ARENA PHARMACEUTICALS INC
Form 10-Q
May 12, 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 March 31, 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)

Delaware	**23-2908305**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
6154 Nancy Ridge Drive, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

858.453.7200

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x 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 x 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 x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The number of shares of common stock outstanding as of the close of business on May 6, 2014:

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	219,650,003

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In this Quarterly Report on Form 10-Q, Arena Pharmaceuticals, Arena, we, us and our refer to Arena Pharmaceu 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 under a different trade name for chronic weight management. Lorcaserin may also be marketed as BELVIQ or under a different trade name 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.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands)

	March 31, 2014 (Unaudited)	December 31, 2013[1]
Assets		
Current assets:		
Cash and cash equivalents	$ 203,272	$ 221,878
Short-term investments, available-for-sale	53,234	0
Accounts receivable	1,552	10,602
Inventory	11,947	12,759
Prepaid expenses and other current assets	6,363	3,571
Total current assets	276,368	248,810
Land, property and equipment, net	78,046	77,388
Intangibles, net	10,071	10,182
Other non-current assets	3,211	3,427
Total assets	$ 367,696	$ 339,807
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 6,806	$ 7,317
Payable to Eisai	19,321	19,305
Accrued compensation	3,285	4,205
Current portion of deferred revenues	35,393	37,861
Current portion of lease financing obligations	2,161	2,056
Total current liabilities	66,966	70,744
Deferred rent	281	247
Deferred revenues, less current portion	99,225	101,329
Derivative liabilities	5,002	4,892
Lease financing obligations, less current portion	70,167	70,738
Commitments and contingencies		
Stockholders equity:		
Common stock	22	22

Additional paid-in capital	1,299,968	1,293,840
Accumulated other comprehensive income	59,053	5,728
Accumulated deficit	(1,232,988)	(1,207,733)
Total stockholders equity	126,055	91,857
Total liabilities and stockholders equity	$ 367,696	$ 339,807

[1] 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.

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ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except per share data)

(Unaudited)

	Three months ended March 31,	
	2014	**2013**
Revenues:		
Net product sales	$ 2,882	$ 0
Eisai collaborative revenue	3,347	1,495
Manufacturing services	448	765
Other collaborative revenue	137	113
Total revenues	6,814	2,373
Operating Costs and Expenses:		
Cost of product sales	831	473
Cost of manufacturing services	496	1,645
Research and development	20,988	14,008
General and administrative	8,037	7,251
Total operating costs and expenses	30,352	23,377
Loss from operations	(23,538)	(21,004)
Interest and Other Income (Expense):		
Interest income	29	24
Interest expense	(1,747)	(1,787)
Gain (Loss) from valuation of derivative liabilities	(110)	3,859
Other	111	32
Total interest and other income (expense), net	(1,717)	2,128
Net loss	$ (25,255)	$ (18,876)
Net loss per share:		
Basic	$ (0.12)	$ (0.09)
Diluted	$ (0.12)	$ (0.09)
Shares used in calculating net loss per share:		
Basic	219,222	217,503

Diluted	219,222	217,503
Comprehensive Income (Loss):		
Net loss	$ (25,255)	$ (18,876)
Foreign currency translation gain (loss)	91	(1,588)
Unrealized gain on investment	53,234	0
Comprehensive income (loss)	$ 28,070	$ (20,464)

See accompanying notes to unaudited condensed consolidated financial statements.

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ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Cash Flow Statements

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2014	**2013**
Operating Activities		
Net loss	$ (25,255)	$ (18,876)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,992	1,950
Amortization of intangibles	181	99
Share-based compensation	3,201	1,785
(Gain) Loss from valuation of derivative liabilities	110	(3,859)
Amortization of prepaid financing costs	34	34
Gain on sale of equipment	(45)	0
Changes in assets and liabilities:		
Accounts receivable	8,934	4,013
Inventory	903	(1,300)
Prepaid expenses and other assets	(2,806)	(333)
Accounts payable, payable to Eisai and accrued liabilities	(1,613)	(810)
Deferred revenues	(4,786)	(954)
Deferred rent	34	27
Net cash used in operating activities	(19,116)	(18,224)
Investing Activities		
Purchases of property and equipment	(2,469)	(1,266)
Proceeds from sale of equipment	45	0
Other non-current assets	209	(52)
Net cash used in investing activities	(2,215)	(1,318)
Financing Activities		
Principal payments on lease financing obligations	(466)	(372)
Proceeds from issuance of common stock	2,927	450
Net cash provided by financing activities	2,461	78
Effect of exchange rate changes on cash	264	(377)
Net decrease in cash and cash equivalents	(18,606)	(19,841)
Cash and cash equivalents at beginning of period	221,878	156,091
Cash and cash equivalents at end of period	$ 203,272	$ 136,250

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.

