0
Research supply costs	1.4	1.5	4.1	4.0
Other	0.6	0.5	1.9	1.8
<b>Total research and development expenses</b>	<b>\$ 24.5</b>	<b>\$ 14.6</b>	<b>\$ 72.5</b>	<b>\$ 47.4</b>

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

Type of expense	Three months ended		Nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 3.1	\$ 2.9	\$ 9.7	\$ 8.2
Legal, accounting and other professional fees	1.3	1.6	4.7	6.0
Non-cash share-based compensation	1.7	1.1	4.7	3.5
Facility and equipment costs	1.3	1.4	4.1	3.7
Other	0.6	0.8	2.0	2.2
Total general and administrative expenses	\$ 8.0	\$ 7.8	\$ 25.2	\$ 23.6

**THREE MONTHS ENDED SEPTEMBER 30, 2014, AND 2013**

**Revenues.** We recognized revenues of \$8.2 million for the three months ended September 30, 2014, compared to \$3.6 million for the three months ended September 30, 2013. This increase was primarily due to an increase of \$3.7 million in net product sales of BELVIQ primarily related to an increase in the volume of bottles sold to distributors and an increase of \$0.9 million in the amortization of upfront payments from Eisai resulting from the additional \$60.0 million upfront payment we received in connection with expanding our collaboration with Eisai in November 2013.

When collaborators pay us before revenues are earned, we record such payments as deferred revenues. As of September 30, 2014, we had a total of \$115.0 million in deferred revenues. Of such amount, \$96.4 million is attributable to upfront payments we received under our collaboration with Eisai, \$11.7 million is attributable to product supply of BELVIQ, and the remaining amount is primarily attributable to the upfront payments we received under our other collaborative agreements for BELVIQ.

We expect our 2014 revenues will primarily consist of (i) revenues from net product sales of BELVIQ, (ii) amortization of the upfront payments we have received from Eisai and (iii) reimbursements from Eisai for development expenses.

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

With respect to the United States, 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 or timing of such sales or the related revenues we will generate. We believe that future sales of BELVIQ will depend on, among other factors, the availability and use of BELVIQ, the effectiveness of Eisai's marketing program and other efforts, competition and reimbursement coverage. We also believe that demand for BELVIQ may fluctuate based on various other outside forces, such as economic changes, national and world events, holidays and seasonal changes. We believe that demand for weight-management products may be lower around certain holidays and in the second half of any particular year, and it is unknown whether, or to the extent by which, Eisai's marketing program and other efforts will offset favorably any such outside forces that are negative.

Revenues we generate from Eisai's sales of BELVIQ depend on Eisai's net product sales of BELVIQ, which are the gross invoiced sales less certain deductions described in the Eisai Agreement. Deductions from gross sales to net product 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, savings cards or other promotions for free or discounted product. The majority of all BELVIQ prescriptions utilized vouchers or savings cards.

In addition to revenues from Eisai's commercialization of BELVIQ in the United States, we expect that our revenues in the longer term will be impacted by whether and when BELVIQ receives regulatory approval, and is commercialized, outside of the United States.

**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. We recognized cost of products sold of \$1.8 million for the three months ended September 30, 2014, and \$0.5 million for the three months ended September 30, 2013.

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**Cost of manufacturing services.** Cost of manufacturing services consists primarily of direct and indirect costs associated with manufacturing drug products for Siegfried AG, or Siegfried, under our amended manufacturing services agreement, including related salaries, other personnel costs, machinery depreciation costs and amortization expense related to our manufacturing facility production licenses. Cost of manufacturing services decreased by \$0.5 million to \$0.1 million for the three months ended September 30, 2014, from \$0.6 million for the three months ended September 30, 2013, primarily due to the reduced volume of manufacturing services performed.

**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, 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 \$9.9 million to \$24.5 million for the three months ended September 30, 2014, from \$14.6 million for the three months ended September 30, 2013. This increase was primarily due to increases of (i) \$8.5 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs, primarily related to the Phase 2 clinical trial evaluating BELVIQ as an aid to smoking cessation, CAMELLIA and manufacturing costs for non-commercial products, (ii) \$0.6 million in salary and personnel costs, primarily due to an increase in headcount, and (iii) \$0.6 million in non-cash share-based compensation expense. We expect to continue to incur substantial research and development expenses in 2014, which we expect will be substantially higher than in 2013. Such expenses will include costs for FDA-required and non-FDA required development work relating to BELVIQ, including CAMELLIA and studies for smoking cessation and a once-daily formulation, as well as our other research and development programs.

Included in the \$10.5 million of total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the three months ended September 30, 2014, was \$7.6 million related to non-commercial manufacturing and other development costs related to BELVIQ, \$1.8 million related to APD334 and \$0.9 million related to ralinepag. Included in the \$2.0 million of total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the three months ended September 30, 2013, was \$1.8 million related to non-commercial manufacturing and other development costs related to BELVIQ and \$0.1 million related to APD371.

**General and administrative expenses.** General and administrative expenses increased by \$0.2 million to \$8.0 million for the three months ended September 30, 2014, from \$7.8 million for the three months ended September 30, 2013. This increase was primarily due to increases of \$0.6 million in non-cash share-based compensation expense and \$0.2 million in salary and personnel costs, which were partially offset by a \$0.3 million decrease in legal, accounting and other professional fees. We expect that our 2014 general and administrative expenses will be higher than in 2013.

**Interest and other income, net.** Interest and other income, net, increased to income of \$15.5 million for the three months ended September 30, 2014, from income of \$2.7 million for the three months ended September 30, 2013. This increase of \$12.8 million is primarily due to a gain on sale of available-for-sale securities of \$16.3 million during the three months ended September 30, 2014, related to our sale of shares we held in TaiGen, which was partially offset by a \$1.6 million increase in foreign currency transaction loss and a \$1.5 million decrease in gain on valuation of derivative liabilities.

