ARENA PHARMACEUTICALS INC
Form 10-Q
May 09, 2016
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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 March 31, 2016
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 000-31161

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. 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 May 5, 2016:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	243,044,672

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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").

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements.

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

	March 31, 2016 (Unaudited)	December 31, 2015[1]
Assets		
Current assets:		
Cash and cash equivalents	$ 139,533	$ 156,184
Accounts receivable	6,166	4,934
Inventory	9,054	9,502
Prepaid expenses and other current assets	5,362	4,218
Total current assets	160,115	174,838
Land, property and equipment, net	71,003	71,828
Intangibles, net	7,945	7,775
Other non-current assets	2,301	2,351
Total assets	$ 241,364	$ 256,792
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 8,190	$ 10,127
Accrued clinical and preclinical study fees	3,349	3,286
Payable to Eisai	13,583	12,080
Current portion of deferred revenues	22,243	21,425
Current portion of lease financing obligations	3,108	2,978
Total current liabilities	50,473	49,896
Deferred rent	494	470
Deferred revenues, less current portion	88,389	87,617
Lease financing obligations, less current portion	64,450	65,267
Commitments and contingencies		
Stockholders' equity:		
Common stock	24	24
Additional paid-in capital	1,433,890	1,430,917
Accumulated other comprehensive income (loss)	1,412	(1,179)
Accumulated deficit	(1,397,768)	(1,376,220)
Total stockholders' equity	37,558	53,542
Total liabilities and stockholders' equity	$ 241,364	$ 256,792

[1] The balance sheet data at December 31, 2015, 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 March 31,	
	2016	2015
Revenues:		
Net product sales	$3,518	$6,618
Other Eisai collaborative revenue	3,226	2,136
Toll manufacturing	1,023	346
Other collaborative revenue	2,080	3,156
Total revenues	9,847	12,256
Operating Costs and Expenses:		
Cost of product sales	2,428	3,191
Cost of toll manufacturing	1,188	402
Research and development	18,502	21,968
General and administrative	6,924	8,439
Total operating costs and expenses	29,042	34,000
Loss from operations	(19,195)	(21,744)
Interest and Other Income (Expense):		
Interest income	88	34
Interest expense	(1,679)	(1,696)
Loss from valuation of derivative liabilities	0	(1,549)
Other	(762)	660
Total interest and other expense, net	(2,353)	(2,551)
Net loss	$(21,548)	$(24,295)
Net loss per share:		
Basic	$(0.09)	$(0.10)
Diluted	$(0.09)	$(0.10)
Shares used in calculating net loss per share:		
Basic	242,876	235,703
Diluted	242,876	235,703
Comprehensive Loss:		
Net loss	$(21,548)	$(24,295)
Foreign currency translation gain (loss)	2,591	(145)
Comprehensive loss	$(18,957)	$(24,440)

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)

	Three months ended March 31,	
	2016	2015
Operating Activities		
Net loss	$(21,548)	$(24,295)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,356	2,425
Amortization of intangibles	67	27
Share-based compensation	2,809	3,833
Loss from valuation of derivative liabilities	0	1,549
Amortization of prepaid financing costs	34	34
Gain on sale of equipment	(135)	0
Changes in assets and liabilities:		
Accounts receivable	(1,067)	(8,612)
Inventory	973	(197)
Prepaid expenses and other assets	(1,112)	257
Payables and accrued liabilities	(966)	(6,711)
Deferred revenues	986	8,644
Deferred rent	24	29
Net cash used in operating activities	(17,579)	(23,017)
Investing Activities		
Purchases of property and equipment	(247)	(1,069)
Proceeds from sale of property and equipment	135	0
Net cash used in investing activities	(112)	(1,069)
Financing Activities		
Principal payments on lease financing obligations	(687)	(570)
Proceeds from issuance of common stock	127	101,979
Net cash provided by (used in) financing activities	(560)	101,409
Effect of exchange rate changes on cash	1,600	449
Net increase (decrease) in cash and cash equivalents	(16,651)	77,772
Cash and cash equivalents at beginning of period	156,184	163,209
Cash and cash equivalents at end of period	$139,533	$240,981

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, 2015, as filed with the Securities and Exchange Commission, or SEC, from which we derived our balance sheet as of December 31, 2015. The accompanying financial statements have been prepared in accordance with US generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, “Revenue from Contracts with Customers.” ASU No. 2014-09 outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. ASU No. 2014-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 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.