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.

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 March 31, 2014, and December 31, 2013, in thousands:

	Fair Value Measurements at March 31, 2014			
	Balance at March 31, 2014	Quoted Prices in Active Markets	Significant Other Observable Inputs	Significant Unobservable Inputs (Level 3)

		(Level 1)	(Level 2)	
Assets:				
Money market funds [1]	$ 183,861	$ 183,861	$ 0	$ 0
TaiGen equity securities [2]	$ 53,234	$ 53,234	$ 0	$ 0
Liabilities:				
Warrant derivative liabilities	$ 5,002	$ 0	$ 5,002	$ 0

1 Included in cash and cash equivalents on our condensed consolidated balance sheets.
2 Included in short-term investments, available-for-sale on our condensed consolidated balance sheets.

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

[1] Included in cash and cash equivalents on our condensed consolidated balance sheets.

3. Short-term investments, available-for-sale

We have 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 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 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 in the stockholders equity section of our condensed consolidated balance sheets. At March 31, 2014, our investment in TaiGen had a fair value of approximately $53.2 million (see Note 2). We began recording our investment in TaiGen at fair value based on the trading price of TaiGen s common stock, and it is 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.

4. Inventory

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

	March 31, 2014	December 31, 2013
Raw materials	$ 692	$ 657
Work in process	4,028	4,104
Finished goods at Arena GmbH	0	0
Finished goods at Eisai	7,227	7,998
Total inventory	$ 11,947	$ 12,759

5. Accounts Payable and Other Accrued Liabilities

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

	March 31, 2014	December 31, 2013
Accounts payable	$ 2,863	$ 3,721
Accrued expenses	1,346	1,477
Accrued clinical and preclinical study fees	2,067	1,317
Loss provision	497	567
Other accrued liabilities	33	235
Total accounts payable and other accrued liabilities	$ 6,806	$ 7,317

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6. 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. As of March 31, 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. The outstanding warrant, which was valued at $5.0 million and $4.9 million as of March 31, 2014, and December 31, 2013, respectively, is recorded as a long-term derivative liability on our condensed consolidated balance sheets.

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). We recognized a loss of $0.1 million in the three months ended March 31, 2014, and a gain of $3.9 million in the three months ended March 31, 2013, from revaluation of the warrants outstanding in each period.

7. Marketing and Supply Agreement with Eisai

In November 2013, Arena Pharmaceuticals GmbH, or Arena GmbH, our wholly owned subsidiary, and Eisai Inc. and Eisai Inc. s parent company, 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 it 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 received an upfront payment and are entitled to receive milestone payments based on the achievement of regulatory filings and approvals, one-time purchase price adjustment payments and other payments, and payments from sales of BELVIQ.

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 months ended March 31, 2014, and 2013, in thousands:

	March 31,	
	2014	**2013**
Net product sales	$ 2,882	$ 0
Amortization of upfront payments	1,975	861
Reimbursement of research and development expenses	745	2
Milestone payments	500	500

Reimbursement of patent and trademark expenses	127	132
Subtotal Eisai collaborative revenue	3,347	1,495
Total	$ 6,229	$ 1,495

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

	March 31, 2014	December 31, 2013
Upfront payments	$ 100,130	$ 102,104
Net product sales	27,836	30,299
Total deferred revenues attributable to Eisai	127,966	132,403
Less current portion	(34,839)	(37,301)
Deferred revenues attributable to Eisai, less current portion	$ 93,127	$ 95,102

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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, including $0.5 million earned in March 2014 upon Eisai filing for regulatory approval of BELVIQ in Brazil, and we are eligible to receive up to an aggregate of $176.0 million in additional regulatory and development milestone payments.

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 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.

We recognized total revenues from BELVIQ net product sales of $2.9 million in the three months ended March 31, 2014, of which $2.7 million related to sales at the Product Purchase Price and $0.2 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, savings cards and deductions for certain items related to product launch. These excess payments, which reflect both the amounts Eisai has sold to date and the product supply remaining in Eisai s inventory at March 31, 2014, are included in the $19.3 million classified as Payable to Eisai on our condensed consolidated balance sheets. 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.

