ARENA PHARMACEUTICALS INC
Form 10-Q
November 09, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2015

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

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

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

The number of shares of common stock outstanding as of the close of business on November 4, 2015:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	242,549,640

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TRADEMARKS AND CERTAIN TERMS

Arena Pharmaceuticals®, Arena® and our corporate logo are registered service marks of Arena. BELVIQ® and BELVIQ XR® are registered trademarks of our wholly owned subsidiary, 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.

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

Lorcaserin has been approved for marketing in the United States and South Korea for weight management, and is being commercialized under the brand name BELVIQ (which is pronounced as "BEL-VEEK"). There are pending applications for the regulatory approval of lorcaserin for weight management in a number of additional territories.

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements.

ARENA PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2015 (Unaudited)	December 31, 2014[1]
Assets		
Current assets:		
Cash and cash equivalents	$181,280	$163,209
Accounts receivable	3,514	3,712
Inventory	10,243	10,831
Prepaid expenses and other current assets	5,179	4,144
Total current assets	200,216	181,896
Land, property and equipment, net	74,752	82,919
Intangibles, net	8,121	8,482
Other non-current assets	3,038	3,088
Total assets	$286,127	$276,385
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and other accrued liabilities	$7,318	$10,209
Accrued clinical and preclinical study fees	3,627	7,027
Payable to Eisai	10,566	23,705
Current portion of deferred revenues	23,215	15,238
Current portion of lease financing obligations	2,852	2,492
Payable to Siegfried for acquisition of land and building	0	8,217
Derivative liabilities	0	474
Total current liabilities	47,578	67,362
Deferred rent	447	369
Deferred revenues, less current portion	89,845	93,064
Lease financing obligations, less current portion	66,056	68,245
Commitments and contingencies		
Stockholders' equity:		
Common stock	24	22
Additional paid-in capital	1,427,529	1,312,656
Accumulated other comprehensive income	409	2,908
Accumulated deficit	(1,345,761)	(1,268,241)
Total stockholders' equity	82,201	47,345
Total liabilities and stockholders' equity	$286,127	$276,385

[1] The balance sheet data at December 31, 2014, 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 Loss
(In thousands, except per share data)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Revenues:				
Net product sales	$4,884	$5,726	$15,787	$12,137
Other Eisai collaborative revenue	2,065	2,133	7,414	14,034
Toll manufacturing	1,463	158	3,199	1,184
Other collaborative revenue	726	147	4,175	424
Total revenues	9,138	8,164	30,575	27,779
Operating Costs and Expenses:				
Cost of product sales	1,635	1,755	6,129	4,049
Cost of toll manufacturing	1,584	81	3,798	1,124
Research and development	22,072	24,508	68,241	72,521
General and administrative	9,028	8,029	26,311	25,198
Total operating costs and expenses	34,319	34,373	104,479	102,892
Loss from operations	(25,181)	(26,209)	(73,904)	(75,113)
Interest and Other Income (Expense):				
Interest income	37	16	105	69
Interest expense	(1,683)	(1,723)	(5,133)	(5,205)
Gain from valuation of derivative liabilities	852	2,593	474	3,489
Gain on sale of available-for-sale securities	0	16,276	0	49,553
Other	(443)	(1,625)	938	(1,240)
Total interest and other income (expense), net	(1,237)	15,537	(3,616)	46,666
Net loss	$(26,418)	$(10,672)	$(77,520)	$(28,447)
Net loss per share:				
Basic	$(0.11)	$(0.05)	$(0.32)	$(0.13)
Diluted	$(0.11)	$(0.05)	$(0.32)	$(0.13)
Shares used in calculating net loss per share:				
Basic	242,257	219,866	240,033	219,592
Diluted	242,257	219,866	240,033	219,592
Comprehensive Loss:				
Net loss	$(26,418)	$(10,672)	$(77,520)	$(28,447)
Foreign currency translation loss	(2,881)	(1,626)	(2,499)	(2,019)
Reclassification adjustment for realized gain on sale of available-for-sale securities	0	(16,276)	0	(49,553)
Unrealized holding gain (loss) on available-for-sale securities	0	(2,037)	0	49,553
Comprehensive loss	$(29,299)	$(30,611)	$(80,019)	$(30,466)

See accompanying notes to unaudited condensed consolidated financial statements.

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ARENA PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2015	2014
Operating Activities		
Net loss	$(77,520)	$(28,447)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,401	6,434
Amortization of intangibles	147	394
Share-based compensation	11,795	9,941
Gain from valuation of derivative liabilities	(474)	(3,489)
Gain on sale of available-for-sale securities	0	(49,553)
Amortization of prepaid financing costs	102	102
Loss on sale of property and equipment	1,007	172
Changes in assets and liabilities:		
Accounts receivable	116	7,279
Inventory	1,240	211
Prepaid expenses and other assets	(366)	(2,551)
Payables and accrued liabilities	(21,271)	3,420
Deferred revenues	4,506	(22,998)
Deferred rent	78	93
Net cash used in operating activities	(73,239)	(78,992)
Investing Activities		
Proceeds from sale of available-for-sale securities	0	49,553
Purchases of property and equipment	(10,800)	(6,444)
Proceeds from sale of property and equipment	2,232	47
Other non-current assets	(55)	209
Net cash provided by (used in) investing activities	(8,623)	43,365
Financing Activities		
Principal payments on lease financing obligations	(1,829)	(1,507)
Proceeds from issuance of common stock	102,934	4,892
Net cash provided by financing activities	101,105	3,385
Effect of exchange rate changes on cash	(1,172)	(1,308)
Net increase (decrease) in cash and cash equivalents	18,071	(33,550)
Cash and cash equivalents at beginning of period	163,209	221,878
Cash and cash equivalents at end of period	$181,280	$188,328

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, 2014, as filed with the Securities and Exchange Commission, or SEC, from which we derived our balance sheet as of December 31, 2014. The accompanying financial statements have been prepared in accordance with US generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, “Revenue from Contracts with Customers.” ASU No. 2014-09 outlines a comprehensive revenue recognition model which will supersede most current revenue recognition guidance. ASU No. 2014-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2017. ASU No. 2014-09 allows for two methods of adoption: (a) “full retrospective” adoption, meaning the standard is applied to all periods presented, or (b) “modified retrospective” adoption, meaning the cumulative effect of applying ASU No. 2014-09 is recognized as an adjustment to the opening retained earnings balance for the year of implementation. We have not yet selected an adoption method as we are currently evaluating the impact of ASU No. 2014-09 on our consolidated financial statements.

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

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

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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, in thousands:

	Fair Value Measurements at September 30, 2015			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds[1]	$133,026	$133,026	$0	$ 0

	Fair Value Measurements at December 31, 2014			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds[1]	$143,913	$143,913	$0	$ 0
Liabilities:				
Warrant derivative liabilities	$474	$0	$474	$ 0

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(1) Included in cash and cash equivalents on our condensed consolidated balance sheets.

On August 14, 2015, the warrant expired pursuant to its terms. (See Note 6.)

3. Inventory

Inventory consisted of the following, in thousands:

	September 30, 2015	December 31, 2014
Raw materials	$ 2,412	$1,167
Work in process	3,043	3,520
Finished goods at Arena GmbH	828	3,681
Finished goods at Eisai	2,922	2,463
Finished goods at Ildong	1,038	0
Total inventory	$ 10,243	$10,831

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4. Land, Property and Equipment

Land, property and equipment consisted of the following, in thousands:

	September 30, 2015	December 31, 2014
Cost	$173,820	$174,938
Less accumulated depreciation and amortization	(99,068)	(92,019)
Land, property and equipment, net	$74,752	$82,919

5. Accounts Payable and Other Accrued Liabilities

Accounts payable and other accrued liabilities consisted of the following, in thousands:

	September 30, 2015	December 31, 2014
Accounts payable	$1,556	$2,844
Accrued compensation	4,222	4,792
Other accrued liabilities	1,540	2,573
Total accounts payable and other accrued liabilities	$7,318	$10,209

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 expired on August 14, 2015. As a result of the warrant's anti-dilution provision and certain of our subsequent equity issuances, the number of shares issuable upon exercise of the warrant increased and the exercise price decreased. The warrant, which was valued at $0.5 million at December 31, 2014, was recorded as a current derivative liability on our condensed consolidated balance sheets. On August 14, 2015, the warrant expired pursuant to its terms, and, thus, we recorded a gain in our condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2015.

The warrant was 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 loss.

7. Marketing and Supply Agreement with Eisai

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

Prior to entering into the Eisai Agreement, Arena GmbH and Eisai Inc. entered into the original marketing and supply agreement in July 2010, under which we granted Eisai Inc. exclusive commercialization rights for lorcaserin 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.

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The following table summarizes the revenues we recognized under our collaboration with Eisai for the periods presented, in thousands:

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Net product sales	$3,274	$5,726	$11,603	$12,137
Amortization of upfront payments	1,886	1,885	5,656	5,745
Reimbursement of development expenses	107	143	1,454	7,456
Milestone payment	0	0	0	500
Reimbursement of patent and trademark expenses	72	105	304	333
Subtotal other Eisai collaborative revenue	2,065	2,133	7,414	14,034
Total	$5,339	$7,859	$19,017	$26,171

The following table summarizes the deferred revenues under our collaboration with Eisai, in thousands:

	September 30, 2015	December 31, 2014
Upfront payments	$88,818	$94,474
Net product sales	12,520	7,081
Total deferred revenues attributable to Eisai	101,338	101,555
Less current portion	(20,061)	(14,622)
Deferred revenues attributable to Eisai, less current portion	$81,277	$86,933

Upfront and Milestone Payments.

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

Product Purchase Price and Purchase Price Adjustment Payments.

We manufacture lorcaserin at our facility in Switzerland, and sell lorcaserin 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 Eisai Product Purchase Price, in the respective territory. The Eisai 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 Eisai 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 Eisai 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 the use of vouchers and product samples is based on our cost of goods sold.