**NINE MONTHS ENDED SEPTEMBER 30, 2014, AND 2013**

**Revenues.** We recognized revenues of \$27.8 million for the nine months ended September 30, 2014, compared to \$74.9 million for the nine months ended September 30, 2013. This decrease was primarily due to \$65.0 million of non-refundable milestone payments from Eisai that we earned in the nine months ended September 30, 2013, in connection with the final scheduling designation of BELVIQ by the US Drug Enforcement Administration, or DEA, partially offset by revenue earned in the nine months ended September 30, 2014, of \$12.1 million from net product sales of BELVIQ, \$7.9 million in development and patent reimbursements from Eisai and a \$3.1 million increase in amortization of upfront payments from Eisai resulting from the additional \$60.0 million upfront payment we received in connection with expanding our collaboration with Eisai in November 2013. The revenue recognized for the nine months ended September 30, 2013, included \$3.3 million from net product sales of BELVIQ and 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 increase in net product sales of \$8.8 million in the nine months ended September 30, 2014, compared to the nine months ended September 30, 2013, primarily related to an increase in the volume of bottles sold to distributors.

**Cost of product sales.** We recognized cost of product sales of \$4.0 million for the nine months ended September 30, 2014, compared to \$1.5 million for the nine months ended September 30, 2013, which included unused capacity costs totaling \$0.5 million for one month in which no BELVIQ manufacturing was performed.

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**Cost of manufacturing services.** Cost of manufacturing services decreased by \$2.2 million to \$1.1 million for the nine months ended September 30, 2014, from \$3.3 million for the nine months ended September 30, 2013. This decrease was primarily due to the reduced volume of manufacturing services performed for the nine months ended September 30, 2014, and the recognition of \$0.7 million for our contract loss provision for these services for the nine months ended September 30, 2013.

**Research and development expenses.** Research and development expenses increased by \$25.1 million to \$72.5 million for the nine months ended September 30, 2014, from \$47.4 million for the nine months ended September 30, 2013. This increase was primarily due to increases of (i) \$20.4 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs, primarily related to manufacturing costs for non-commercial products, CAMELLIA, and the Phase 2 clinical trial evaluating BELVIQ as an aid to smoking cessation, (ii) \$2.3 million in non-cash share-based compensation expense and (iii) \$2.2 million in salary and personnel costs, primarily due to an increase in headcount.

Included in the \$30.8 million total external clinical and preclinical study fees and internal non-commercial manufacturing costs for the nine months ended September 30, 2014, was \$25.3 million related to non-commercial manufacturing and other development costs related to BELVIQ, \$3.3 million related to APD334 and \$1.7 million related to ralinepag. Included in the \$10.4 million of total external clinical and preclinical study fees and expenses for the nine months ended September 30, 2013, was \$6.6 million related to non-commercial manufacturing and other development costs related to BELVIQ, \$1.7 million related to ralinepag, \$1.2 million related to APD334 and \$0.7 million related to APD371.

**General and administrative expenses.** General and administrative expenses increased by \$1.6 million to \$25.2 million for the nine months ended September 30, 2014, from \$23.6 million for the nine months ended September 30, 2013. This increase was primarily due to increases of (i) \$1.5 million in salary and personnel costs, (ii) \$1.2 million in non-cash share-based compensation and (iii) \$0.3 million in insurance expense, which were partially offset by a \$1.3 million decrease in patent and trademark fees.

**Interest and other income, net.** Interest and other income, net, increased to income of \$46.7 million for the nine months ended September 30, 2014, from income of \$5.0 million for the nine months ended September 30, 2013. This increase of \$41.7 million is primarily due to a gain on sale of available-for-sale securities of \$49.6 million during the nine months ended September 30, 2014, related to our sale of shares we held in TaiGen, which was partially offset by a \$6.6 million decrease in gain on valuation of derivative liabilities and a \$1.1 million increase in foreign currency transaction loss.

**LIQUIDITY AND CAPITAL RESOURCES**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures incurred with respect to BELVIQ and while seeking to identify and validate new drug targets and develop other compounds that could become marketed drugs. In June 2013, BELVIQ was made available to patients by prescription in the United States by our collaborator, Eisai, and we believe that payments we will receive from the commercialization of BELVIQ in the United States will be a primary source of our cash from operations for at least the short term. It is difficult to predict such payments, any payments we may receive in any other territory in which BELVIQ may be approved for marketing, or other payments under current or future collaborations. We may incur substantial losses for at least the short term as a result of manufacturing BELVIQ for commercial sale and studies, conducting required postmarketing and other studies of BELVIQ, and advancing our research and development programs.



*Short term*

As of September 30, 2014, we had \$188.3 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 short-term operating expenses will be substantial as we continue to fund BELVIQ-related activities, and, at the same time, advance certain of our research and development programs.

In addition to payments expected from Eisai for purchases of BELVIQ product supply, 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 one or more of our drug candidates or programs, (iii) milestone and other payments from collaborators other than Eisai and (iv) the sale or lease of facilities or other assets we own.

Due to prior impairment charges, our investment in TaiGen Biotechnology Co., Ltd., or TaiGen, had a cost basis of zero from December 31, 2011, to January 17, 2014. On January 17, 2014, TaiGen completed an initial public offering on the GreTai Securities Listed Market, valuing our investment at a fair value of \$49.1 million. In accordance with generally accepted accounting principles, on January 17, 2014, we recorded our investment in TaiGen at fair value, with the unrealized gain recorded as a component of accumulated other comprehensive income in the stockholders equity section of our March 31, 2014, condensed consolidated balance sheet. During the nine months ended September 30, 2014, we sold all of our shares of TaiGen and recorded a gain of \$49.6 million; therefore, there is no remaining amount recorded in accumulated other comprehensive income for our former investment in TaiGen as of September 30, 2014.

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Eisai is commercializing BELVIQ in the United States, and, subject to applicable regulatory approval, we expect Eisai to commercialize BELVIQ in additional territories under the Eisai Agreement. Our collaborators have filed regulatory applications for approval of BELVIQ in a number of countries outside of the United States, but there is no assurance of whether, where or when our collaborators will file any additional applications. There is also no assurance of whether, where or when BELVIQ will be approved for marketing outside of the United States. Therefore, we expect that all or most of the revenues for BELVIQ sales in the short term will be from Eisai's commercialization of BELVIQ in the United States.

We manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Eisai for Eisai's commercialization in the United States and, subject to applicable regulatory approval, in the other territories under the Eisai Agreement (other than Europe, China and Japan) for a purchase price starting at 31.5% and 30.75%, respectively (and starting at 27.5% in Europe, China and Japan), of Eisai's aggregate annual net product sales (which are the gross invoiced sales less certain deductions described in the Eisai Agreement), or the Product Purchase Price, in the respective territory. The Product Purchase Price will increase on a tiered basis in the United States and the other territories (other than Europe, China and Japan) to as high as 36.5% and 35.75%, respectively, on the portion of Eisai's annual aggregate net product sales exceeding \$750.0 million in all territories other than Europe, China and Japan. The Product Purchase Price will increase to 35% in Europe, China and Japan on the portion of Eisai's annual aggregate net product sales exceeding \$500.0 million in such territories. The Product Purchase Price is subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country. The revenue we recognize for net product sales of BELVIQ related to redemption of vouchers is based on our cost of goods sold. Under the Eisai Agreement, we are eligible to receive up to an aggregate of \$176.0 million in additional regulatory and development milestone payments. In the short term, we do not expect to receive the majority (or potentially any) of such milestone payments or for the purchase price percentages to increase beyond the starting percentage in any territory.

The purchase price for BELVIQ that Eisai has sold to date was lower than the initial estimated price that Eisai paid us for such product, primarily because the price that Eisai paid us did not include deductions for the use of vouchers and savings cards, for certain items related to product launch or for Eisai's recent allocation of certain bottles of BELVIQ for product sampling. Excess payments to us related to these deductions and product sampling are reflected in the Payable to Eisai on our condensed consolidated balance sheets, which at September 30, 2014, was \$19.1 million. On a quarterly basis, subsequent to the end of each calendar quarter, we will refund to Eisai the portion of these excess payments related to product sampling for product shipped to physicians during the quarter. On an annual basis, subsequent to the end of Eisai's fiscal year, we will refund to Eisai the portion of these excess payments related to our product sold by Eisai to their distributors through March 31.

As part of the US approval of BELVIQ, the FDA is requiring the evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors (which is the FDA required portion of CAMELLIA), as well as the conduct of postmarketing 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 FDA-required portion of the cardiovascular outcomes trial, and we will share equally with Eisai the expenses of certain pediatric studies.

Eisai is responsible for the regulatory activities related to BELVIQ under the Eisai Agreement. If the regulatory authority for a country in the additional territories requires development work before or following approval of BELVIQ in such country, we and Eisai will share expenses for such work. In addition, Ildong, CYB and Teva are responsible for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in South Korea, Taiwan and Israel, respectively, including, with respect to Ildong and CYB, related development costs and other expenses.

We expect to incur additional expenses for the development of lorcaserin products that are in addition to BELVIQ for weight management. We expect Eisai to share such expenses, but, nevertheless, that such expenses will be significant. Under the Eisai Agreement, we and Eisai have initially prioritized the development areas of smoking cessation, a once-daily formulation and co-administration with phentermine, as well as potentially exploring, including as part of CAMELLIA, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

In January 2008, under an asset purchase agreement, we acquired from Siegfried certain drug product facility and real estate assets in Zofingen, Switzerland, including approximately 67,000 square feet of space in a building that consists of approximately 134,000 square feet of space. These assets are being used to manufacture BELVIQ as well as certain drug products for Siegfried. Under such agreement, we had the option to purchase the remaining portion of the building we are occupying at a price of CHF

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15.0 million, plus an inflation adjustment. Siegfried also had the option to sell us such remaining portion of the building at a price of CHF 8.0 million, plus an inflation adjustment. In July 2014, Siegfried provided us notice of its exercise of the option to sell us the remaining portion of the building we are occupying at a price of CHF 8.0 million, plus an inflation adjustment. Under our agreement, we are required to purchase such remaining portion of the building in July 2015.

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, sale leaseback transactions and the sale of available-for-sale securities. Although 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. 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 adequate or available on terms that we or our stockholders view as favorable.

### *Long term*

It will require 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 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 postmarketing 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 development work not required by the FDA that we or Eisai may conduct relating to BELVIQ, we would expect to incur additional expenses, which may be significant regardless of whether we share the expenses with Eisai. Expenses for the portion of CAMELLIA not required by the FDA (most of which we do not expect will be incurred for several years, if ever) will be shared equally by Eisai and us for up to an aggregate of \$40.0 million each, and, thereafter, Eisai will be responsible for 100% of such expenses.

Subject to applicable regulatory approval, we expect Eisai to commercialize BELVIQ in additional territories under the Eisai Agreement. Under such agreement, in addition to potential payments for purchases of BELVIQ and milestone payments, we are eligible to receive up to an aggregate of \$1.56 billion in one-time purchase price adjustment payments and other payments. These payments include up to an aggregate of \$1.19 billion that are based on Eisai's annual net product sales of BELVIQ in all of the territories under the Eisai 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. The \$1.56 billion also includes \$370.0 million in one-time purchase price adjustment payments we are eligible to receive based on annual net product sales in the non-US territories, comprised of \$185.0 million based on Eisai's annual net product sales in the non-US territories in North and South America and \$185.0 million based on Eisai's annual net product sales in the territories outside of North and South America. The first and last amounts are payable upon first achievement of annual net product sales of \$100.0 million and \$1.0 billion, respectively, with respect to each of the following areas: (i) the non-US territories in North and South America and (ii) the territories outside of North and South America. In addition, we are also eligible to receive certain payments by Eisai if certain annual minimum sales requirements in Mexico, Canada and Brazil are not met during the first ten years after initial commercial sale in such territories.

Under the Ildong BELVIQ Agreement and the Teva Agreement, we are eligible to receive payments upon regulatory approval (and, with respect to the Teva Agreement, regulatory submission) of BELVIQ. We are also eligible to receive payments from net product sales of BELVIQ under the Ildong BELVIQ Agreement, the Teva Agreement and the CYB Agreement. If BELVIQ is approved in the applicable territory, we will sell BELVIQ to Ildong for a purchase price of 35% of Ildong's annual net product sales, with the purchase price increasing on a tiered basis up to 45% on the portion of annual net product sales exceeding \$15.0 million; to Teva for a purchase price of 35% of Teva's annual net product sales; and to CYB for a purchase price of 45% of CYB's annual net product sales. We are also eligible to receive additional milestone payments and/or purchase price adjustment payments under these collaborators.

In addition to potential payments from Eisai and other current 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, 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

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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.

We evaluate from time to time potential acquisitions and in-licensing and other opportunities. Any such transaction may impact our liquidity as well as affect our expenses if, for example, our operating expenses increase as a result of such acquisition or license or we use our cash to finance the acquisition or license.