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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 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 exploring, including as part of the CVOT, BELVIQ s effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

The below chart 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

	United States	**Rest of North and South America**	**Remaining Territories**
BELVIQ for weight management - ***Pre-approval****	Not Applicable	**General** Eisai: 90%; Arena: 10% **Certain stability work** Eisai: 50%; Arena: 50%	Up to total of $100.0 million - Eisai: 50%; Arena: 50% Thereafter, Eisai: 100%
BELVIQ for weight management - ***Post-approval****	**General** - Eisai: 90%; Arena 10% **Non-FDA required portion of CVOT** Up to $80.0 million - Eisai: 50%; Arena: 50% Thereafter, Eisai: 100%	**General** Eisai: 90%; Arena: 10% **Certain stability work** Eisai: 50%; Arena: 50%	Up to total of $50.0 million - Eisai: 50%; Arena: 50% Thereafter, Eisai: 90%; Arena: 10%

	Certain pediatric studies
	Eisai: 50%; Arena: 50%
Products other than BELVIQ for weight management	Up to total of $250.0 million (as reduced by up to $80.0 million for non-FDA required portion of CVOT) -
- Pre-approval	Eisai: 50%; Arena: 50%
Products other than BELVIQ for weight management	Up to a total of $100.0 million in the aggregate across all additional products -
- Post-approval	Eisai: 50%; Arena: 50%
	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.

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8. Share-based Activity

Share-based Compensation

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

	Three months ended March 31,	
	2014	**2013**
Cost of product sales	$ 0	$ 17
Research and development	1,781	725
General and administrative	1,420	1,043
Total share-based compensation expense	$ 3,201	$ 1,785
Total share-based compensation expense capitalized into inventory	$ 0	$ 11

Share-based Award Activity

The following table summarizes our stock option activity during the three months ended March 31, 2014, in thousands (except per share data):

	Options	**Weighted-Average Exercise Price**
Outstanding at January 1, 2014	14,681	$ 4.99
Granted	2,091	6.81
Exercised	(594)	4.40
Forfeited/cancelled/expired	(10)	10.67
Outstanding at March 31, 2014	16,168	$ 5.24

The following table summarizes activity with respect to our time-based restricted stock unit awards, or RSUs, during the three months ended March 31, 2014, in thousands (except per share data):

	RSUs	**Weighted-Average Grant-Date Fair Value**
Unvested at January 1, 2014	369	$ 7.23
Granted	0	

Vested	(33)		8.81
Forfeited/cancelled	0		
Unvested at March 31, 2014	336	$	7.07

In the three months ended March 31, 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 their 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 their 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

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In the three months ended March 31, 2013, we granted our executive officers PRSUs with substantially the same terms as the PRSUs granted in 2014. In the aggregate, the target number of shares of common stock that may be earned under the 2013 PRSUs is 780,000; however, the actual number of shares that may be earned ranges from 0% to 200% of such amount. The three-year performance period for the 2013 PRSUs began March 1, 2013.

All of the PRSUs granted to date were outstanding and unvested at March 31, 2014.

9. 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 March 31,	
	2014	2013
Eisai marketing and supply agreement	91.4%	63.0%
Manufacturing services agreement with Siegfried	6.6%	32.2%
Other collaborative agreements	2.0%	4.8%
Total percentage of revenues	100.0%	100.0%

Our investment in TaiGen equity securities is subject to market price volatility. See Note 3. Fluctuations in the market price of publicly traded securities may result from perceived changes in the underlying economic characteristics of the issuer, the relative price of alternative investments, general market conditions and other factors.

10. 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.

Since we are in a net loss position, we have excluded 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. The table below presents the potentially dilutive securities that were excluded from our calculation of diluted net loss per share for the periods presented, in thousands.