In addition to payments for purchases of lorcaserin, 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 lorcaserin 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

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territories in North and South America and $185.0 million based on Eisai's annual net product sales in the territories outside of North and South America. The first and last amounts are payable upon first achievement of annual net product sales of $100.0 million and $1.0 billion, respectively, with respect to each of the following areas: (i) the non-US territories in North and South America and (ii) the territories outside of North and South America. In addition, we are also eligible to receive certain payments by Eisai if certain annual minimum sales requirements in Mexico, Canada and Brazil are not met during the first ten years after initial commercial sale in such territories.

The amount that Eisai pays us for lorcaserin product supply is based on Eisai's estimated price at the time the order is shipped, which is Eisai's estimate of the Eisai Product Purchase Price, and is subject to change on April 1 and October 1 of each year. At the end of Eisai's fiscal year (March 31), the estimated price paid to us for product that Eisai sold to their distributors is compared to the Eisai 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. The Eisai Product Purchase Price for the product Eisai has sold to date has been lower than the initial estimated price that Eisai has paid us for such product, primarily due to an increase in deductions from savings cards and returns, partially offset by a decrease in vouchers. In January 2015, Eisai announced the launch of a new savings card which enables eligible patients without commercial coverage for BELVIQ to pay no more than $75 for each monthly prescription while those patients with commercial coverage for BELVIQ are able to use the card to obtain additional savings if their copay is greater than $50 per monthly prescription. Subsequent to the end of Eisai's fiscal year, we refund the portion of these excess payments, which total the $10.6 million classified as Payable to Eisai on our condensed consolidated balance sheet at September 30, 2015, related to product sold by Eisai to their distributors through March 31.

Development Payments.

In connection with the US approval of BELVIQ, the US Food and Drug Administration, or FDA, is requiring (i) an evaluation as part of the cardiovascular outcomes trial, or CVOT, of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors and (ii) the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric and adolescent patients. In addition to the FDA-required studies, we and Eisai have prioritized the development and approval of a once-daily formulation of lorcaserin, as well as potentially exploring, including as part of the CVOT, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

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The chart below summarizes the general agreement regarding cost sharing between Eisai and us for significant development activities under the Eisai Agreement. In addition, Eisai or we may from time to time conduct approved development of lorcaserin at such party's own expense.

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

	United States	Rest of North and South America	Remai
BELVIQ - Pre-approval*	Not Applicable	General Eisai: 90%; Arena: 10% Certain stability work Eisai: 50%; Arena: 50%	Up to Eisai: Therea
BELVIQ - 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% Certain pediatric studies Eisai: 50%; Arena: 50%	General Eisai: 90%; Arena: 10% Certain stability work Eisai: 50%; Arena: 50%	Up to Eisai: Therea Arena
Lorcaserin products other than BELVIQ - Pre-approval	Up to a total of $250.0 million (as reduced by up to $80.0 million for non-FDA required portion of CVOT -Eisai: 50%; Arena: 50%		
Lorcaserin products other than BELVIQ - Post-approval	Up to a total of $100.0 million in the aggregate across all additional products - 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, 2014, for additional information regarding termination, indemnification, product liability, certain limitations and other provisions included in the Eisai Agreement.

8. Marketing and Supply Agreement with Ildong

In November 2012, Arena GmbH and Ildong Pharmaceutical Co., Ltd., or Ildong, entered into the Marketing and Supply Agreement, or Ildong Agreement. Under this agreement, we granted Ildong exclusive rights to commercialize BELVIQ in South Korea for weight loss or weight management in obese and overweight patients. We also provide certain services and will manufacture and sell BELVIQ to Ildong. Ildong has agreed not to conduct activities outside of our agreement related to the approval or commercialization of any other pharmaceutical product for weight loss, weight management or obesity in South Korea, with the exception of phentermine.

In connection with entering into the Ildong Agreement, we received from Ildong an upfront payment of $5.0 million, less withholding taxes. Revenues from this upfront payment were deferred, as we determined that the exclusive rights did not have standalone value without our ongoing development and regulatory activities. Accordingly, this payment is recognized ratably as revenue over the period in which we expect the services to be rendered, which is approximately 14 years. In addition to the upfront payment, we received a milestone payment of $3.0 million, less withholding taxes, in March 2015, which we earned upon the February 2015 approval of BELVIQ for marketing in South Korea for weight management.

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We manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Ildong for a purchase price starting at the higher of the defined minimum amount or 35% of Ildong's annual net product sales (which are the gross invoiced sales less certain deductions described in the Ildong Agreement), or the Ildong Product Purchase Price. The Ildong Product Purchase Price will increase on a tiered basis up to the higher of the defined minimum amount or 45% on the portion of annual net product sales exceeding $15.0 million. However, in no event will the Ildong Product Purchase Price be less than a defined minimum amount adjusted annually based on a consumer price index. For the three and nine months ended September 30, 2015, the Ildong Product Purchase Price equaled the defined minimum amount (which exceeded the amounts calculated using the applicable percentages for the applicable tiers of Ildong's annual net product sales for these periods). 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. We recognized revenues from our portion of Ildong net product sales of BELVIQ of $1.6 million and $4.2 million for the three and nine months ended September 30, 2015, respectively.

9. Share-based Activity

Share-based Compensation.

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Research and development	$2,097	$1,753	$6,338	$5,276
General and administrative	1,751	1,645	5,457	4,665
Total share-based compensation expense	$3,848	$3,398	$11,795	$9,941
Total share-based compensation expense capitalized into inventory	$41	$22	$146	$61

Share-based Award Activity.

The following table summarizes our stock option activity during the nine months ended September 30, 2015, in thousands (except per share data):

	Options	Weighted-Average Exercise Price
Outstanding at January 1, 2015	15,831	$5.25
Granted	3,072	4.46
Exercised	(801)	2.05
Forfeited/cancelled/expired	(750)	6.40
Outstanding at September 30, 2015	17,352	$5.20

The following table summarizes activity with respect to our time-based restricted stock unit awards, or RSUs, during the nine months ended September 30, 2015, in thousands (except per share data):

	RSUs	Weighted-Average Grant-Date Fair Value
Unvested at January 1, 2015	456	$5.72
Granted	281	4.11
Vested	(159)	5.44
Forfeited/cancelled	0	
Unvested at September 30, 2015	578	$5.02

In March 2015, March 2014 and March 2013, we granted our executive officers Total Stockholder Return, or TSR, performance restricted stock unit, or PRSU, awards. The PRSUs may be earned and converted into outstanding shares of our common stock based on the TSR of our common stock relative to the TSR over a three-year performance period beginning March 1 of the year granted of the NASDAQ Biotechnology Index. In the aggregate, the target

number of shares of common stock that could be be earned under the PRSUs granted in March 2015, March 2014 and March 2013 were originally 745,000, 695,000 and 780,000, respectively; however, the actual number of shares that may be earned ranges from 0% to 200% of such

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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 each award, and funding is capped at 100% if the absolute 3-year TSR is negative even if performance is above the median. As these awards contain a market condition, we used a Monte Carlo simulation model to estimate the grant-date fair value, which totaled $3.4 million, $5.0 million and $5.9 million for the March 2015, March 2014 and March 2013 grants, respectively, and which is being recognized ratably as services are provided by the executive officers over the performance period.

The following table sets forth the assumptions used to value the PRSUs granted in March 2015 and their estimated grant-date fair value:

Risk-free interest rate	1.1	%
Dividend yield	0	%
Expected volatility	75	%
Remaining performance period (years)	2.97	
Estimated fair value per share of PRSUs granted	$4.50	

Of the target number of shares of 745,000 for the March 2015 grants, 695,000 for the March 2014 grants and 780,000 for the March 2013 grants, 276,389, 169,445 and 113,334, respectively, will not be eligible to vest at the end of the performance period due to our former Chief Executive Officer's retirement on October 5, 2015, and our former Chief Financial Officer's resignation on July 10, 2015. (See Note 15.)

All of the PRSUs granted to date were outstanding and unvested at September 30, 2015.

10. Concentrations 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 and Ildong are the exclusive distributors of BELVIQ in the United States and South Korea, respectively, which are the only jurisdictions for which BELVIQ has received regulatory approval for marketing. We also produce drug products for Siegfried AG, or Siegfried, under a toll manufacturing agreement, and most of our toll manufacturing revenues are attributable to Siegfried.

Percentages of our total revenues are as follows:

	Three months ended September 30,				Nine months ended September 30,			
	2015		2014		2015		2014	
Eisai Agreement	58.4	%	96.3	%	62.2	%	94.2	%
Ildong Agreement	18.6	%	1.1	%	24.4	%	1.0	%
Toll manufacturing agreements	16.0	%	1.9	%	10.5	%	4.3	%
Other collaborative agreements	7.0	%	0.7	%	2.9	%	0.5	%
Total percentage of revenues	100.0	%	100.0	%	100.0	%	100.0	%

11. Net Loss Per Share

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

Since we are in a net loss position, in addition to excluding potentially dilutive out-of-the money securities, we exclude from our calculation of diluted net loss per share all potentially dilutive in-the-money (i) stock options, (ii) RSUs, (iii) PRSUs, (iv) unvested restricted stock in our deferred compensation plan and (v) our previously outstanding warrant, and our diluted net loss per share is the same as our basic net loss per share.

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The following table presents the weighted-average number of potentially dilutive securities that were excluded from our calculation of diluted net loss per share for the periods presented, in thousands:

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Stock options	17,462	15,729	17,033	15,541
Warrant	0	55	26	490
RSUs, PRSUs and unvested restricted stock	690	537	576	467
Total	18,152	16,321	17,635	16,498

Because the market condition for 745,000 PRSUs issued in March 2015, 695,000 PRSUs issued in March 2014, and 780,000 PRSUs issued in March 2013, was not satisfied at September 30, 2015, such securities are excluded from the table above for the three and nine months ended September 30, 2015. Because the market condition for 695,000 PRSUs issued in March 2014, and 780,000 PRSUs issued in March 2013, was not satisfied at September 30, 2014, such securities are excluded from the table above for the three and nine months ended September 30, 2014.