*Sources and Uses of Our Cash*

Net cash used in operating activities was \$79.0 million in the nine months ended September 30, 2014, compared to net cash provided by operating activities of \$27.3 in the nine months ended September 30, 2013. This difference was primarily the result of (i) the \$65.0 million non-refundable milestone payment that we received from Eisai in the nine months ended September 30, 2013, in connection with the DEA's final scheduling designation of BELVIQ while no similar milestone payment was received in the nine months ended September 30, 2014, (ii) payments of \$23.1 million received for sales of BELVIQ to Eisai in the nine months ended September 30, 2013, while no payments were received in the nine months ended September 30, 2014, and (iii) increased payments made for external clinical and preclinical study fees and internal non-commercial manufacturing costs in the nine months ended September 30, 2014, compared to the nine months ended September 30, 2013.

Net cash provided by investing activities was \$43.4 million in the nine months ended September 30, 2014, compared to net cash used in investing activities of \$4.1 million in the nine months ended September 30, 2013. This difference was primarily due to proceeds from the sale of available-for-sale securities of \$49.6 million in the nine months ended September 30, 2014.

Net cash of \$3.4 million was provided by financing activities in the nine months ended September 30, 2014, as a result of net proceeds of \$4.9 million from stock option exercises and purchases under our employee stock purchase plan, which were partially offset by \$1.5 million for payments on our lease financing obligations. Net cash of \$1.5 million was provided by financing activities in the nine months ended September 30, 2013, primarily as a result of net proceeds of \$2.6 million from stock option exercises and purchases under our employee stock purchase plan. Such proceeds were partially offset by \$1.2 million for payments on our lease financing obligations.

**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, services (joint steering committee and research and development services) and manufactured products. Consideration we receive under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments and payments for 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 on our consolidated balance sheets. 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 revenues from net product sales when Eisai ships BELVIQ to their distributors.

We manufacture and sell BELVIQ to Eisai for Eisai's marketing and distribution in the United States and, subject to applicable regulatory approval, expect to do so in most territories worldwide. The net product sales price Eisai pays us for product supply for commercialization in the United States starts at 31.5% of their gross invoiced sales, less certain deductions described in the Eisai Agreement. The amount we recognize for BELVIQ product revenue related to redemption of vouchers and product samples is based on our cost of goods sold.

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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. If the delivered element does not have standalone value without one of the undelivered elements in the arrangement, we combine such elements and account for them as a single unit of accounting. 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 all elements in the arrangement, 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 the delivered element does not have standalone value without one of the undelivered elements in the arrangement, or fair value does not exist for certain undelivered elements, we combine such delivered and undelivered elements and account for them as a single unit of accounting.

Non-refundable upfront payments received under our collaborative agreements for commercialization rights have been deferred as such rights have not been deemed to have standalone value without the ongoing services required under the agreement. Such amounts are recognized as revenue on a straight-line basis over the period in which we expect to perform the services. Amounts we receive as reimbursement for our research and development expenditures are recognized as revenue as the services are performed.

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 under 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-based payments received are recognized when earned.

We manufacture drug products under a manufacturing services agreement for a single customer, Siegfried. Upon Siegfried's acceptance of drug products manufactured by us, we recognize manufacturing services revenues.

**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.

**Income taxes.** Significant judgment is required by management to determine our provision for income taxes, our deferred tax assets and liabilities, and the valuation allowance to record against our net deferred tax assets, which are



based on complex and evolving tax regulations throughout the world. Our tax calculation is impacted by tax rates in the jurisdictions in which we are subject to tax and the relative amount of income earned in each jurisdiction. Our deferred tax assets and liabilities are determined using the enacted tax rates expected to be in effect for the years in which those tax assets are expected to be realized.

The effect of an uncertain income tax position is recognized at the largest amount that is more-likely-than-not to be sustained under audit by the taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The realization of our deferred tax assets is dependent upon our ability to generate sufficient future taxable income. We establish a valuation allowance when it is more-likely-than-not that the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available evidence, both positive and negative. As of December 31, 2013, we concluded that it was more-likely-than-not that our deferred tax assets would not be realized.

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*The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our audited consolidated financial statements and notes thereto included in our 2013 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.*

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

We received preferred stock in connection with our collaboration with TaiGen Biotechnology Co., Ltd., which has since converted into common stock. This investment had a cost basis of zero from December 31, 2011, through December 31, 2013.

On January 17, 2014, TaiGen (under the name TaiGen Biopharmaceuticals Holding Limited ) completed an initial public offering and its common stock began to trade on the GreTai Securities Listed Market. Such market is deemed to be comparable to a US over-the-counter market, and, as such, the fair value of our investment in TaiGen became readily determinable under generally accepted accounting principles. As a result, we began to record our investment in TaiGen on our financial statements based on the trading price of TaiGen's common stock.

During the nine months ended September 30, 2014, we sold all of our shares of TaiGen, and, as of such date, we no longer have any market risk related to fluctuations in the market price of TaiGen's securities.

Except as described above in this section, 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, 2013.

### **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 were 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 sought unspecified monetary damages and other relief. 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 March 28, 2013, the Court dismissed the consolidated amended complaint without prejudice. On May 13, 2013, the lead plaintiff filed a second consolidated amended complaint. On November 5, 2013, the Court dismissed the second consolidated amended complaint without prejudice as to all parties except for Robert E. Hoffman, who was dismissed from the action with prejudice. On November 27, 2013, the lead plaintiff filed a motion for leave to amend the second consolidated amended complaint. On March 20, 2014, the Court denied plaintiff's motion and dismissed the second consolidated amended complaint with prejudice. On April 18, 2014, the lead plaintiff filed a notice of appeal, and on August 27, 2014, the lead plaintiff filed his appellate brief in the US Court of Appeals for the Ninth Circuit. On October 24, 2014, we filed our answering brief in response to the lead plaintiff's appeal. 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.

In addition to the class actions, a complaint involving similar legal and factual issues had been brought by an individual stockholder. On March 29, 2013, the Court dismissed the matter, in part without prejudice. On May 13, 2013, the individual stockholder filed a new amended complaint. On March 20, 2014, the Court dismissed the matter in part, and remanded the remaining claims to state court. On May 5, 2014, we and the individual stockholder agreed to resolve this dispute, and the state court dismissed the complaint with prejudice on May 16, 2014.