	Three months ended March 31,	
	2014	**2013**
Stock options	4,581	5,961
Warrants	679	982
RSUs and unvested restricted stock	99	82
Total	5,359	7,025

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11. Legal Proceedings

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. On December 30, 2011, we filed a motion to dismiss the consolidated amended complaint. On March 28, 2013, the Court granted our motion to dismiss the consolidated amended complaint without prejudice. On May 13, 2013, the lead plaintiff filed a new consolidated amended complaint. On June 14, 2013, we filed a motion to dismiss the new consolidated amended complaint. On November 5, 2013, the Court granted our motion to dismiss the new 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 now-dismissed new consolidated amended complaint. On March 20, 2014, the Court denied plaintiff s motion for leave to amend and dismissed the consolidated amended complaint with prejudice. On April 18, 2014, the lead plaintiff filed a notice of appeal.

In addition to the class actions, a complaint involving similar legal and factual issues has been brought by an individual stockholder. On December 30, 2011, we filed a motion to dismiss the individual stockholder s complaint in federal court. On March 29, 2013, the Court granted our motion to dismiss, in part without prejudice. On May 13, 2013, the individual stockholder filed a new amended complaint. On June 14, 2013, we filed a motion to dismiss the new amended complaint. On March 20, 2014, the Court granted our motion to dismiss in part and remanded the remaining claims to state court.

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.

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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, pred 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 under a different trade name for chronic weight management. Lorcaserin may also be marketed as BELVIQ or under a different trade name 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.

BELVIQ, our internally discovered drug for chronic weight management, is approved for marketing in the United States and was made 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 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 Inc. s parent company, Eisai Co., Ltd., which we refer to collectively with Eisai Inc. as Eisai.

With respect to the United States, Eisai is focused on physician awareness and education efforts, securing broad reimbursement coverage, and creating patient awareness and access for BELVIQ. The sales force for BELVIQ totaled approximately 400 representatives around the end of 2013, and Eisai recently announced plans to add approximately 200 more representatives by July 2014, increasing the number of representatives for BELVIQ to approximately 600. Eisai believes this expansion of the sales force will enable Eisai to reach approximately 90,000 physicians in the United States. Eisai also recently announced that its continued work to expand reimbursement has resulted in additional insurance coverage for BELVIQ. In addition, Eisai recently 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.

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 also has marketing and supply agreements with Ildong Pharmaceutical Co., Ltd., or Ildong, for BELVIQ in South Korea, which we refer to as the Ildong BELVIQ Agreement, and with CY Biotech Company Limited, or CYB, in Taiwan, which we refer to as the CYB Agreement. We intend to enter into additional collaborative agreements for the potential regulatory approval and commercialization of BELVIQ in Australia, New Zealand and Israel.

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The marketing of BELVIQ is subject to applicable regulatory approval. BELVIQ has been approved for marketing in the United States, but currently not in any other country.

Our collaborators are responsible for regulatory activities related to obtaining marketing approval of BELVIQ in the territories covered under the respective agreement. Eisai filed applications for regulatory approval of BELVIQ in Mexico and Canada in March and June of 2013, respectively, and in Brazil in February 2014. In addition, Ildong submitted an application for regulatory approval of BELVIQ in South Korea in November 2013. We previously filed applications for marketing approval of BELVIQ with the regulatory authorities for the European Union and Switzerland, and these regulatory authorities notified us that we had not yet satisfactorily addressed their concerns and that our applications would not be approved. We expect to continue to work with Eisai in pursuing regulatory approvals for BELVIQ in Europe and other territories outside the United States. In addition, CYB intends to file an application for regulatory approval of BELVIQ in Taiwan.

In addition to commercializing BELVIQ as a monotherapy for chronic weight management, we intend to explore, with our collaborators or independently, BELVIQ s therapeutic potential in combination with other drugs, for other indications, and using different formulations. 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 exploring BELVIQ s effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes. In March 2014, we and Eisai initiated a Phase 2 clinical trial to evaluate the potential of lorcaserin as a drug candidate for smoking cessation, for which we and Eisai will share equally the expenses. This 12-week trial will enroll approximately 600 active smokers. We have completed an initial study to evaluate the safety, tolerability and pharmacokinetic properties of different formulations of lorcaserin 20 mg extended release tablets, and selected a once-daily formulation for further development. We and Eisai will share equally the expenses related to the once-daily formulation. In November 2013, Eisai initiated dosing, and it recently completed enrollment, in a pilot study of 12-week duration to preliminarily assess as the primary outcome the short-term safety and tolerability of lorcaserin and phentermine when co-administered, for which Eisai is responsible for 100% of the expenses.