In January 2016, the FASB issued ASU No. 2016-01, “Recognition and Measurement of Financial Assets and Financial Liabilities.” ASU No. 2016-01 supersedes and amends the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. ASU No. 2016-01 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2017, and calls for prospective application, with early application permitted. We do not expect the adoption of ASU No. 2016-01 to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, “Leases.” ASU No. 2016-02 amends the accounting guidance for leases. The amendments contain principles that will require lessees to recognize most leases on the balance sheet by recording a right-of-use asset and a lease liability, unless the lease is a short-term lease that has an accounting lease term of twelve months or less. The amendments also contain other changes to the current lease guidance that may

result in changes to how entities determine which contractual arrangements qualify as a lease, the accounting for executory costs such as property taxes and insurance, as well as which lease origination costs will be capitalizable. The new standard also requires expanded quantitative and qualitative disclosures. ASU No. 2016-02 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2018, with early adoption permitted. ASU No. 2016-02 requires the use of the modified retrospective transition method, whereby the new guidance will be applied at the beginning of the earliest period presented in the financial statements of the period of adoption. We are currently evaluating the impact of ASU No. 2016-02 on our consolidated financial statements.

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In March 2016, the FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting.” ASU No. 2016-09 is designed to simplify several aspects of accounting for share-based payment award transactions, including income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. ASU No. 2016-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016, with early adoption permitted. We are currently evaluating the impact of ASU No. 2016-09 on our consolidated financial statements.

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

2. Fair Value Disclosures

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

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

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

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

Level 3 - Significant unobservable inputs based on our assumptions.

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 March 31, 2016			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds[1]	$98,168	$ 98,168	$ 0	$ 0

	Fair Value Measurements at December 31, 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]	$113,080	$ 113,080	$ 0	$ 0

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

3. Inventory

Inventory consisted of the following, in thousands:

	March 31, 2016	December 31, 2015
Raw materials	$ 2,724	$ 2,487
Work in process	2,977	2,781
Finished goods at Arena GmbH	0	165
Finished goods at Eisai	2,720	3,309
Finished goods at Ildong	633	760

Total inventory	$ 9,054	$ 9,502

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4. Land, Property and Equipment

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

	March 31, 2016	December 31, 2015
Cost	$172,002	$172,729
Less accumulated depreciation and amortization	(100,999)	(100,901)
Land, property and equipment, net	$71,003	$71,828

5. Accounts Payable and Other Accrued Liabilities

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

	March 31, 2016	December 31, 2015
Accounts payable	$1,891	$ 2,078
Accrued compensation	5,177	5,118
Accrued workforce reduction expenses	78	1,793
Other accrued liabilities	1,044	1,138
Total accounts payable and other accrued liabilities	$8,190	$ 10,127

6. 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 and marketed as BELVIQ 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.

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

	Three months ended March 31,	
	2016	2015
Net product sales	$2,459	$4,436
Amortization of upfront payments	1,885	1,885
Reimbursement of development expenses	1,231	191
Reimbursement of patent and trademark expenses	110	60
Subtotal other Eisai collaborative revenue	3,226	2,136
Total	$5,685	$6,572

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

	March 31, 2016	December 31, 2015
Upfront payments	$85,048	$86,933
Net product sales	7,426	10,754
Total deferred revenues attributable to Eisai	92,474	97,687
Less current portion	(14,967)	(18,295)
Deferred revenues attributable to Eisai, less current portion	$77,507	$79,392

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 for a purchase price starting at 31.5% 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. Subject to regulatory approval, the Eisai Product Purchase Price starts at 27.5% and 30.75% of Eisai's annual aggregate net product sales in (i) Europe, China and Japan, and (ii) the other territories under the Eisai Agreement, respectively. The Eisai Product Purchase Price will increase on a tiered basis with increasing sales, and is subject to reduction (for sales in a particular territory), including in the event of generic competition in the applicable territory. The revenue we recognize for BELVIQ product revenue related to the redemption 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. 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, among other information provided to us, the most current Eisai Product Purchase Price, 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 estimated price that Eisai 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 primarily comprises the $13.6 million classified as Payable to Eisai on our condensed consolidated balance sheet at March 31, 2016, related to product sold by Eisai to their distributors through March 31.

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Development Payments.