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*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.*

*BELVIQ® (pronounced BEL-VEEK ) is the trade name for the finished drug product containing the active pharmaceutical ingredient lorcaserin hydrochloride, or lorcaserin, that is marketed for chronic weight management in the United States. Lorcaserin may in the future be marketed in the United States or in other countries as BELVIQ or under a different trade name for chronic weight management, for a different indication, in a different formulation or in combination with another drug. In this report, we use BELVIQ to refer to the finished drug product containing lorcaserin and/or, depending on the context, the active pharmaceutical ingredient lorcaserin, and without regard to the current or potential indication, formulation or combination.*

*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, 2013, as filed with the Securities and Exchange Commission, or SEC.*

***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.**

Our prospects are highly dependent on the success of BELVIQ, which is approved for chronic weight management by the US Food and Drug Administration, or FDA, and is our first and only drug approved by any regulatory agency. 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. As we have granted rights to commercialize BELVIQ to collaborators for most of the territories in the world, we are highly dependent on collaborators for obtaining marketing approval and commercializing BELVIQ. We do not know whether or when BELVIQ will be approved for sale or commercialized in any territories outside of the United States, and BELVIQ may not receive marketing approval from any other regulatory agency or be commercialized in any other territories. 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.

BELVIQ became available in June 2013 to patients in the United States by prescription, and is being marketed in the United States by Eisai under a marketing and supply agreement, among our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, Eisai Inc. and Eisai Co., Ltd. (collectively with Eisai Inc., Eisai). 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.

Under the marketing and supply agreement with Eisai, Arena GmbH also granted Eisai exclusive rights to market and distribute BELVIQ in all of the other countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. In addition, Arena GmbH has entered into marketing and supply agreements with Ildong Pharmaceutical Co., or Ildong, for South Korea; with CY Biotech Company Limited, or CYB, for Taiwan; and with Teva Pharmaceutical Industries Ltd. s local Israeli subsidiary, Abic Marketing Limited, or Teva, for Israel, 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 marketing and supply agreement with Eisai (and, to a lesser extent, the other BELVIQ Agreements) will constitute the majority of our revenues over the next several years, and future payments to us under the BELVIQ Agreements will substantially depend on BELVIQ product sales and the achievement of milestones, and potentially on other BELVIQ products, if any. Each of the BELVIQ Agreements may be terminated early in certain circumstances, in which case we may not receive additional milestone or other payments under the terminated agreement. We cannot guarantee future BELVIQ product sales or achievement of any other milestones under the BELVIQ Agreements.

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We and our collaborators have filed applications for regulatory approval for BELVIQ outside of the United States, and we expect our collaborators will seek regulatory approval for BELVIQ in additional territories in the future. There is no assurance that any pending or future regulatory applications will be approved. For example, we withdrew our Marketing Authorization Application, or MAA, for BELVIQ in the European Union, and Swissmedic determined not to approve our MAA for BELVIQ in Switzerland. We also plan to enter into marketing and supply agreements or similar arrangements with one or more pharmaceutical companies to commercialize BELVIQ in the territories not already under collaboration, 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;

market acceptance and use of BELVIQ, which may depend on the public's view of BELVIQ, economic changes, national and world events, potentially seasonal and other fluctuations in demand, the timing and impact of current or new 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 of BELVIQ (such as BELVIQ for a different indication, in a different formulation or in combination with another drug) or related drugs or drug candidates;

physicians may not prescribe, and patients may not take, BELVIQ until at least results from our required postmarketing 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, marketing team, strategy and program and medical affairs group and related functions, as well as 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 placement of BELVIQ on third-party payer formularies, and the ability of patients and physicians and other providers to obtain and maintain adequate reimbursement, if any, by third-party payers, including government payers;

the ability and desire 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;

the development of the market for weight-management medications;

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 lower-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.

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We cannot predict with certainty the extent to which BELVIQ will be accepted or utilized by patients, physicians, healthcare insurers, maintenance organizations or the medical community in general. 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. 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, our collaborators may negatively change marketing strategies or resources, our relationships with collaborators may be modified or terminated and we may not be profitable.

**\*BELVIQ or any of our future drugs may not be commercially successful if not widely covered and adequately reimbursed by third-party payers, and we may depend on others to obtain and maintain third-party payer access; 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.**

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 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 the potential to significantly affect the pharmaceutical industry. In addition to extending coverage to patients otherwise uninsured, PPACA includes, among several other provisions relating to pharmaceuticals, measures that enhance remedies against healthcare fraud and abuse, add new transparency requirements, impose a new annual nondeductible fee on certain branded drugs based on market share in government healthcare programs, increases in rebates for government programs such as Medicaid, expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale discount off the negotiated price of applicable branded drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D, 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. In addition, many countries outside of the United States have nationalized healthcare systems in which the government pays for all such products and services and must approve product pricing.

The ability to successfully commercialize any drug depends, in part, on the extent to which coverage and reimbursement for the drug is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers. It is increasingly difficult to obtain coverage and adequate reimbursement levels from third-party payers, and significant uncertainty exists as to the coverage and reimbursement of newly approved prescription drug products. We or our collaborators also face competition in negotiating for coverage from pharmaceutical companies and others with competitive drugs or other treatment, and such competitors may have significantly more negotiating leverage or success with respect to the individual payers than we or our collaborators may have.

With respect to BELVIQ, we depend on Eisai and our other collaborators for the achievement of third-party payer coverage and acceptable reimbursement and negotiating with individual payers. In the United States, even if a third-party payer ultimately elects to cover and reimburse for BELVIQ, most payers will not reimburse 100% of the



cost, but rather require patients to pay a portion of the cost through a co-payment. Thus, even if reimbursement is available, the percentage of drug cost required to be borne by the patients may make use of BELVIQ financially undesirable, difficult or impossible for certain patients, which would have a negative impact on sales of BELVIQ, including related revenues. For example, payers may approve coverage for BELVIQ in tiers requiring unacceptably high patient co-payments or only as a second- or later-line treatment. Since launch, several third-party payers have approved coverage for BELVIQ with limitations, including co-payments that may be unacceptably high for certain patients regardless of the availability of any coupon, voucher or other discount program. In addition, even if a payer approves coverage for BELVIQ, individual employers or others may not opt to provide such coverage. Failure to improve coverage or the reduction or loss of coverage could materially harm the ability to successfully market BELVIQ. Achieving coverage and acceptable reimbursement levels typically involves negotiating with individual payers and is a time-consuming and costly process. In addition, Medicare explicitly excludes coverage for drugs for weight loss. While new legislation may in the future remove this exclusion, there is no assurance any such legislation will be approved, and Medicare may continue to exclude drugs for weight loss from its coverage.