In January 2014, Eisai initiated enrollment in the cardiovascular outcomes trial, or CVOT, required by the US Food and Drug Administration, or FDA, as a postmarketing commitment. The CVOT is also referred to as CAMELLIA (Cardiovascular And Metabolic Effects of Lorcaserin In Overweight And Obese Patients). We and Eisai will be responsible for 10% and 90%, respectively, of the expenses for the FDA-required portion of such trial. In addition, CAMELLIA will also evaluate 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 and Eisai will share equally the expenses for this non-FDA required portion of the trial 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:

- APD811, an agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension, has completed single- and multiple-ascending dose Phase 1 trials and is expected to begin a Phase 2 trial around the middle of 2014.

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, which we refer to as the Ildong Temanogrel Agreement, 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 the Phase 1 trial in the first quarter of 2014 to evaluate the safety of co-administration of temanogrel with aspirin and clopidogrel.

APD334, an agonist of the sphingosine 1-phosphate subtype 1, or $S1P_1$, receptor intended for the treatment of a number of conditions related to autoimmune diseases, which has completed a Phase 1 single-ascending dose trial. We plan to initiate a Phase 1 multiple-ascending dose trial around the middle of 2014.

APD371, an agonist of the cannabinoid-2 receptor intended for the treatment of pain, for which we have initiated a Phase 1 single-ascending dose trial.

Developing marketed drugs is a long, uncertain and expensive process, and our ability to achieve our goals, including furthering our collaborators commercialization of BELVIQ, and obtaining regulatory approval of, and commercializing, BELVIQ in additional territories, 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.

We 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. Accordingly, we will need to receive additional funds

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under our existing collaborative agreements, under future collaborative agreements for BELVIQ or one or more of our drug candidates or programs, or by raising additional funds through equity, debt or other 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

	Three months ended March 31,	
Source of revenue	**2014**	**2013**
Net product sales	$ 2.9	$ 0.0
Amortization of upfront payments from Eisai	2.0	0.9
Reimbursements of development and patent/trademark expenses from Eisai	0.9	0.1
Milestone payment from Eisai	0.5	0.5
Manufacturing services agreement with Siegfried	0.4	0.8
Other collaborative agreements	0.1	0.1
Total revenues	$ 6.8	$ 2.4

Research and development expenses

	Three months ended March 31,	
Type of expense	**2014**	**2013**
Salary and other personnel costs (excluding non-cash share-based compensation)	$ 7.5	$ 6.8
External clinical and preclinical study fees and internal non-commercial manufacturing costs	7.4	2.1
Facility and equipment costs	2.4	2.6
Non-cash share-based compensation	1.7	0.7
Research supply costs	1.3	1.3
Other	0.7	0.5
Total research and development expenses	$ 21.0	$ 14.0

General and administrative expenses

Type of expense	Three months ended March 31, 2014	2013
Salary and other personnel costs (excluding non-cash share-based compensation)	$ 3.1	$ 2.5
Legal, accounting and other professional fees	1.4	2.0
Facility and equipment costs	1.4	1.1
Non-cash share-based compensation	1.4	1.0
Other	0.7	0.7
Total general and administrative expenses	$ 8.0	$ 7.3

THREE MONTHS ENDED MARCH 31, 2014, AND 2013

Revenues. We recognized revenues of $6.8 million for the three months ended March 31, 2014, compared to $2.4 million for the three months ended March 31, 2013. This increase was primarily due to $2.9 million from net product sales of BELVIQ and a $1.1 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.

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When collaborators pay us before revenues are earned, we record such payments as deferred revenues. As of March 31, 2014, we had a total of $134.6 million in deferred revenues. Of such amount, $100.1 million is attributable to upfront payments we received under our collaboration with Eisai, $27.8 million is attributable to the BELVIQ product supply, $4.5 million is attributable to the upfront payment we received under the Ildong BELVIQ Agreement and $2.1 million is attributable to the upfront payment we received under the CYB Agreement.

Absent any new collaborations, 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. Future sales of BELVIQ will depend on, among other factors, the availability and use of BELVIQ, the effectiveness of Eisai s marketing program, competition and reimbursement coverage. 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. Eisai has reported that a 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 any significant revenues in the short term will depend on 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 $0.8 million for the three months ended March 31, 2014, and $0.5 million for the three months ended March 31, 2013, which reflected unused capacity costs for one month in which no BELVIQ manufacturing was performed.