12. Legal Proceedings

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints were brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. The plaintiffs sought unspecified monetary damages and other relief. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. On March 28, 2013, the Court dismissed the consolidated amended complaint without prejudice. On May 13, 2013, the lead plaintiff filed a second consolidated amended complaint. On November 5, 2013, the Court dismissed the second consolidated amended complaint without prejudice as to all parties except for Robert E. Hoffman, who was dismissed from the action with prejudice. On November 27, 2013, the lead plaintiff filed a motion for leave to amend the second consolidated amended complaint. On March 20, 2014, the Court denied plaintiff's motion and dismissed the second consolidated amended complaint with prejudice. On April 18, 2014, the lead plaintiff filed a notice of appeal, and on August 27, 2014, the lead plaintiff filed his appellate brief in the US Court of Appeals for the Ninth Circuit. On October 24, 2014, we filed our answering brief in response to the lead plaintiff's appeal. On December 5, 2014, the lead plaintiff filed his reply brief. 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.

13. Issuance of Common Stock

In January 2015, we sold 21,000,000 shares of our common stock, par value $0.0001 per share, at a price of $4.8139 per share to the underwriters. We received approximately $100.7 million in net proceeds from this offering after deducting offering expenses.

14. Development, Marketing and Supply Agreement with Roivant

In May 2015, Arena GmbH and Roivant Sciences Ltd., or Roivant, entered into a Development, Marketing and Supply Agreement for nelotanserin, our internally discovered inverse agonist of the serotonin 2A receptor that we previously studied for insomnia before discontinuing development for such indication. Under this agreement, we granted Roivant exclusive worldwide rights to develop and commercialize nelotanserin, subject to regulatory approval.

In connection with entering into the agreement, we received an upfront payment of $4.0 million from Roivant in May 2015. Revenues from this upfront payment were deferred, as we determined that the exclusive rights did not have standalone value without our ongoing development and regulatory activities. Accordingly, this payment is recognized ratably as revenue over the period in which we expect the services to be rendered, which is approximately five years. We are also eligible to receive up to $41.5 million in development and regulatory milestone payments and are eligible

to receive payments from sales of nelotanserin and purchase price adjustment payments based on the annual net product sales of nelotanserin.

In October 2015, Roivant assigned the exclusive rights to develop and commercialize nelotanserin to its subsidiary, Axovant Sciences Ltd.

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15. Subsequent Events

Retirement of Former President and Chief Executive Officer.

On October 5, 2015, at the request of our Board of Directors, Jack Lief, our former President, Chief Executive Officer and principal financial officer, retired from the company, including from our Board of Directors. In connection with his retirement, we entered into a separation agreement with Mr. Lief, which provides that he will be entitled to receive the following severance compensation and other benefits (which amounts are consistent with our Amended and Restated Severance Benefit Plan, dated effective December 30, 2008, as amended): (1) a cash severance payment of approximately $1.8 million (subject to applicable withholdings); (2) continuation of health insurance coverage for a period of 18 months; (3) acceleration of the stock options and restricted stock units (other than performance-based restricted stock units, or PRSUs) held by Mr. Lief that would otherwise have vested through the 18-month period following the date of his resignation; and (4) continued stock option exercisability until the later of (i) the original post-termination exercise period provided in the applicable stock option agreement or (ii) 18 months (but not beyond the original contractual life of the option). In addition, with respect to outstanding PRSUs, when the Compensation Committee of our Board of Directors determines our relative performance for an applicable performance period, a pro-rata portion of the relevant PRSUs held by Mr. Lief is eligible to vest (based on the percentage of the performance period that Mr. Lief provided service prior to his retirement). The pro-rata vesting may be accelerated if we undergo a change in control before the scheduled end of the performance period.

We expect to record a charge of $2.9 million, which includes a non-cash, share-based compensation charge of $1.1 million, related to these benefits in the fourth quarter of 2015.

Appointment of Interim Chief Executive Officer.

On October 5, 2015, our Board of Directors appointed Harry F. Hixson, Jr., Ph.D., one of our directors, as our interim Chief Executive Officer and interim principal financial officer.

Workforce Reduction.

On October 27, 2015, as part of a restructuring plan, we committed to a reduction in our US workforce of approximately 35%, or a total of approximately 80 employees, which we plan to substantially complete by December 31, 2015. As a result of this workforce reduction, we expect to incur restructuring charges, primarily in the fourth quarter of 2015, of approximately $3.3 million (substantially all of which is cash expenditures) in connection with one-time employee termination costs, including severance and other benefits.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

This discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this quarterly report on Form 10-Q, or Quarterly Report, and the audited consolidated financial statements and notes thereto included in our annual report on Form 10-K for the year ended December 31, 2014, or 2014 Annual Report, as filed with the Securities and Exchange Commission, or SEC. Operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report includes forward-looking statements that involve a number of risks, uncertainties and assumptions. These forward-looking statements can generally be identified as such because the context of the statement will include words such as “may,” “will,” “intend,” “plan,” “believe,” “anticipate,” “expect,” “estimate,” “predict,” “ “continue,” “likely,” or “opportunity,” the negative of these words or other similar words. Similarly, statements that describe our plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report was filed with the SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, the risk factors identified in our SEC reports, including this Quarterly Report. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of

operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements.

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OVERVIEW AND RECENT DEVELOPMENTS

We are a biopharmaceutical company focused on discovering, developing and commercializing novel, small molecule drugs that target G protein-coupled receptors, or GPCRs. To date, our efforts have resulted in an approved drug, lorcaserin (which is marketed under the brand name "BELVIQ" for weight management to adults who are overweight with a comorbidity or obese), and a pipeline of compounds in various stages of research, development and clinical trials, all of which were internally discovered by our scientists. 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.

We intend to focus our near-term activities and resources primarily on:

- advancing our program for APD334 (a modulator of the sphingosine 1-phosphate subtype 1, or S1P1, receptor), including our recently initiated Phase 2 clinical trial for ulcerative colitis, and potentially exploring additional indications beyond inflammatory bowel disease through small pilot studies;
- advancing our program for ralinepag (an agonist of the prostacyclin receptor and formerly known as APD811), including our ongoing Phase 2 clinical trial for pulmonary arterial hypertension, or PAH, and possibly exploring potential enhanced efficacy with other classes of PAH agents;
- advancing our program for APD371 (an agonist of the cannabinoid-2, or CB2, receptor) through our recently initiated Phase 1 multiple-ascending dose clinical trial;
- supporting Eisai to advance the major adverse cardiovascular events, or MACE, diabetes conversion, MACE plus and other endpoints of the ongoing BELVIQ cardiovascular outcomes trial, or CVOT, also known as the CAMELLIA study, and seeking regulatory approval (initially in the United States) for BELVIQ XR, a once-daily formulation of BELVIQ;
- maintaining our core research capabilities to discover and advance drug candidates;
- pursuing strategic collaboration opportunities for certain of our clinical- and earlier-stage programs; and
- meeting manufacturing obligations to our collaborators and others, while reducing commercial manufacturing overhead to achieve potential savings.

With respect to BELVIQ, we have granted exclusive marketing rights to Eisai Inc. and Eisai Co., Ltd., which we refer to collectively as Eisai, for most countries in the world; to Ildong Pharmaceutical Co., Ltd., or Ildong, for South Korea; to CY Biotech Company Limited, or CYB, for Taiwan; and to Teva Pharmaceuticals Ltd.'s Israeli subsidiary, Abic Marketing Limited, or Teva, for Israel. BELVIQ is currently approved for marketing in the United States and South Korea: Eisai began marketing in the United States in June 2013, and Ildong began marketing in South Korea in early 2015.

Our collaborators have pending applications for the potential marketing of BELVIQ in certain territories, including Mexico, Brazil, Israel and Taiwan, and we have had prior applications in certain territories that were withdrawn or rejected. With respect to Taiwan, CYB recently submitted an application for the approval of BELVIQ with the Taiwanese health authority. There is no assurance of whether, where or when BELVIQ will be approved for marketing in any additional territories.

In addition to our collaborations for BELVIQ, we have collaborations for other of our internally discovered drug candidates. For example, we have a collaboration with Axovant Sciences Ltd., or Axovant, for nelotanserin, our internally discovered inverse agonist of the serotonin 2A receptor that we previously studied in Phase 2 trials for insomnia. (Such collaboration was with Roivant Sciences Ltd., or Roivant, until Roivant assigned the agreement to its subsidiary, Axovant in October 2015.) Under this collaboration, Axovant has exclusive rights to develop and commercialize nelotanserin, subject to regulatory approval.

In November 2015, Axovant announced that it intends to initiate two Phase 2 clinical trials with nelotanserin in the first quarter of 2016, with the first trial in patients with either dementia with Lewy bodies, or DLB, or Parkinson's disease dementia who suffer from visual hallucinations, and the second trial in DLB patients experiencing REM Behavior Disorder. Axovant announced that it also intends, pending additional data available in 2016, to initiate programs for nelotanserin in Alzheimer's disease psychosis and Parkinson's disease psychosis.

With respect to our management, on October 5, 2015, at the request of our Board of Directors, Jack Lief, our former President, Chief Executive Officer and principal financial officer, retired from our company. In connection with his

retirement,

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we entered into a separation agreement with Mr. Lief, which provides that he will be entitled to receive a cash severance payment of approximately $1.8 million (subject to applicable withholdings) and other separation benefits. On the same date, our Board of Directors appointed Harry F. Hixson, Jr., Ph.D., one of our directors since September 2004, to the position of interim Chief Executive Officer and interim principal financial officer. We have initiated a search for a new chief executive officer. In addition, our former Senior Vice President, Finance and Chief Financial Officer, Robert E. Hoffman terminated his employment with us in July 2015.

In general, developing drugs and obtaining marketing approval is a long, uncertain and expensive process, and our ability to achieve our goals, including supporting our collaborators' efforts, depends on numerous factors, many of which we do not control. To date, we have generated limited revenues from sales of BELVIQ and other sources. We expect to continue to incur substantial net losses for at least the short term as we advance our clinical development programs, continue our research efforts to discover and develop additional drug candidates, and manufacture BELVIQ for commercial sale and studies.