Given the continuing discussion regarding the cost of healthcare, managed care, universal healthcare coverage and other healthcare reform measures proposed or yet to be proposed, we cannot predict with certainty what additional healthcare initiatives, if any, will be implemented or the effect any future legislation or regulation will have on our business. PPACA and any additional legislation or regulations may limit our commercial opportunities by reducing the amount a potential collaborator is willing to pay to

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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 expect that the PPACA, as well as other federal and state healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product, and could seriously decrease our future revenues. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, commercialize our products or establish and maintain collaborations.

The full impact of these new laws, as well as laws and other reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on pharmaceutical pricing, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

**\*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 a large extent on our collaborators, particularly Eisai, conducting commercial activities and providing us with 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, including fluctuations in demand for various reasons, such as fluctuations related to economic changes, national and world events, holidays and seasonal changes;

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

lack of patient and physician familiarity with BELVIQ;

lack of patient use and physician prescribing history;

lack of commercialization experience with BELVIQ, in particular, and weight loss or management 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 the world, 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.

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**\*Data generated or analyzed with respect to product use in the market or required postmarketing 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. Eisai is the NDA holder of BELVIQ, and we expect that Eisai and other of our collaborators will hold the BELVIQ regulatory approvals, if any, in territories outside of the United States. Eisai, we and others will assess and monitor the safety of BELVIQ in the marketplace, and will receive reports of adverse safety events. In addition, as a condition to obtaining FDA approval of BELVIQ, the FDA required the conduct of postmarketing 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 (otherwise known as the cardiovascular outcomes trial, or CVOT). The FDA-required portion of the trial is designed to evaluate BELVIQ's effect on the incidence of major adverse cardiovascular events, or MACE, (non-fatal myocardial infarction, non-fatal stroke and cardiovascular death) compared to placebo, with a non-inferiority margin for the hazard ratio of 1.4. The trial will also include FDA-required echocardiographic assessments. Along with the FDA-required portion of the trial, we expect that the trial may include the non-FDA required evaluation of whether lorcaserin reduces the incidence of conversion to type 2 diabetes in patients without type 2 diabetes at baseline and the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure, or any coronary revascularization), both as compared to placebo. We expect that the trial (including the non-FDA required portion) will run approximately five years. The FDA is also requiring as a postmarketing commitment the assessment of the safety and efficacy of BELVIQ for weight management in obese pediatric patients. In addition, we expect that, from time to time, we or others will 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 postmarketing 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.

**\*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 with respect to BELVIQ and in seeking to identify and validate new drug targets and develop other 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.

Cash we may generate in the future from sales of BELVIQ or otherwise is uncertain and difficult to predict. 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 intend to explore BELVIQ's therapeutic potential for other indications, in combination with other drugs or using different formulations, and from time to time we expect to collaborate with Eisai or others, or, possibly, to work independently, on related studies and trials. We also intend to advance other of our drug candidates and preclinical compounds in our pipeline. It takes many years and potentially hundreds of millions of dollars to successfully develop a drug candidate or preclinical compound into a marketed drug, and our efforts may not result in marketed drugs.

We cannot assure you that any additional amounts paid to us or others under the BELVIQ Agreements will be sufficient to fund our planned research and development and other activities. We may enter into collaborative agreements to research, develop and commercialize other drug candidates in our pipeline, and we may not be able to enter into any such agreement on terms that we or third parties, including investors or analysts, view as favorable, if at all.

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Our ability to enter into new collaborations for any of our programs or drug candidates may depend on the outcomes of additional preclinical and clinical testing or regulatory applications for marketing approval. We do not control these outcomes.

We may seek to obtain additional funding from the capital markets or we may eliminate, scale back or delay some or all of our research or development programs. Any such additional funding may dilute or otherwise negatively impact your ownership interest, and any such reductions or failure to apply our resources effectively may narrow, slow or otherwise adversely impact the development and commercialization of our pipeline, which we believe may reduce our opportunities for success and have a material adverse effect on our business and prospects.

We may allocate our resources in ways that do not improve our results of operations or enhance the value of our assets, and our stockholders and others may also not agree with the manner in which we choose to allocate our resources or obtain additional funding. Any failure to apply our resources effectively, how we obtain additional funding and the related views of stockholders or others 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, 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.

**\*If BELVIQ is not approved for marketing outside the United States, or if any such approval is significantly delayed or limited, our results of operations and business may be materially adversely affected and our stock price may decline.**

We or our collaborators have filed applications for regulatory approval of BELVIQ outside of the United States, and we expect that our current or future collaborators or we will seek regulatory approval for the marketing of BELVIQ in additional territories. The FDA's approval of a drug does not assure or predict with any certainty that any other regulatory authority will grant marketing approval for such drug. For example, as described below, we withdrew 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. We cannot assure or predict with any certainty that BELVIQ will be approved in any additional territories or the expected timeframe of any such approval. 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, may interpret or weigh the importance of data differently or require additional information for approval.

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 postmarketing 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 2013, the EMA's CHMP 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. 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 withdrew the BELVIQ MAA for the European Union. We also previously filed an MAA for approval of BELVIQ in Switzerland, and Swissmedic provided us feedback that included major objections that were similar to those identified with respect to our MAA for the European Union and determined not to approve our application. We expect Eisai to potentially submit for regulatory approval in Europe at a later date, but BELVIQ may not be submitted for regulatory approval in Europe 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.

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**Our commercialization and continuing development 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, the FDA required the conduct of postmarketing studies, including the CVOT described above. The results of such trial and assessments may be unfavorable. Unfavorable results from these studies or other studies we or others conduct, including for related development programs, 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.**

Our collaborators have primary responsibility for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in the territory or territories under the applicable collaboration. We have limited or no 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 commercialization or development of BELVIQ;

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



our collaborators may not allocate adequate resources or otherwise support BELVIQ or may have limited experience in a particular territory; and

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.