In connection with the US approval of BELVIQ, the US Food and Drug Administration, or FDA, is requiring (i) an evaluation as part of the cardiovascular outcomes trial, or CVOT, of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors and (ii) the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric 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, which we refer to as BELVIQ XR, and the FDA has accepted for filing our submission for the marketing approval of BELVIQ XR. Eisai and we have also prioritized potentially exploring, including as part of the CVOT, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

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

Cost Sharing for Development with Eisai

	United States	Rest of North and South America	Remaining Territories
BELVIQ - Pre-approval*	Not Applicable	General Eisai: 90%; Arena: 10% Certain stability work Eisai: 50%; Arena: 50%	Up to a total of $100.0 million** - Eisai: 50%; Arena: 50% Thereafter, Eisai: 100%
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 a total of $50.0 million - Eisai: 50%; Arena: 50% Thereafter, Eisai: 90%; Arena: 10%
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% Eisai: 90%; Arena: 10%		Therea

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

** Under the collaborative agreement, the amount for BELVIQ pre-approval in the Remaining Territories was decreased and the amount for lorcaserin products other than BELVIQ pre-approval was increased by such amount.

Certain Other Terms.

Please refer to our Annual Report on Form 10-K for the year ended December 31, 2015, for additional information regarding termination, indemnification, product liability, certain limitations and other provisions included in the Eisai Agreement.

7. 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 manufacture and sell BELVIQ to Ildong. Ildong has agreed not to conduct activities outside of our agreement related to the

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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.

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 increases 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 months ended March 31, 2016, 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 this period). 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 $1.1 million and $2.2 million for the three months ended March 31, 2016, and 2015, respectively.

8. Share-based Activity

Share-based Compensation.

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

	Three months ended March 31,	
	2016	2015
Cost of product sales	$20	$0
Research and development	1,763	2,056
General and administrative	1,026	1,777
Total share-based compensation expense	$2,809	$3,833
Total share-based compensation expense capitalized into inventory	$37	$62

Share-based Award Activity.

The following table summarizes our stock option activity during the three months ended March 31, 2016, in thousands (except per share data):

	Options	Weighted-Average Exercise Price
Outstanding at January 1, 2016	16,407	$ 5.01
Granted	8,786	1.55
Exercised	(26)	1.52
Forfeited/cancelled/expired	(373)	12.63
Outstanding at March 31, 2016	24,794	$ 3.64

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The following table summarizes activity with respect to our time-based restricted stock unit awards, or RSUs, during the three months ended March 31, 2016, in thousands (except per share data):

	RSUs	Weighted-Average Grant-Date Fair Value
Unvested at January 1, 2016	273	$ 4.67
Granted	0	
Vested	(70)	4.11
Forfeited/cancelled	0	
Unvested at March 31, 2016	203	$ 4.87

During the three months ended March 31, 2016, the remaining Total Stockholder Return, or TSR, performance restricted stock unit, or PRSU, awards that we had granted to our executive officers in March 2013 were forfeited without any earnout based on the TSR of our common stock relative to the TSR of the NASDAQ Biotechnology Index over the three-year performance period that began on March 1, 2013. In the aggregate, the target number of shares of common stock that could have been earned under the PRSUs granted in March 2013 was 780,000. Except for those cancelled due to employment separation from Arena, the PRSU awards issued in March 2014 and March 2015 are still outstanding at March 31, 2016.

9. 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, and, to a lesser extent, another third party under toll manufacturing agreements.

In May 2015, Arena GmbH and Roivant Sciences, Ltd., or Roivant, entered into a Development, Marketing and Supply Agreement, or Axovant Agreement, under which Arena GmbH granted Roivant exclusive worldwide rights to develop and commercialize nelotanserin, subject to regulatory approval. In October 2015, Roivant assigned the Axovant Agreement to its subsidiary, Axovant Sciences Ltd., or Axovant. We also provide certain services and will manufacture and sell nelotanserin to Axovant.

In December 2015, we and Boehringer Ingelheim GmbH, or Boehringer Ingelheim, entered into an exclusive agreement, or Boehringer Ingelheim Agreement, to conduct joint research to identify drug candidates targeting an undisclosed GPCR that belongs to the group of orphan central nervous system, or CNS, receptors.