On October 27, 2015, we committed to a reduction of our US workforce of approximately 80 employees or 35%. As a result of the workforce reduction, which we expect will be substantially complete by December 31, 2015, we estimate that we will incur restructuring charges, primarily in the fourth quarter of 2015, of approximately $3.3 million (substantially all of which is cash expenditures) in connection with one-time employee termination costs, including severance and other benefits. We estimate that the reduction will decrease annualized cash expenditures for personnel by approximately $11.0 million. We plan to implement additional cost control measures to further reduce our expenditures, including reductions at our wholly owned Swiss subsidiary, Arena Pharmaceuticals GmbH. As part of our new strategic focus and cost reduction plan, we will continue working with Eisai on the CAMELLIA study and seeking regulatory approval of BELVIQ XR, but we do not intend to currently advance the evaluation of BELVIQ in combination with phentermine or for smoking cessation.

We expect our cash used in operations to be lower in 2016 compared to 2015 due to cost savings from the workforce reduction and by implementing additional cost control measures. Even with these initiatives, we will need to receive additional funds under our existing collaborative agreements, under any new collaborative agreements we may enter into in the future (including for one or more of our drug candidates or programs), or by raising additional funds through equity, debt or other transactions. We will continue to monitor and evaluate the level of our expenditures, and may further adjust our expenditures based upon a variety of factors, such as our available cash, ability to obtain additional cash through collaborations and other sources, the results of our development and research programs, the timing and costs related to our clinical trials, nonclinical studies and regulatory decisions, as well as the global economic environment.

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

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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 September 30,		Nine months ended September 30,	
Source of revenue	2015	2014	2015	2014
Arena's portion of Eisai net product sales	$3.3	$5.7	$11.6	$12.1
Amortization of upfront payments from Eisai	1.9	1.8	5.7	5.7
Arena's portion of Ildong net product sales	1.6	0.0	4.2	0.0
Toll manufacturing agreements	1.5	0.2	3.2	1.2
Other collaborative agreements	0.6	0.1	0.9	0.2
Reimbursement of development expenses and patent and trademark expenses from Eisai	0.2	0.3	1.8	7.8
Amortization of upfront payment from Ildong	0.0	0.1	0.2	0.3
Milestone payment from Ildong	0.0	0.0	3.0	0.0
Milestone payment from Eisai	0.0	0.0	0.0	0.5
Total revenues	$9.1	$8.2	$30.6	$27.8

Research and development expenses

	Three months ended September 30,		Nine months ended September 30,	
Type of expense	2015	2014	2015	2014
External clinical and preclinical study fees and internal non-commercial manufacturing costs	$8.1	$10.5	$24.8	$30.8
Salary and other personnel costs (excluding non-cash share-based compensation)	7.3	7.5	23.1	22.8
Facility and equipment costs	2.7	2.6	7.5	7.5
Non-cash share-based compensation	2.1	1.8	6.3	5.3
Research supply costs	1.5	1.4	5.3	4.1
Other	0.4	0.7	1.2	2.0
Total research and development expenses	$22.1	$24.5	$68.2	$72.5

General and administrative expenses

	Three months ended September 30,		Nine months ended September 30,	
Type of expense	2015	2014	2015	2014
Salary and other personnel costs (excluding non-cash share-based compensation)	$3.0	$3.2	$9.9	$9.8
Legal, accounting and other professional fees	2.5	1.6	5.7	6.0
Non-cash share-based compensation	1.8	1.6	5.5	4.7
Facility and equipment costs	1.4	1.0	4.0	3.1
Other	0.3	0.6	1.2	1.6
Total general and administrative expenses	$9.0	$8.0	$26.3	$25.2

THREE MONTHS ENDED SEPTEMBER 30, 2015, AND 2014

Revenues. We recognized revenues of $9.1 million for the three months ended September 30, 2015, compared to $8.2 million for the three months ended September 30, 2014. This increase was primarily due to increases of $1.6 million

in our portion of Ildong net product sales of BELVIQ due to sales of BELVIQ in South Korea commencing in February 2015 and $1.3 million of toll manufacturing revenue, partially offset by a decrease of $2.4 million in our portion of Eisai net product sales of BELVIQ in the United States. The decrease in our portion of Eisai net product sales was due to a decrease in the number of

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tablets sold in the United States and a lower per tablet sales price primarily related to Eisai's January 2015 launch of the new savings card.

When collaborators pay us before revenues are earned, we record such payments as deferred revenues. At September 30, 2015, we had a total of $113.1 million in deferred revenues. Of such amount, $88.8 million is attributable to upfront payments we received under our collaboration with Eisai, $14.3 million is attributable to product supply of BELVIQ and the remaining amount is primarily attributable to the upfront payments we received under our other collaborative agreements.

Absent any new collaborations, we expect that our 2015 revenues will primarily relate to (i) net product sales of BELVIQ, (ii) amortization of the upfront payments we have received from Eisai, (iii) toll manufacturing, (iv) reimbursements from Eisai for development expenses and (v) milestone payments from our collaborators. 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 from quarter to quarter and year to year. In the short term, we do not expect the amount of BELVIQ sales to increase significantly or to receive the majority (or potentially any) of such milestone payments.

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

Revenues we generate from sales of BELVIQ depend on net product sales of BELVIQ, which are the gross invoiced sales less certain deductions described in the applicable collaborative agreements. 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 may include deductions for vouchers, savings cards or other promotions for free or discounted product. In the United States, the majority of all BELVIQ prescriptions utilized vouchers or savings cards.

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

Cost of product sales. Cost of product sales consists primarily of direct and indirect costs related to manufacturing BELVIQ, including, among other costs, salaries, share-based compensation and other personnel costs, machinery depreciation costs and amortization expense related to our manufacturing facility production licenses. We recognized cost of products sold of $1.6 million for the three months ended September 30, 2015, and $1.8 million for the three months ended September 30, 2014.

Cost of toll manufacturing. Cost of toll manufacturing consists primarily of direct and indirect costs associated with manufacturing drug products for Siegfried AG, or Siegfried, under a toll manufacturing agreement, including related salaries, other personnel costs, machinery depreciation costs and amortization expense related to our manufacturing facility production licenses. Cost of toll manufacturing increased by $1.5 million to $1.6 million for the three months ended September 30, 2015, from $0.1 million for the three months ended September 30, 2014, primarily due to the increased volume of toll manufacturing performed. We entered into a new toll manufacturing agreement with a third party in April 2015, and may consider entering into additional toll manufacturing agreements in the future to increase revenues and increase utilization of our drug-product manufacturing facility.

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

Research and development expenses decreased by $2.4 million to $22.1 million for the three months ended September 30, 2015, from $24.5 million for the three months ended September 30, 2014. This decrease was primarily due to a decrease of $2.4 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs. Although we expect to incur substantial research and development expenses in 2015, we expect these expenses will be lower than in 2014,

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primarily due to lower external clinical and preclinical study fees and internal non-commercial manufacturing costs. Such expenses will include costs for FDA-required development work relating to lorcaserin as well as expenses for our other research and development programs.

Included in the $8.1 million of total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the three months ended September 30, 2015, were the following:

- $3.8 million related to lorcaserin and non-commercial manufacturing costs,
- $1.9 million related to APD334, and
- $1.4 million related to ralinepag.

Included in the $10.5 million of total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the three months ended September 30, 2014, were the following:

- $7.6 million related to lorcaserin and non-commercial manufacturing costs,
- $1.8 million related to APD334, and
- $0.9 million related to ralinepag.

General and administrative expenses. General and administrative expenses increased by $1.0 million to $9.0 million for the three months ended September 30, 2015, from $8.0 million for the three months ended September 30, 2014. This increase was primarily due to an increase in the use of consulting services. We expect that our 2015 general and administrative expenses will be higher than in 2014.

Interest and other income (expense), net. Interest and other income (expense), net, was expense of $1.2 million for the three months ended September 30, 2015, compared to income of $15.5 million for the three months ended September 30, 2014. This change of $16.7 million was primarily due to a gain on sale of available-for-sale securities of $16.3 million realized in the three months ended September 30, 2014, related to our sale of shares we held in TaiGen Biotechnology Co., Ltd., or TaiGen.

NINE MONTHS ENDED SEPTEMBER 30, 2015, AND 2014

Revenues. We recognized revenues of $30.6 million for the nine months ended September 30, 2015, compared to $27.8 million for the nine months ended September 30, 2014. This increase was primarily due to (i) an increase of $3.7 million in net product sales of BELVIQ, (ii) the $3.0 million milestone payment from Ildong that we earned in February 2015 for the approval of BELVIQ in South Korea and (iii) an increase of $2.0 million of toll manufacturing revenue, partially offset by a decrease of $6.0 million of reimbursements of development expenses and patent and trademark expenses from Eisai. The increase in net product sales of BELVIQ was primarily due to sales of BELVIQ in South Korea commencing in February 2015.

Cost of product sales. We recognized cost of product sales of $6.1 million for the nine months ended September 30, 2015, compared to $4.0 million for the nine months ended September 30, 2014.

Cost of toll manufacturing. Cost of toll manufacturing increased by $2.7 million to $3.8 million for the nine months ended September 30, 2015, from $1.1 million for the nine months ended September 30, 2014, primarily due to the increased volume of toll manufacturing performed.

Research and development expenses. Research and development expenses decreased by $4.3 million to $68.2 million for the nine months ended September 30, 2015, from $72.5 million for the nine months ended September 30, 2014. This decrease was primarily due to a decrease of $6.0 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs, partially offset by increases of $1.2 million in research supply costs and $1.0 million in non-cash share-based compensation expense.

Included in the $24.8 million of total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the nine months ended September 30, 2015, were the following:

- $13.2 million related to lorcaserin and non-commercial manufacturing costs,
- $5.8 million related to APD334, and
- $4.0 million related to ralinepag.

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Included in the $30.8 million of total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the nine months ended September 30, 2014, were the following:

- $25.3 million related to lorcaserin and non-commercial manufacturing costs,
- $3.3 million related to APD334, and
- $1.7 million related to ralinepag.

General and administrative expenses. General and administrative expenses increased by $1.1 million to $26.3 million for the nine months ended September 30, 2015, from $25.2 million for the nine months ended September 30, 2014. This increase was primarily due to increases of $0.9 million in facility and equipment costs and $0.8 million in non-cash share-based compensation expense, partially offset by $0.3 million of product liability insurance refunds.