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**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.**

Under each of the BELVIQ Agreements, we are the exclusive supplier of BELVIQ. Our Swiss subsidiary owns and operates 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. Accordingly, we must either rely on third-party manufacturers for such production or develop or acquire such facilities, which, in either case, would require substantial time and funds. With respect to BELVIQ, we estimate that it could take two years or longer and a substantial amount of financial and other resources to secure another source for finished drug product.

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. Instead, 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, or 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;

having the ability to adjust to changes in actual or anticipated use of the facility, including with respect to having sufficient capacity and a sufficient number of qualified personnel;

facility contamination by microorganisms or viruses or cross contamination;

compliance with regulatory requirements, including inspectional notices of violation and warning letters;

maintenance and renewal of any required licenses or certifications;

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 or maintain 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 inspection (which may be unannounced) by the FDA, the DEA, corresponding state and foreign authorities and other regulatory

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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 certain business and technical 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 business and technical 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 collaborators, distributors and licensees, 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 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, as well as related decisions, 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 (including development programs related to BELVIQ) 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 decisions regarding the focus and prioritization of our research and development efforts, 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 our 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.

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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, the FDA required the conduct of the CVOT described above as well as postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients. 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 for chronic weight management, for a different indication, in a different formulation or in combination with another drug. Certain countries in the European Union have denied Eisai's application to conduct the CVOT in their countries until the major objections identified in the MAA for BELVIQ for weight management that was withdrawn from the European Medicines Agency have been addressed. We may be similarly restricted in additional territories in the future, and restrictions may cause delay or otherwise negatively impact our ability to conduct and complete clinical trials for BELVIQ. Unfavorable results or delays with respect to studies, trials or analyses for BELVIQ could negatively impact market acceptance of BELVIQ, limit the revenues we generate from sales, negatively impact regulatory agencies' views or restrictions on BELVIQ, 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 (including related development programs).

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 seek regulatory approval or commercialize BELVIQ with one or more collaborators, our lack of corporate experience and resources may negatively impact our ability to commercialize BELVIQ independently.**

Subject to applicable regulatory approval, we expect our collaborators to commercialize BELVIQ under the BELVIQ Agreements. We may not be able to maintain the BELVIQ Agreements or enter into new agreements for BELVIQ on acceptable terms, if at all. If we are unable to maintain or enter into agreements to commercialize BELVIQ 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.

If our competitors have commercialization arrangements with companies who allocate substantially greater resources than we allocate (or, with respect to commercializing BELVIQ in a territory under one of the BELVIQ Agreements, than our collaborator allocates) to the respective drugs, 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

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resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies. We are subject to periodic inspections (which may be unannounced) 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 the issuance of an NDA approval letter, and the timing and outcome of such DEA process is uncertain. For example, the FDA approved the NDA for BELVIQ in June 2012, subject to the final scheduling of BELVIQ by the DEA. 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 different 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

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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.

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, therefore, we withdrew the MAA. We expect Eisai to potentially submit for regulatory approval of BELVIQ in Europe at a later date. If such an application is submitted, the regulatory authority could determine that the 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 to 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 also previously filed an MAA for approval of BELVIQ in Switzerland, and Swissmedic provided us feedback that included major objections that were similar to those identified with respect to our MAA for the European Union and determined not to approve our application. While we expect to continue to work with Eisai to pursue regulatory approval in Switzerland, BELVIQ may not be approved for marketing in Switzerland when expected or ever. In addition, Eisai filed regulatory applications for marketing approval of BELVIQ in Mexico, Canada and Brazil, and Ildong filed a regulatory application for marketing approval in South Korea. We expect that we or our collaborators will submit applications for regulatory approval of BELVIQ in additional territories in the future, but there is no guarantee that we or any of our collaborators will submit any additional regulatory applications.

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 postmarketing 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 postmarketing 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, the FDA

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required the conduct of the CVOT described above as well as postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients. Along with being costly and time consuming, a delay or 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 different 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 us 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 or related materials to be imported into or exported from the United States or other countries;

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.

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**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 general marketplace for the particular drug;

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 the conduct of postmarketing studies of BELVIQ, and we or others may from time to time 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 approval or agreement from the applicable regulatory authority to commence a clinical trial or 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;





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

changes in applicable regulatory policies and regulations;

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

uncertainty regarding proper dosing;

unfavorable results from ongoing clinical trials or preclinical studies;

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

scheduling conflicts with participating clinicians and clinical institutions;

failure to design appropriate clinical trial protocols;

insufficient data to support regulatory approval;

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

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

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

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

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

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We have experienced setbacks in our internal and partnered development programs and 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 additional revenues.

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**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 increase or they 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, VIVUS and Orexigen Therapeutics, Inc., announced the US market availability of their drugs for chronic weight management in September 2012 and October 2014, respectively. We also face competition from other drugs that may be indicated or used off label or otherwise for weight loss and from other approaches for weight loss, including behavior modification (such as diet and exercise), surgical approaches (such as gastric bypass surgery and gastric banding), and herbal or other supplements. 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. For example, in December 2013, Orexigen Therapeutics, Inc., announced that it filed an MAA for the approval of its drug candidate for chronic weight management in the European Union; and, in December 2013, Novo Nordisk announced that it has filed submissions for regulatory approval in the United States and Europe of its drug candidate for the treatment of obesity that is currently approved for the treatment of type 2 diabetes.

Our competitors, particularly large pharmaceutical companies, may have substantially greater research, development and marketing capabilities and greater financial, scientific and human resources than we do. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before we do for the same indication may achieve a significant competitive advantage, including certain patent and marketing exclusivity rights. In addition, our competitors' drugs may have fewer side effects, more desirable characteristics (such as efficacy, route of administration or frequency of dosing), or be viewed more favorably by patients, healthcare providers, healthcare payers, the medical community, the media or others than our drug candidates or drugs, if any, for the same indication. Our competitors may also market generic or other drugs that compete with our drugs at a lower

price than our drugs, which may negatively impact our drug sales, if any. Any results from our research and development efforts, or from our joint efforts with our existing or any future collaborators, may not compete successfully with existing or newly discovered products or therapies.

**Collaborative relationships may lead to disputes and delays in drug development and commercialization, and we may not realize the full commercial potential of our drug candidates or drugs.**

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:

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unwillingness on the part of a collaborator to pay for studies or other research, milestones, 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 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, including by making it more difficult to enter into agreements with pharmaceutical companies to collaborate or commercialize our drugs and diminishing our revenues. 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.