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 $1.1 million to $0.5 million for the three months ended March 31, 2014, from $1.6 million for the three months ended March 31, 2013, primarily due to our contract loss provision for these services, which is the result of providing the services at sales prices that are less than our costs, as well as 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 (including payments to contract research organizations, or CROs), preclinical study fees, manufacturing costs for non-commercial products, costs for

the development of our earlier-stage programs and technologies, research supply costs and facility and equipment costs. We expense research and development costs as they are incurred when these expenditures have no alternative future uses. We generally do not track our earlier-stage, internal research and development expenses by project; rather, we track such expenses by the type of cost incurred.

Research and development expenses increased by $7.0 million to $21.0 million for the three months ended March 31, 2014, from $14.0 million for the three months ended March 31, 2013. This was primarily due to increases of (i) $5.3 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs, primarily related to manufacturing costs for non-commercial products and the BELVIQ cardiovascular outcomes trial, (ii) $1.0 million in non-cash share-based compensation expense and (iii) $0.7 million in salary and personnel costs. 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 $7.4 million total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the three months ended March 31, 2014, was $3.7 million related to non-commercial manufacturing costs, $2.9 million related to BELVIQ, $0.4 million related to APD811 and $0.1 million related to APD334. Included in the $2.1 million total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the three

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months ended March 31, 2013, was $1.0 million related to non-commercial manufacturing costs, $0.5 million related to BELVIQ, $0.3 million related to APD811 and $0.1 million related to APD334.

General and administrative expenses. General and administrative expenses increased by $0.7 million to $8.0 million for the three months ended March 31, 2014, from $7.3 million for the three months ended March 31, 2013. This was primarily due to increases of (i) $0.6 million in salary and personnel costs, (ii) $0.4 million in non-cash share-based compensation and (iii) $0.3 million in accounting and auditing fees, which were partially offset by a $0.7 million decrease in patent and trademark fees. We expect that our 2014 general and administrative expenses will be higher than in 2013.

Interest and other income (expense), net. Interest and other income (expense), net, decreased to an expense of $1.7 million for the three months ended March 31, 2014, from income of $2.1 million for the three months ended March 31, 2013. This $3.8 million decrease was primarily due to a $0.1 million non-cash loss from revaluation of our derivative liabilities for the three months ended March 31, 2014, compared to a $3.9 million gain for the three months ended March 31, 2013.

LIQUIDITY AND CAPITAL RESOURCES

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. In June 2013, BELVIQ was made available to patients by prescription in the United States by our collaborator, Eisai. It is difficult to predict the payments we will receive from commercialization of BELVIQ in the United States or in any other territory in which BELVIQ may be approved for marketing. 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, including other indications and formulations, and advancing our research and development programs.

Short term

As of March 31, 2014, we had $203.3 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 BELVIQ in additional territories or 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 impairment charges, our investment in TaiGen Biotechnology Co., Ltd., or TaiGen, has had a cost basis of zero since December 31, 2011. 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 such fair value, with the unrealized gain recorded as a component of accumulated other comprehensive income (loss) in the stockholders equity section of our condensed consolidated balance sheets. As of March 31, 2014, our investment in TaiGen was recorded at its fair value of $53.2 million, with the unrealized gain recorded in accumulated other comprehensive income (loss).

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. Eisai and we have regulatory applications for approval of BELVIQ under review in a number of countries outside of the United States. We also expect that Eisai will file additional regulatory applications for approval of BELVIQ in additional territories under the Eisai Agreement, but there is no assurance of whether, where or when Eisai may 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, and, 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 BELVIQ product revenue 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

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$176.0 million in additional regulatory and development milestone payments. We do not expect to receive the majority (or potentially any) of such payments in the short term.

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

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 exploring, including as part of CAMELLIA, BELVIQ s effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

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

Long term

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

We expect to continue to incur substantial costs for BELVIQ, including costs related to manufacturing and required 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 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 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 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.