Interest and other income (expense), net. Interest and other income (expense), net, was an expense of $3.6 million for the nine months ended September 30, 2015, compared to income of $46.7 million for the nine months ended September 30, 2014. This change of $50.3 million was primarily due to a gain on sale of available-for-sale securities of $49.6 million realized in the nine months ended September 30, 2014, related to our sale of shares we held in TaiGen.

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. As described above, our internally discovered drug, lorcaserin, has been approved for marketing for weight management in the United States and South Korea, under the brand name BELVIQ. To date, we have received lower than anticipated revenues from sales of BELVIQ, and it is difficult to predict the future payments we will receive from commercialization of BELVIQ in the United States, South Korea or in any other territory in which BELVIQ may be approved for marketing. We expect to continue to incur substantial losses for at least the short term.

Short term.

At September 30, 2015, we had $181.3 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 advance certain of our research and development programs, conduct studies of lorcaserin and operate our manufacturing facility.

In addition to payments expected from Eisai and Ildong for purchases of product supply of BELVIQ, other potential sources of liquidity in the short term include (i) milestone and other payments from collaborators, (ii) entering into new collaborative, licensing or commercial agreements for one or more of our drug candidates or programs, (iii) the sale or lease of our facilities or other assets and (iv) equity, debt or other financing.

Eisai is commercializing BELVIQ in the United States, and, subject to applicable regulatory approval, we expect Eisai to commercialize lorcaserin in additional territories under our collaboration. In addition, in February 2015, Ildong began commercializing BELVIQ in South Korea. Our collaborators have filed regulatory applications for approval of lorcaserin in a number of territories outside of the United States and South Korea, but there is no assurance of whether, where or when our collaborators will file any additional applications. There is also no assurance of whether, where or when lorcaserin will be approved for marketing in any other territories. Therefore, we expect that all or most of the revenues for sales of BELVIQ in the short term will be from commercialization of BELVIQ in the United States and South Korea.

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 our Eisai collaboration (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 Eisai Product Purchase Price, in the respective territory. The Eisai 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 Eisai 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 Eisai Product Purchase Price is subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country. The revenue we recognize for net product sales of BELVIQ related to redemption of vouchers and product samples is based on our cost of goods sold. Under our Eisai collaboration, we are eligible to receive up to an aggregate of $176.0 million in additional regulatory and development milestone payments. In the short term, we do not expect to receive

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the majority (or potentially any) of such milestone payments, the amount of BELVIQ sales to increase significantly or the purchase price percentages to increase beyond the starting percentage in any territory.

The purchase price for BELVIQ that Eisai has sold to date has been lower than the initial estimated price that Eisai has paid us for such product, primarily due to an increase in deductions from savings cards and returns, partially offset by a decrease in vouchers. Subsequent to the end of Eisai's fiscal year, we refund the portion of these excess payments, which total the $10.6 million classified as Payable to Eisai on our condensed consolidated balance sheets at September 30, 2015, related to product sold by Eisai to their distributors through March 31.

Under the Ildong Agreement, we receive payments from net product sales of BELVIQ. We sell BELVIQ to Ildong for a purchase price starting at the higher of a defined minimum amount or 35% of Ildong's annual net product sales (which are the gross invoiced sales less certain deductions described in the Ildong Agreement), or the Ildong Product Purchase Price. The Ildong Product Purchase Price will increase on a tiered basis up to the higher of a defined minimum amount or 45% on the portion of annual net product sales exceeding $15.0 million. However, in no event will the Ildong Product Purchase Price be less than a defined minimum amount adjusted annually based on a consumer price index. For the three and nine months ended September 30, 2015, the Ildong Product Purchase Price equaled the defined minimum amount (which exceeded the amounts calculated using the applicable percentages for the applicable tiers of Ildong's annual net product sales for these periods). In the short term, we do not expect for the amount of BELVIQ sales to increase substantially.

As part of the US approval of BELVIQ, the FDA is requiring the evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors (which is the FDA-required portion of CAMELLIA), as well as the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric and adolescent 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 and adolescent studies. As part of CAMELLIA, we expect to evaluate BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes, and Eisai and we will share the related expenses.

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

In January 2008, we acquired from Siegfried certain drug product facility and real estate assets in Zofingen, Switzerland, including approximately 67,000 square feet of space in a building that consists of approximately 134,000 square feet of space. These assets are being used to manufacture BELVIQ as well as certain drug products for Siegfried. Under our acquisition agreement, we had the option to purchase the remaining Siegfried-occupied portion of the building we are occupying along with the underlying land at a price of CHF 15.0 million, plus an inflation adjustment. Siegfried also had the option to sell us such remaining Siegfried-occupied portion of the building with the underlying land at a price of CHF 8.0 million, plus an inflation adjustment. In July 2014, Siegfried provided us notice of its exercise of the option to sell us the remaining portion of the building with the underlying land. In December 2014, we took title of the remaining portion of the building with the underlying land, and in July 2015 we paid the purchase price of CHF 8.2 million to Siegfried. In connection with the exercise of the option, we entered into an agreement to lease this newly acquired building space back to Siegfried through December 31, 2016, for an annual base rent amount of CHF 0.4 million. Siegfried has the right to partially or fully terminate this lease with six months' notice, provided that Siegfried cannot terminate any portion of the lease prior to December 31, 2015. Siegfried has an annual option to extend the lease for an additional year with the last extension term ending on December 31, 2019. At any time during the extension terms, we have the right to partially or fully terminate this lease with six months' notice, but with a termination date no earlier than December 31, 2017.

To date, we have obtained cash and funded our operations primarily through equity financings, payments from collaborators, the issuance of debt and related financial instruments, sale leaseback transactions and the sale of

available-for-sale securities. We expect to continue to evaluate various funding alternatives on an ongoing basis. If we determine it is advisable to raise additional funds, we do not know whether adequate funding will be available to us or, if available, that such funding will be adequate or available on terms that we or our stockholders view as favorable. We expect that our research and development expenditures will continue to be high in 2016, but less than they will be in 2015. As described in the above overview, we recently committed to a reduction in our US workforce of approximately 35%, or a total of approximately 80 employees, which we expect will be substantially complete by December 31, 2015. As a result of

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this workforce reduction, we expect to incur restructuring charges, primarily in the fourth quarter of 2015, of approximately $3.3 million (substantially all of which is cash expenditures) in connection with one-time employee termination costs, including severance and other benefits. We expect this workforce reduction will result in annual operating cost savings of approximately $11.0 million in personnel costs. Even with this workforce reduction and our our plans to implement additional cost control measures, we may not have sufficient cash to meet all of our objectives beyond the next 12 months, which include advancing certain of our clinical- and earlier- stage programs and maintaining our manufacturing capabilities. If we do not generate sufficient funding, we may need to further eliminate or postpone or scale back some or all of our research and development programs and further reduce our expenses.

Long term.

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

We expect to continue to incur substantial costs for lorcaserin, including costs related to manufacturing and required postmarketing and potentially other studies. As described above under “short term,” we will be responsible for a portion of the expenses for lorcaserin development work required by regulatory agencies. In addition, with respect to any development work not required by the FDA that we or Eisai may conduct relating to lorcaserin, 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 in the short term, if ever) will be shared equally by Eisai and us for up to an aggregate of $40.0 million each, and, thereafter, Eisai will be responsible for 100% of such expenses.

Subject to applicable regulatory approval, we expect Eisai to commercialize lorcaserin in additional territories under the Eisai Agreement. Under such agreement, in addition to potential payments for purchases of lorcaserin and milestone payments, we are eligible to receive up to an aggregate of $1.56 billion in one-time purchase price adjustment payments and other payments. These payments include up to an aggregate of $1.19 billion that are based on Eisai’s annual net product sales of lorcaserin 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 our Teva collaboration, we are eligible to receive payments upon regulatory approval of BELVIQ for weight loss or weight management. We are also eligible to receive payments from net product sales of BELVIQ under our Teva and CYB collaborations. If BELVIQ is approved in the applicable territory, we will sell BELVIQ to Teva for a purchase price of 35% of Teva’s annual net product sales and to CYB for a purchase price of 45% of CYB’s annual net product sales. We are also eligible to receive additional milestone payments and/or purchase price adjustment payments under these collaborations.

In addition to potential payments from Eisai, Ildong 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.

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

Sources and uses of our cash.

Net cash used in operating activities decreased by $5.8 million to $73.2 million in the nine months ended September 30, 2015, compared to $79.0 million in the nine months ended September 30, 2014. This decrease was primarily the result of (i) net payments of $8.8 million received for shipments of BELVIQ to Eisai and Ildong in the nine months ended September 30, 2015, compared to $1.3 million in the nine months ended September 30, 2014, (ii) the $4.0 million upfront payment from Roivant that we received in May 2015, and (iii) the $3.0 million milestone payment from Ildong that we received, less withholding taxes, in March 2015 for the marketing approval of BELVIQ in South Korea. The decrease was partially offset by increased payments made for external clinical and preclinical study fees and decreased payments received for reimbursement of development expenses from Eisai in the nine months ended September 30, 2015, compared to the nine months ended September 30, 2014.

Net cash used in investing activities was $8.6 million in the nine months ended September 30, 2015, compared to net cash provided by investing activities of $43.4 million in the nine months ended September 30, 2014. This change of $52.0 million was primarily due to (i) proceeds from the sale of available-for-sale securities of $49.6 million received in the nine months ended September 30, 2014, and (ii) $10.8 million in purchases of property and equipment in the nine months ended September 30, 2015, compared to $6.4 million in the nine months ended September 30, 2014, partially offset by net proceeds from our sale of an unoccupied building in San Diego of $2.2 million received in the nine months ended September 30, 2015. Our 2015 capital expenditures will increase over the 2014 amount primarily due to the payment in July 2015 of CHF 8.2 million for the acquisition of building space and land in Switzerland.