**We and our collaborators may from time to time rely on third parties to conduct clinical trials and 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 and our collaborators may from time to time rely on third parties, including laboratories, investigators, clinical research organizations and manufacturers, to perform critical services. 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., D.Sc., 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.

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**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 face an even greater risk with the commercialization of BELVIQ as well as any other drug that may be approved for marketing. In addition, under the marketing and supply agreement with Eisai, Arena GmbH and Eisai will, in general, share equally in losses resulting from third-party product liability claims, with certain limited exceptions.

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 results of operations and financial condition.

We expect that Arena GmbH will manufacture BELVIQ for commercialization and, from time to time, for clinical trials or other studies. Arena GmbH also manufactures certain generic 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.



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**We may be subject, directly or indirectly, to federal and state healthcare laws, including but not limited to fraud and abuse and false claims laws. 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 research, manufacturing, sales, marketing and education programs for our drugs.

The Federal Anti-Kickback Statute prohibits persons and entities from knowingly and willingly soliciting, offering, receiving or providing any remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the purchase, lease, order or the furnishing or arranging for, a good, item, facility or service, for which payment may be made, in whole or in part, 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 Federal Anti-Kickback Statute is broad and, despite a series of narrow statutory exceptions and regulatory safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Moreover, the PPACA, among other things, amended 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. 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, among other things, persons or entities from knowingly presenting, or causing to be presented, 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 can be brought by any individual on behalf of the government, known as *qui tam* actions, and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The filing of *qui tam* actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim, in addition to other penalties that may apply. Various states have also enacted laws modeled after the Federal False Claims Act, some of which are broader in scope and may apply regardless of payer.

The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The Federal Physician Payment Sunshine Act, created under the PPACA, and its implementing regulations requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under

Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the US Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

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We are unable to predict whether we could be subject to actions under any of these fraud and abuse or other 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, criminal and/or administrative penalties, damages, fines, individual imprisonment, disgorgement, possible 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 supply chain, regulatory compliance, distribution of finished products, alliance management, and 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 US 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 business and operations might be adversely affected by business disruptions and security breaches, including any cybersecurity incidents.**

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.

We depend on the efficient and uninterrupted operation of our computer and communications systems, which we use for, among other things, sensitive company data, including our intellectual property and proprietary business information. We maintain our information technology, or IT, infrastructure for our San Diego campus, and, at least for the near term, we have contracted with Siegfried to use their IT infrastructure for our manufacturing facility in Switzerland. We are in the process of building our own IT infrastructure for such manufacturing facility, but the timing and outcome of such process is uncertain.

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While certain of our operations have business continuity and disaster recovery plans and other security measures intended to prevent and minimize the impact of IT-related interruptions, our IT infrastructure and the IT infrastructure of our current and any future collaborators, contractors and vendors are vulnerable to damage from cyberattacks, computer viruses, unauthorized access, electrical failures and natural disasters or other catastrophic events. Siegfried or we could experience failures in our information systems and computer servers, which could result in an interruption of our normal business operations and require substantial expenditure of financial and administrative resources to remedy. System failures, accidents or security breaches can cause interruptions in our operations and can result in a material disruption of our research and development programs, manufacturing or commercialization activities and other business operations. The loss of data from completed or future studies or clinical trials could result in delays in our research, development or regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Similarly, we rely on third parties to supply materials for the manufacture of BELVIQ and our drug candidates, conduct studies and clinical trials of our drug candidates and warehouse, market and distribute BELVIQ, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the development of any of our other drug candidates and the commercialization of BELVIQ could be delayed or otherwise adversely affected.

Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors' insurance policies or for which we or our contractors do not have coverage. For example, we are not insured against a terrorist attack. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs and adversely affect, which may include stopping, our commercial production.

### **Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.**

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our stock. Our executive officers and directors may sell stock in the future, either as part, or outside, of trading plans under SEC Rule 10b5-1.

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

We primarily spend and generate cash in US dollars, and present our consolidated financial statements in US dollars. However, a portion of our expected and potential payments and receipts under our agreements are in foreign currencies, including Swiss francs. For example, payments and receipts under our agreements with Siegfried are required to be paid in Swiss francs. A fluctuation of the exchange rates of foreign currencies versus the US dollar may, thus, adversely affect our financial results, including cash balances, expenses and revenues. We may in the future enter into hedging transactions to try to reduce our foreign currency exposure, 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.

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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 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.



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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.

There could 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 communicated that it believes 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 were held 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.

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***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, 2012, to November 3, 2014, the market price of our stock was as low as \$1.51 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:

regulatory actions or decisions or legislation 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 trends or other 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;

fluctuation in prescriptions, sales or financial 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 (including related development programs);

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 November 3, 2014, we had outstanding a warrant to purchase 1,965,418 shares of our common stock at an exercise price of \$4.34 per share that expires on August 14, 2015. 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 November 3, 2014, there were (i) options to purchase 15,413,277 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$5.29 per share, (ii) 612,534

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restricted stock unit awards outstanding under our equity incentive plans, (iii) performance restricted stock unit awards outstanding under our equity incentive plans targeted at 1,475,000 shares (however, the actual number of shares that may be awarded ranges from 0% to 200% of such amount), (iv) 22,070,661 additional shares of common stock remaining issuable under our 2013 Long-Term Incentive Plan, (v) 677,374 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 November 3, 2014, there were 220,114,995 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 been opportunistic in our efforts to obtain cash, and we expect to continue to evaluate various funding alternatives from time to time. We have primarily financed our operations, and we may continue to finance our operations, by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. We may issue additional shares of common stock or convertible securities that could dilute your ownership in our company and may include terms that give new investors rights that are superior to yours. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. In addition, we may also raise additional funds through the incurrence of debt, and the holders of any debt we may issue would have rights superior to your rights in the event we are not successful and are forced to seek the protection of bankruptcy laws.

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

A small number of stockholders may hold or acquire a significant amount of our outstanding stock. 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 proxy contests or 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 interests.**

There is a standstill provision in our marketing and supply agreement with Eisai, 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 interests. 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.

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NO.	DESCRIPTION
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Certificate of Amendment No. 3 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.4 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
3.5	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on October 9, 2014, 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*	Summary of compensation for non-employee directors
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.



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**SIGNATURES**

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

Date: November 6, 2014

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)

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