Under the Ildong BELVIQ Agreement and CYB Agreement, we are eligible to receive additional payments upon regulatory approval, as well as payments from net product sales of BELVIQ. We will manufacture BELVIQ at our facility in Switzerland, and

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sell BELVIQ to Ildong for marketing and distribution in South Korea for a purchase price starting at 35% of Ildong s annual net product sales (which are the gross invoiced sales less certain deductions described in the Ildong BELVIQ Agreement). The purchase price will increase on a tiered basis up to 45% on the portion of annual net product sales exceeding $15.0 million. If certain annual net product sales amounts are not met, we can convert Ildong s right to commercialize BELVIQ in South Korea to be non-exclusive. Additionally, we will manufacture and sell BELVIQ to CYB for a purchase price starting at 45% of CYB s annual net product sales (which are the gross invoiced sales less certain deductions described in the CYB Agreement). With respect to commercializing BELVIQ in countries that are not currently under collaboration (Australia, New Zealand and Israel), we will need additional funds or a collaborative or other agreement with one or more pharmaceutical companies.

In addition to potential payments from Eisai and other 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 studies, our research, development, manufacturing and commercialization costs (including personnel costs), our progress in any programs under collaborations, costs associated with intellectual property, our capital expenditures, and costs associated with securing any in-licensing opportunities. Any significant shortfall in funding may result in us reducing our development and/or research activities, which, in turn, would affect our development pipeline and ability to obtain cash in the future. If we determine it is advisable to raise additional funds, we do not know whether adequate funding will be available to us or, if available, that such funding will be available on acceptable terms.

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

Sources and Uses of Our Cash

Net cash used in operating activities increased by $0.9 million to $19.1 million in the three months ended March 31, 2014, compared to $18.2 million in the three months ended March 31, 2013. This was primarily the result of a $6.4 million increase in our net loss, which was partially offset by a change from a gain of $3.9 million from the revaluation of our derivative liabilities in the three months ended March 31, 2013, to a loss of $0.1 million from the revaluation of our derivative liabilities in the three months ended March 31, 2014, and a $1.4 million increase in non-cash share-based compensation expense.

Net cash used in investing activities increased by $0.9 million to $2.2 million in the three months ended March 31, 2014, compared to $1.3 million in the three months ended March 31, 2013. This increase was primarily the result of purchases of equipment and improvements to our facilities, primarily for our manufacturing facility in Switzerland. We expect that our 2014 capital expenditures will increase over the 2013 amount due to deferments of capital spending in previous years and purchases of equipment for our manufacturing facility in Switzerland.

Net cash of $2.5 million was provided by financing activities in the three months ended March 31, 2014, as a result of net proceeds of $2.9 million from stock option exercises and purchases under our employee stock purchase plan, which were partially offset by $0.4 million for payments on our lease financing obligations. Net cash of $0.1 million was provided by financing activities in the three months ended March 31, 2013, as a result of net proceeds of $0.5 million from stock option exercises and purchases under our employee stock purchase plan, which were partially

offset by $0.4 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

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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, 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 is based on our cost of goods sold.

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

Since adoption of this guidance, we evaluate deliverables in a multiple-element arrangement to determine whether each deliverable represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer. 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.

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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.

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.

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 its intent to appeal the matter.

In addition to the class actions, a complaint involving similar legal and factual issues has 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.

We are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to all the above claims.

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Item 1A. Risk Factors.
RISK FACTORS

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

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 under a different trade name for chronic weight management. Lorcaserin may also in the future be marketed as BELVIQ or under a different trade name 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 was 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 Inc. s parent company, 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 and with CY Biotech Company Limited, or CYB, for Taiwan, granting them exclusive rights to market and distribute BELVIQ in the respective territories for weight loss or weight management in obese and overweight patients, subject to applicable regulatory approval. We refer collectively to all of these marketing and supply agreements as the BELVIQ Agreements.

We expect that revenues under the marketing and supply agreement with Eisai (and, to a lesser extent, the marketing and supply agreements with Ildong and CYB) will constitute the majority of our revenues over the next several years, and future payments to us under the 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.

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,

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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 of BELVIQ, which may depend on the public s view of BELVIQ, 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 or related drugs or drug candidates (such as BELVIQ in combination with another drug or using another formulation);
- 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.

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 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

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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 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. 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 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.

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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;
- 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 all of the countries in the world, except for Australia, New Zealand and Israel, 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.

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. 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 will 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. 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.

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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 in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses and operating expenses will continue to be substantial for at least the short term.

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 expect to enter into marketing and supply agreements or other arrangements with one or more pharmaceutical companies to commercialize BELVIQ in territories not already under collaboration and to research, develop and commercialize other drug candidates in our pipeline. 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.