Net cash of $101.1 million was provided by financing activities in the nine months ended September 30, 2015, as a result of net proceeds of $100.7 million from the January 2015 offering of 21,000,000 shares of common stock, which we sold to the underwriters at a price of $4.8139 per share, and net proceeds of $2.2 million from stock option exercises and purchases under our employee stock purchase plan, which were partially offset by $1.8 million for payments on our lease financing obligations. Net cash of $3.4 million was provided by financing activities in the nine months ended September 30, 2014, as a result of net proceeds of $4.9 million from stock option exercises and purchases under our employee stock purchase plan, which were partially offset by $1.5 million for payments on our lease financing obligations.

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 condensed 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 and management estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and there have been no material changes during the nine months ended September 30, 2015.

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, 2014.

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 interim Chief Executive Officer (our principal executive and financial officer), of the effectiveness of our disclosure controls and procedures, our interim Chief Executive

Officer has concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities

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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.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints were brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. The plaintiffs sought unspecified monetary damages and other relief. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. On March 28, 2013, the Court dismissed the consolidated amended complaint without prejudice. On May 13, 2013, the lead plaintiff filed a second consolidated amended complaint. On November 5, 2013, the Court dismissed the second consolidated amended complaint without prejudice as to all parties except for Robert E. Hoffman, who was dismissed from the action with prejudice. On November 27, 2013, the lead plaintiff filed a motion for leave to amend the second consolidated amended complaint. On March 20, 2014, the Court denied plaintiff's motion and dismissed the second consolidated amended complaint with prejudice. On April 18, 2014, the lead plaintiff filed a notice of appeal, and on August 27, 2014, the lead plaintiff filed his appellate brief in the US Court of Appeals for the Ninth Circuit. On October 24, 2014, we filed our answering brief in response to the lead plaintiff's appeal. On December 5, 2014, the lead plaintiff filed his reply brief. Due to the stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

Item 1A. Risk Factors.

RISK FACTORS

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

The risk factors set forth below with an asterisk (*) before the title are new risk factors or ones containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission, or SEC.

Risks Relating to Our Business

*If we do not realize the expected benefits from the reduction in force and additional cost control measures that we announced in October 2015, our operating results and financial conditions would be negatively impacted.

We announced in October 2015 a reduction in our US workforce of approximately 35% (approximately 80 employees) and plans to implement additional cost control measures, which are designed to focus our resources on prioritized activities and reduce our cash expenditures. We cannot guarantee that we will be able to realize sufficient cost savings and other anticipated benefits from such efforts, that such efforts will not interfere with our ability to achieve our business objectives, or that we will not have to undertake future restructuring and cost control activities.

*Our prospects are dependent on the success of BELVIQ, our first and only marketed 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 internally discovered drug, lorcaserin, has been approved for marketing for weight management in the United States and South Korea, and has been marketed by our collaborators under the brand name BELVIQ since June 2013 in the United States and February 2015 in South Korea. We believe our prospects are dependent on, and a significant portion of the value of our company relates to, the success of BELVIQ, which is our first and only drug approved by any regulatory agency and has not been approved for marketing outside of the United States or South Korea. We have granted rights to commercialize BELVIQ to collaborators for most of the territories in the world, and are highly dependent on our collaborators for obtaining marketing approval and commercializing BELVIQ. In this regard, we are particularly dependent on Eisai Inc. and Eisai Co.,

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Ltd. (collectively with Eisai Inc., Eisai) as Eisai has commercialization and other rights to BELVIQ for the United States and the vast majority of all other territories. We do not know whether or when BELVIQ will be approved for sale or commercialized in any additional territories, and BELVIQ may not receive marketing approval from any other regulatory agency or be commercialized in any other territories.

We expect that revenues generated by BELVIQ will constitute the majority of our revenues over the next several years, which will substantially depend on product sales of BELVIQ and the achievement of milestones under our collaborations. We cannot guarantee future product sales or achievement of any other milestones. In addition, any of our collaborations for lorcaserin may be terminated early in certain circumstances, which may result in us not receiving additional milestone or other payments under the terminated agreement.

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

- the number of patients eligible to receive BELVIQ, the number of patients treated with BELVIQ and the results achieved by such patients;
- market acceptance and use of BELVIQ, which may depend on the public's view of BELVIQ, economic changes, national and world events, potentially seasonal and other fluctuations in demand, the timing and impact of current or new competition, and BELVIQ's perceived advantages or disadvantages over alternative treatments (including relative convenience, ease of administration, and prevalence and severity of any adverse events, including any unexpected adverse events);
- the actual and perceived safety and efficacy of BELVIQ on both a short- and long-term basis among actual or potential patients, healthcare providers and others in the medical community, regulatory agencies and insurers and other payers, including related decisions by any such entity or individual;
- incidence and severity of any side effects, including as a result of off-label use or in combination with one or more drugs;
- new data relating to lorcaserin, including as a result of additional studies, trials or analyses of lorcaserin or related drugs or drug candidates;
- some physicians and patients may not use 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, or any comparable foreign authorities;
- Our collaborator'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;
- the price and perceived cost-effectiveness of BELVIQ, including as compared to possible alternatives;
- the ability of patients and physicians and other providers to obtain and maintain coverage and 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 maintenance of adequate commercial manufacturing capabilities ourselves or through third-party manufacturers, our ability to meet commercial demand for BELVIQ and supply-chain issues.

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The sales of BELVIQ to date have been less than we and others anticipated. If BELVIQ does not achieve sufficient market acceptance in the United States and South Korea, and ultimately in other territories, the revenues we generate from sales of BELVIQ will be limited, our collaborators may negatively change marketing strategies or resources, our collaborations may be modified or terminated and we may not be profitable.

We also intend to seek regulatory approval (initially in the United States) of a once-daily formulation of BELVIQ, which we refer to as BELVIQ XR. We do not know whether or when BELVIQ XR will be approved for sale or commercialized in any territory, or, if BELVIQ XR is approved, whether the advantages of a once-daily formulation will result in increased sales. Many of the same risks described in these risk factors would also apply to BELVIQ XR, if approved.

If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

BELVIQ or any of our future drugs may not be commercially successful if not widely covered and adequately reimbursed by third-party payers, and we may depend on others to obtain and maintain third-party payer access; inadequate third-party coverage and reimbursement could make entering into agreements with pharmaceutical companies to collaborate or commercialize our drugs more difficult and diminish our revenues.

Our and our collaborators' ability to successfully 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. We expect government and third-party payers will continue their efforts to contain healthcare costs by limiting coverage and reimbursement levels for new drugs. 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. A government or third-party payer decision not to approve pricing, or provide adequate coverage and reimbursements, for our drugs, if any, could limit market acceptance of and demand for our drugs.

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 these competitors may have significantly more negotiating leverage or success with respect to individual payers than we or our collaborators may have.

In the United States, even if a third-party payer ultimately elects to cover and reimburse for BELVIQ, most payers will not reimburse 100% of the cost, but rather require patients to pay a portion of the cost through a co-payment. Thus, even if reimbursement is available, the percentage of drug cost required to be borne by the patients may make use of BELVIQ financially undesirable, difficult or impossible for certain patients, which would have a negative impact on sales of BELVIQ, including related revenues. For example, payers may approve coverage for BELVIQ in tiers requiring unacceptably high patient co-payments or only as a second- or later-line treatment. Several third-party payers have approved coverage for BELVIQ with limitations, including co-payments that may be unacceptably high for certain patients, regardless of the availability of any coupon, voucher or other discount program. In addition, even if a payer approves coverage for BELVIQ, individual employers or others may not opt to select a plan that provides such coverage. Failure to improve coverage or the reduction or loss of coverage could materially harm the ability to successfully market BELVIQ. Achieving coverage and acceptable reimbursement levels typically involves negotiating with individual payers and is a time-consuming and costly process. In addition, Medicare explicitly excludes coverage for drugs for weight loss.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, as well as other federal and state healthcare reform measures that have and may be implemented in the future, may result in more rigorous coverage criteria, more limited coverage and downward pressure on the price that we may receive for any approved product, which 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 also 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, which may prevent us from being able to generate revenue, attain profitability, commercialize our products or establish and maintain collaborations.

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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 particular market, including fluctuations in demand for various reasons, such as fluctuations related to economic changes, national and world events, holidays and seasonal changes;
- pricing (including discounting or other promotions), reimbursement, product returns or recalls, competition, labeling, DEA scheduling, adverse events and others items that impact commercialization;
- lack of patient and physician familiarity with BELVIQ;
- lack of patient use and physician prescribing history;
- lack of commercialization experience with BELVIQ, in particular, and weight loss or management drugs, in general;
- actual sales to patients may significantly differ from expectations based on sales to wholesalers;
- our collaborators control the commercialization of BELVIQ in most of the world, including related strategy and their allocation of resources, and we expect that any future collaborators for BELVIQ will similarly control the commercialization in the applicable territory; and
- uncertainty relating to when BELVIQ may become commercially available to patients and rate of adoption in other territories.

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, projections 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 and may change from time to time. 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 or trials may result in decreased demand, lower sales, product recall or regulatory action.

A New Drug Application, or NDA, holder (or, with respect to South Korea, a marketing authorization holder) is responsible for assessing and monitoring the safety of a drug that has been approved for marketing. Eisai and Ildong hold the NDA and marketing authorization, respectively, for BELVIQ, and we expect that Eisai and other of our collaborators will hold the lorcaserin regulatory approvals, if any, in territories outside of the United States and South Korea. Eisai, Ildong, we and, potentially, our other collaborators will assess and monitor the safety of BELVIQ in the marketplace, and will receive reports of adverse safety events. In addition, we expect that, from time to time, we or others will conduct additional studies or trials or analyze new or previous data related to lorcaserin, including with respect to required postmarketing studies and in connection with seeking regulatory approval of lorcaserin outside of the United States. For example, as a condition to obtaining FDA approval of BELVIQ, the FDA required the conduct of postmarketing studies, including evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors (otherwise known as the cardiovascular outcomes trial, or CVOT). The FDA-required portion of the trial is designed to evaluate BELVIQ's effect on the incidence of major adverse cardiovascular events, or MACE, (non-fatal myocardial infarction, non-fatal stroke and cardiovascular death) compared to placebo, with a non-inferiority margin for the hazard ratio of 1.4. The trial also includes FDA-required echocardiographic assessments. Along with the FDA-required portion of the trial, we expect that the trial may include the non-FDA required evaluation of whether lorcaserin reduces the incidence of conversion to type 2 diabetes in patients without

type 2 diabetes at baseline and the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure, or any coronary revascularization), both as compared to placebo. We expect that the trial (including the non-FDA required portion) will run

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approximately five years. The FDA is also requiring as a postmarketing commitment the assessment of the safety and efficacy of BELVIQ for weight management in obese pediatric and adolescent patients.