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

For example, if we experience a significant setback or delay, particularly any relating to BELVIQ, 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 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 would

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

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risks and uncertainties, and our or others BELVIQ regulatory submissions may not be satisfactory to the applicable regulatory authorities, including with regard to demonstrating adequate safety and efficacy for regulatory approval. We have made, and expect to make in the future, assumptions, estimations, calculations and decisions as part of our analyses of data and regulatory submissions, and the applicable regulatory authorities may not accept or agree with our assumptions, estimations, calculations, decisions or analyses or may interpret or weigh the importance of data differently.

Furthermore, as was the case with FDA approval, other regulatory approvals, even if obtained, may be limited to specific indications, limit the type of patients in which the drug may be used, or otherwise require specific warning or labeling language, any of which might reduce the commercial potential of BELVIQ. As with the FDA s approval of BELVIQ, regulatory authorities in other territories may condition BELVIQ marketing approval on the conduct of specific 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.

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 to, among other things, evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. As described above, this trial will include echocardiographic assessments in a subset of the patients as well as non-FDA required evaluations. 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.

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

Eisai has primary responsibility for the marketing and distribution of BELVIQ in all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel, and Ildong and CYB have primary responsibility for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in South Korea and Taiwan, respectively. We have limited 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.

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;

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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 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.

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We and certain of our current and former employees and directors have been named as defendants in litigation that could result in substantial costs and divert management s attention.

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

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

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

The results and timing of clinical trials and preclinical studies, 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.

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 postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors. As described above, this trial will include echocardiographic assessments in a subset of the patients as well as non-FDA required evaluations. In addition, we may decide or need to conduct additional studies, clinical trials or analyses of BELVIQ, including in connection with seeking regulatory approval of BELVIQ outside of the United States. Unfavorable results from these studies, trials or analyses could negatively impact market acceptance of BELVIQ, limit the revenues we generate from sales, result in BELVIQ s withdrawal from the market, and preclude us from being profitable.

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

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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 in the few territories outside of such agreements 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 are able to establish commercialization arrangements with companies who have substantially greater resources than we have (or, with respect to commercializing BELVIQ in a territory under one of the BELVIQ Agreements, than our collaborator has), our competitors may be more successful in marketing and selling their drugs, and our ability to successfully commercialize BELVIQ will be limited.

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

The preclinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to BELVIQ and our drug candidates are, and any other resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies. We are subject to periodic 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

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additional preclinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA s interpretation and our interpretation of data from preclinical studies and clinical trials may differ significantly;
- our or our contractors or collaborators failure to comply with applicable FDA and other regulatory requirements, including those identified in other risk factors;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept an NDA or other submission due to, among other reasons, the content or formatting of the submission.

Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations, such as those required by a Risk Evaluation and Mitigation Strategies, or REMS.

With the exception of our regulatory submissions for BELVIQ, we have not previously submitted an application for marketing approval in the United States or any other jurisdiction. This lack of corporate experience may impede our ability to obtain regulatory approval in a timely manner, if at all, for BELVIQ in territories in which regulatory approval is our responsibility or for any of our drug candidates. Our preclinical and clinical data, other information and procedures relating to a drug candidate may not be sufficient to support approval by the FDA or any other US or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we or our collaborators develop.

To market any drugs outside of the United States, we and our current or future collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional risks, some of which may be unanticipated. With respect to our BELVIQ collaborations, our collaborators are responsible for regulatory filings, and we will depend on their capabilities, plans and diligence in obtaining regulatory approval.

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 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.

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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 required the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. As described above, this trial will include echocardiographic assessments in a subset of the patients and other FDA-required as well as non-FDA required evaluations. Along with being costly and time consuming, unfavorable results from these trials could negatively impact market acceptance of BELVIQ; limit the revenues we generate from sales; result in BELVIQ s withdrawal from the market; negatively impact the potential approval of BELVIQ in other territories for weight management, for other indications, in combination with other drugs or using different formulations; and preclude us from being profitable.

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

With regard to BELVIQ and any of our drug candidates that receive regulatory approval, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the drug will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with cGMP regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer s facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. In the United States, the DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing,

security, recordkeeping and distribution of drugs that are considered controlled substances.

The DEA has placed BELVIQ into Schedule IV of the Controlled Substances Act, which subjects us to the DEA s regulations. The scheduling designation can change after finalization. If BELVIQ were to be rescheduled into a 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;

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injunctions, suspensions or revocations of regulatory approvals;

suspension of any ongoing clinical trials;

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