New data relating to lorcaserin, including from adverse event reports or required postmarketing, registration or other studies or trials, may result in label changes, may adversely affect sales or result in withdrawal of BELVIQ from the market. In addition, analyses of previous data can have similar risks. Eisai and we expect to continue to generate data from new studies and trials, as well as to continue analyzing existing data from previously conducted studies and trials, including for potential use in applications for the marketing approval of lorcaserin. Foreign regulatory agencies may consider the new data or analyses in reviewing marketing applications for lorcaserin 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 lorcaserin could have an adverse effect on the lorcaserin program, including commercialization.

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

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

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made with respect to lorcaserin and in seeking to identify and validate new drug targets and develop other compounds that could become marketed drugs. We expect that our losses and operating expenses will continue to be substantial for at least the short term.

Cash we have generated from sales of BELVIQ has been lower than anticipated, and 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 development stage, and we may not have adequate funds to develop our compounds into marketed drugs. 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 any additional marketed drugs.

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

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

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

We may allocate our resources in ways that do not improve our results of operations or enhance the value of our assets, and our stockholders and others may also not agree with the manner in which we choose to allocate our resources or obtain additional funding. Any failure to apply our resources effectively, how we obtain additional funding and the related views of stockholders or others could have a material adverse effect on our business or the development of our drug candidates and cause the market price of our common stock to decline. In addition, we cannot assure you that we will be profitable or, if we are profitable for any particular time period, that we will be profitable in the future.

*If lorcaserin is not approved for marketing in any additional territories, 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; if lorcaserin is approved in any additional territories, commercializing lorcaserin in such territory will carry risks.

We and our collaborators have filed applications for regulatory approval for lorcaserin for weight management or control outside of the United States and South Korea, and we expect our collaborators will seek regulatory approval for lorcaserin in

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additional territories in the future. Marketing approval of a drug by the FDA or any other regulatory authority 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 the MAA we previously submitted for the approval of lorcaserin for weight control in the European Union. We cannot assure or predict with any certainty that lorcaserin will be approved in any additional territories or the expected timeframe of any such approval. The review and potential approval of lorcaserin carries many risks and uncertainties, and our or others' lorcaserin regulatory submissions may not be satisfactory to the applicable regulatory authorities, including with regard to demonstrating adequate safety and efficacy for regulatory approval. We have made, and expect to make in the future, assumptions, estimations, calculations and decisions as part of our analyses of data and regulatory submissions, and the applicable regulatory authorities may not accept or agree with our assumptions, estimations, calculations, decisions or analyses, may interpret or weigh the importance of data differently or require additional information for approval.

Furthermore, as was the case with FDA approval, other regulatory approvals, even if obtained, may be limited to specific indications, limit the type of patients in which the drug may be used, or otherwise require specific warning or labeling language, any of which might reduce the commercial potential of lorcaserin. As with the FDA's approval of BELVIQ, regulatory authorities in other territories may condition marketing approval of lorcaserin 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 lorcaserin or the withdrawal of lorcaserin 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 lorcaserin's overall benefit-risk balance taking these issues into consideration with respect to the proposed indication of weight control. The major objections needed to be addressed before the CHMP could have recommended lorcaserin for marketing approval for weight control 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 lorcaserin MAA for the European Union. We also previously received feedback with respect to regulatory applications in other territories that included major objections. We expect Eisai to submit for regulatory approval of lorcaserin in Europe and in other territories in the future, but such submissions may not occur when expected or ever. With respect to activities related to regulatory efforts and strategy, Eisai and we expect to continue to generate data from new studies and trials, as well as to continue analyzing existing data from previously conducted studies and trials, including for potential use in applications for the marketing approval of lorcaserin in Europe and other territories. As part of such efforts, Eisai and we expect to continue analyzing data from one of our long-term preclinical carcinogenicity studies for lorcaserin. While Eisai and we believe that such studies and analysis may be helpful with respect to regulatory applications, it is unknown whether any new data, or the results of such analysis, will be viewed favorably or if any data or results will positively or negatively impact any regulatory approvals, applications or strategy.

We cannot assure you that our collaborators' 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 lorcaserin program or data, including with regard to lorcaserin's efficacy or safety, as sufficient, or that any other regulatory authority will ever approve lorcaserin.

If lorcaserin is not approved or commercialized in additional territories, the potential revenues we will receive for lorcaserin will be limited and any related regulatory actions may negatively impact the approval or commercialization of lorcaserin in any territories in which it is approved.

If lorcaserin is approved in any additional territories, the degree of market acceptance and commercial success of lorcaserin in such territory, as well as our resulting revenues, will depend on similar factors as in the United States, as well as territory-specific risks.

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

We developed lorcaserin 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, lorcaserin demonstrated affinity

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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 lorcaserin's selectivity profile may not be adequate to avoid these side effects. Lorcaserin's selectivity profile and the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased FDA or other regulatory scrutiny of the safety of lorcaserin, 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 lorcaserin for marketing.

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

Our collaborators have primary responsibility for the regulatory approval and, ultimately, marketing and distribution of lorcaserin in the territory or territories under the applicable collaboration. We have limited or no control over the amount and timing of resources that any of these collaborators will dedicate to such activities. In addition, they are responsible for compliance with certain regulatory requirements. Eisai has exclusive distribution and other rights for lorcaserin in its territories, and our other collaborators have exclusive distribution and other rights for lorcaserin for weight loss or weight management in obese and overweight patients.

We are subject to a number of other risks associated with our dependence on our collaborative agreements for lorcaserin, including:

- our collaborators may not comply with applicable regulatory guidelines with respect to lorcaserin, which could adversely impact the commercialization or development of lorcaserin;
- there could be disagreements regarding the agreements or the study or development of lorcaserin that delay or terminate the commercialization, research, study or development of lorcaserin, delay or eliminate potential payments under the agreements or increase our costs under or outside of the agreements;
- our collaborators may not effectively allocate adequate resources or otherwise support lorcaserin 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 our 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 our marketing and supply agreements for lorcaserin is terminated early, we may not be able to find another company to further develop and commercialize lorcaserin in the covered territory on acceptable terms, if at all, and even if we elected to pursue further development or commercialization of lorcaserin 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 lorcaserin and other drug candidates under our marketing and supply agreements, including for commercial sale. We do or will rely 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 our marketing and supply agreements for lorcaserin, we are the exclusive supplier of lorcaserin. Our drug product manufacturing facility in Switzerland is currently our only source for finished drug product of lorcaserin. Without this facility, we would need to rely on third-party manufacturers for such production or develop or acquire such facilities, which, in either case, would require substantial time and funds. We estimate that it would take a year or

longer and a substantial amount of financial and other resources to secure a second source for finished drug product of lorcaserin, and we may not be successful in securing a second source for such finished drug product.

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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, could result in substantial delay and greater cost. We expect Siegfried AG, or Siegfried, will be the only source of API for BELVIQ 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 result in a product recall or seizure, delay or otherwise adversely affect the sales of BELVIQ or the clinical development or regulatory approval of lorcaserin or one or more of our other 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. For example, in December 2014, Eisai and we discovered that a small number of bottles of BELVIQ in a limited number of lots had a missing or incomplete label, and, as a precautionary measure, Eisai voluntarily initiated a recall from wholesalers of the involved lots for inspection.

The ability to adequately and timely manufacture and supply drug product is dependent on the uninterrupted and efficient operation of the manufacturing facilities, which is impacted by many manufacturing variables, including:

- availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;
- capacity of our facilities or those of our contract manufacturers;
- having the ability to adjust to changes in actual or anticipated use of the facility, including with respect to having sufficient capacity and a sufficient number of qualified personnel;
- facility contamination by microorganisms or viruses or cross contamination;
- compliance with regulatory requirements, including inspectional notices of violation and warning letters;
- maintenance and renewal of any required licenses or certifications;
- changes in actual or forecasted demand;
- timing and number of production runs;
- production success rates and bulk drug yields; and
- timing and outcome of product quality testing.

In addition, we or our third-party manufacturers may encounter delays and problems in manufacturing our drug candidates or drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental unrest or changes, social unrest, intentional misconduct or other factors inherent in operating complex manufacturing facilities. 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

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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.

*Our business may be negatively impacted based on the clinical trials and preclinical studies of, and decisions affecting, BELVIQ or one or more of our drug candidates.

The results and timing of clinical trials and preclinical studies, as well as related decisions, can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies, which are sometimes referred to as nonclinical studies, include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies, including adverse effects, as well as related analyses of such results, of BELVIQ or one or more of our drug candidates (including development programs related to lorcaserin) 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 lorcaserin 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.

We regularly 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.

Information on our drug candidates in clinical development is preliminary and incomplete, and for such drug candidates, particularly in the earlier stages of development, information on approved products in the same or related drug classes may be helpful in predicting potential risks. For example, APD334 is an orally available modulator of the $S1P_1$ receptor, and, in July 2015, we announced our initiation of patient screening in a Phase 2 proof-of-concept clinical trial of this drug candidate in ulcerative colitis. Information on this drug candidate is, therefore, limited and subject to ongoing preclinical and clinical studies, and experience with other drugs may be relevant. An approved drug that is also an orally available modulator of the $S1P_1$ receptor, Gilenya, is associated with risks such as adverse cardiovascular effects, including lowering of the heart rate and heart blocks, infection, macular edema, respiratory effects, fetal risk, and elevations in liver enzymes. These adverse reactions and risks may be associated with S1P receptor modulation and could be found to be associated with the use of APD334. Such adverse reactions and risks, either actual or perceived, could negatively impact its development, approval or commercialization, or our ability to enter into a collaboration on acceptable terms.

In addition, results of completed or new preclinical and clinical studies can be interpreted differently by regulatory agencies, us or others, and can negatively impact even approved products such as lorcaserin. For example, certain countries in the European Union have denied Eisai's application to conduct the CVOT in their countries until the major objections identified in the MAA for lorcaserin for weight management that was withdrawn from the European Medicines Agency have been addressed. We may be similarly restricted in additional territories in the future, and restrictions may cause delay or otherwise negatively impact our ability to conduct and complete clinical trials for lorcaserin. Unfavorable results or delays with respect to studies, trials or analyses for lorcaserin could negatively impact market acceptance of lorcaserin, limit the revenues we generate from sales, negatively impact regulatory

agencies' views or restrictions on lorcaserin, result in lorcaserin'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 our clinical programs.

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We may publicly disclose top-line data from time to time, which is based on a preliminary analysis of then-available efficacy and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations, conclusions 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. In addition, the information we may publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business.

We depend on our collaborators for commercializing lorcaserin, and, without collaborators, our lack of corporate experience and resources may negatively impact our ability to commercialize lorcaserin independently.

We expect our collaborators to commercialize lorcaserin for at least weight management, subject to any applicable regulatory approval. We may not be able to maintain our marketing and supply agreements for lorcaserin or enter into new agreements for lorcaserin on acceptable terms, if at all. If we are unable to maintain or enter into agreements to commercialize lorcaserin and we develop or acquire our own capabilities to commercialize lorcaserin in any territory independently, we may require additional capital to develop such capabilities, and the marketing and sale of lorcaserin 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 lorcaserin 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 lorcaserin independently.

If our competitors have commercialization arrangements with companies who allocate substantially greater resources than we allocate (or, with respect to commercializing lorcaserin in a territory under one of our agreements, than our collaborator allocates) to the respective drugs, our competitors may be more successful in marketing and selling their drugs, and our ability to successfully commercialize lorcaserin 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

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review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other submissions made to 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, and our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval. The number and types of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. Despite the time and expense exerted in preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials.

The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

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

We cannot predict when or whether, or assure you that, our collaborator's or our past or any future regulatory submissions or responses will be sufficient to the applicable regulatory authority or others, that the applicable regulatory authority or others will consider data or our analyses, interpretations or procedures related to any of our drug candidates as sufficient or persuasive, or that any regulatory authority will ever approve any of our drug candidates in the future. For example, we plan to file an NDA for BELVIQ XR. In one of the two Phase 1 clinical trials for such once-daily formulation, the analysis supporting our and Eisai's belief that the once-daily formulation and the twice-daily formulation (which is the approved formulation being marketed as BELVIQ) are bioequivalent excludes data from one participant whose observed drug levels and exposures during the twice-daily dosing portion of the trial were not consistent with taking the prescribed doses. The FDA may conclude that bioequivalence has not been established, including if the FDA includes such participant's data in its analysis of the data, and may require additional testing, analysis or other activities before approving, if ever, the once-daily formulation.

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.

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 of BELVIQ 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

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least 5% greater than that associated with placebo. Also, with respect to our previously filed MAA for lorcaserin for weight management 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 received feedback with respect to regulatory applications in other territories that included major objections.

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.

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.

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 the CVOT described above as well as postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric and adolescent patients. Along with being costly and time consuming, a delay or unfavorable results from these trials could negatively impact market acceptance of BELVIQ; limit the revenues we generate from sales; result in BELVIQ's withdrawal from the market; negatively impact the potential approval of lorcaserin in other territories for weight management, for other indications, in combination with other agents 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, and 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;

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- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by any regulatory agency to approve pending applications or supplements to approved applications filed by us or collaborators;
- refusals to permit drugs or related materials to be imported into or exported from the United States or other countries;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

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

Our ability to generate revenues from BELVIQ or any of our drug candidates that receive regulatory approval will be subject to a variety of risks, many of which are out of our control.

BELVIQ or any of our drug candidates that may be approved for marketing may not gain market acceptance among patients, healthcare providers, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including:

- timing of market introduction of our drugs and competitive drugs and alternative treatments;
- actual and perceived efficacy and safety of our drug candidates;
- incidence and severity of any side effects;
- potential or perceived advantages or disadvantages as compared to alternative treatments;
- strength of sales, marketing and distribution support;
- price of our future products, both in absolute terms and relative to alternative treatments;
- the general marketplace for the particular drug;
- the effect of current and future healthcare laws on our drug candidates;
- availability of coverage and adequate reimbursement from government and other third-party payers; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

If our approved drugs fail to achieve market acceptance, we may not be able to generate significant revenues to be profitable.

Drug development programs are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. In addition, the FDA or other regulatory authority may require us to, or we or others may decide to, conduct additional research and development of any of our approved drugs. Clinical trials and preclinical studies are needed to demonstrate that drug

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candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials and studies are expensive and uncertain processes that may take years to complete. Failure can occur at any stage of the process, and successful early preclinical studies or clinical trials do not ensure that later studies or trials will be successful. In addition, the commencement or completion of our planned preclinical studies or clinical trials could be substantially delayed or prevented by several factors, including the following:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials or animals to conduct our preclinical studies;
- limited number of, and competition for, suitable sites to conduct our clinical trials or preclinical studies;
- delay or failure to obtain approval or agreement from the applicable regulatory authority to commence a clinical trial or approval of a study protocol;
- delay or failure to obtain sufficient supplies of drug candidates, drugs or other materials for the trial or study;
- delay or failure to reach agreement on acceptable agreement terms or protocols; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by collaborators, may take significantly longer and cost more than expected to complete. In addition, the FDA, other regulatory authorities, collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or “clinical holds,” or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials or preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data;
- lack of sufficient funding to continue clinical trials or preclinical studies; or
- changes in business priorities or perceptions of the value of the program.

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There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We have experienced setbacks in our internal and partnered development programs and expect to experience additional setbacks from time to time in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or be profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms we or others believe are favorable, and our stock price may decrease significantly.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates or any approved drugs may not be further developed or have favorable results in later studies or trials.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. Favorable results in early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates or drugs in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated; a program to be abandoned; or negatively impact a related marketed drug.

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with sufficient therapeutic potential, and any of our preclinical compounds may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations or that we will further develop a drug candidate at any stage of development. Even if favorable results are obtained from preclinical studies or trials, our financial resources may not allow us to advance a compound or drug candidate. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate additional revenues.

*Drug discovery and development is intensely competitive in the therapeutic areas on which we focus. If our competitors increase or they develop treatments that are approved faster, marketed better, less expensive or demonstrated to be more effective or safer than our drugs or drug candidates, our commercial opportunities will be reduced or eliminated.

Many of the drugs we or our collaborators are attempting or may attempt to discover and develop may compete with existing therapies in the United States and other territories. In addition, many companies are pursuing the development of new drugs that target the same diseases and conditions that we target.

For example, with regard to BELVIQ's competition, VIVUS, Inc., Orexigen Therapeutics, Inc., and Novo Nordisk have weight-loss drugs being marketed in the United States, and Orexigen has filed for regulatory approval of its drug candidate in South Korea. We also face competition from other drugs that may be indicated or used off label or otherwise for weight loss and from other approaches for weight loss, including behavior modification (such as diet and exercise), surgical approaches (such as gastric bypass surgery and gastric banding), and herbal or other supplements. With respect to future weight-loss treatments, we expect that companies and others may allocate resources to discover and develop additional drugs, additional drug candidates may be approved and competition may increase.

Our competitors, particularly large pharmaceutical companies, may have substantially greater research, development and marketing capabilities and greater financial, scientific and human resources than we do. Companies that complete

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

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

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

We may have conflicts with our prospective, current or past collaborators, such as conflicts concerning rights and obligations under our agreements, the interpretation of preclinical or clinical data, the achievement of milestone or other payments, the ownership of intellectual property, or research and development, regulatory, commercialization or other strategy. Collaborators may stop supporting our drug candidates or drugs, including if they no longer view the program as in their best financial or other interests or they develop or obtain rights to competing drug candidates or drugs. In addition, collaborators may fail to effectively develop, obtain approval for or commercialize our drugs, which may result in us not realizing their full commercial potential. If any conflicts arise with any of our current, past or prospective collaborators, the other party may act in a manner that is adverse to our interests. Any such disagreement could result in one or more of the following, each of which could delay, or lead to termination of, development or commercialization of our drug candidates or drugs, and in turn prevent us from generating revenues:

- unwillingness on the part of a collaborator to pay for studies or other research, milestones, royalties or other payments that we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development, regulatory, commercialization, pharmacovigilance or other activities or to permit public disclosure of the results of those activities;
- slowing or cessation of a collaborator's research, development, regulatory or commercialization efforts with respect to our drug candidates or drugs; or
- litigation or arbitration.

*We have obtained orphan drug designation from the FDA for ralinepag for the treatment of pulmonary arterial hypertension, or PAH, but we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a drug that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the drug is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the drug with orphan drug exclusivity or where the manufacturer is unable to assure sufficient drug quantity.

Even though ralinepag has been granted orphan drug status for the treatment of PAH, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Setbacks and consolidation in the pharmaceutical and biotechnology industries could make entering into agreements with pharmaceutical companies to collaborate or commercialize our drugs more difficult and diminish our revenues. Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to drugs or drug candidates, as well as competition from generic drugs, litigation and industry consolidation, may have an adverse effect on

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us, including by making it more difficult to enter into agreements with pharmaceutical companies to collaborate or commercialize our drugs and diminishing our revenues. For example, the FDA may be more cautious in approving our drug candidates based on safety concerns relating to these or other drugs or drug candidates, or pharmaceutical companies may be less willing to enter into new collaborations or continue existing collaborations if they are integrating a new operation as a result of a merger or acquisition or if their therapeutic areas of focus change following a merger.

We and our collaborators may from time to time rely on third parties to conduct clinical trials and preclinical studies. If those parties do not comply with regulatory and contractual requirements, successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a ti