Percentages of our total revenues are as follows:

	Three months ended March 31,	
	2016	2015
Eisai Agreement (See Note 6)	57.7 %	53.6 %
Boehringer Ingelheim Agreement	13.6 %	0.0 %
Ildong Agreement (See Note 7)	11.6 %	43.0 %
Toll manufacturing agreements	10.4 %	2.8 %
Axovant Agreement	6.0 %	0.0 %
Other collaborative agreements	0.7 %	0.6 %
Total percentage of revenues	100.0%	100.0%

10. Net Loss Per Share

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

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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.

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 March 31,	
	2016	2015
Stock options	19,091	15,949
RSUs and unvested restricted stock	314	512
Warrant	0	131
Total	19,405	16,592

Because the market conditions for the PRSUs were not satisfied at March 31, 2016, and March 31, 2015, such securities are excluded from the table above.

11. Legal Proceedings

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints 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. A panel of the US Court of Appeals for the Ninth Circuit heard oral argument on the appeal on May 4, 2016. 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.

12. Restructuring Charges

In October 2015, we committed to a reduction in our US workforce of approximately 35%, or a total of approximately 80 employees, which we substantially completed by December 31, 2015. In November 2015, we committed to a reduction in our Swiss workforce of approximately 17%, or a total of approximately 14 employees, which we plan to substantially complete by the end of the second quarter of 2016. As a result of these workforce reductions, we recorded a restructuring charge in the fourth quarter of 2015 for termination benefits of $4.0 million. At March 31, 2016, $3.9 million of this charge has been paid, resulting in a remaining accrual of $0.1 million.

13. Subsequent Events

On May 6, 2016, our Board of Directors appointed Amit D. Munshi as our President, Chief Executive Officer and interim principal financial officer, effective May 11, 2016. Mr. Munshi will also join our Board of Directors following our 2016 Annual Stockholders' Meeting. Harry F. Hixson, Jr., Ph.D., who has served as our interim Chief Executive Officer and interim principal financial officer since October 2015 and as a director since 2004, will remain on our Board of Directors.

In connection with such appointment, our Board of Directors' Compensation Committee approved an inducement stock option grant to Mr. Munshi to purchase 3,800,000 shares of our common stock under our 2013 Long-Term Incentive Plan, as amended on May 6, 2016, to reserve an additional 3,800,000 shares of common stock. The nonstatutory stock options will have

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a seven-year term and will vest over four years, with 25% of the shares subject to vesting one year after grant and the remainder of the shares vesting quarterly over the following three years in equal installments, subject to his continued service through the applicable vesting dates and possible acceleration in specified circumstances.

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, 2015, or 2015 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.

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 one approved drug, lorcaserin (which is marketed for weight management under the brand name "BELVIQ"), 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.

On May 6, 2016, our Board of Directors appointed Amit D. Munshi as our President, Chief Executive Officer and interim principal financial officer, effective May 11, 2016. Mr. Munshi will also join our Board of Directors following our 2016 Annual Stockholders' Meeting. Harry F. Hixson, Jr., Ph.D., who has served as our interim Chief Executive Officer and interim principal financial officer since October 2015 and as a director since 2004, will remain on our Board of Directors.

We are currently focusing our activities and resources primarily on the following activities:

- Advancing our proprietary clinical programs:
  - APD334 - a modulator of the sphingosine 1-phosphate subtype 1, or $S1P_1$, receptor - including our ongoing Phase 2 clinical trial for ulcerative colitis, and potentially exploring additional indications beyond inflammatory bowel disease
  - Ralinepag - an agonist of the prostacyclin receptor - including our ongoing Phase 2 clinical trial for pulmonary arterial hypertension, or PAH
  - APD371 - an agonist of the cannabinoid-2, or CB_2, receptor - which recently completed a Phase 1 multiple-ascending dose clinical trial with favorable results
- Pursuing strategic collaborations for certain clinical and pre-clinical programs
- Discovering and developing additional pre-clinical drug candidates

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- Supporting Eisai Inc. and Eisai Co., Ltd. (collectively, Eisai) and our other collaborators in their efforts with respect to BELVIQ, including their work 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)
  - Obtain regulatory approval (initially in the United States) for a once-daily formulation of BELVIQ, which we refer to as BELVIQ XR
  - Obtain regulatory approval in additional territories for BELVIQ and BELVIQ XR
- Collaborating with Axovant Sciences Ltd., or Axovant, in advancing nelotanserin, an orally available inverse agonist of the serotonin 2A receptor, which is in (i) a Phase 2 clinical trial in Lewy body dementia patients who experience frequent visual hallucinations, and (ii) a separate Phase 2 clinical trial to evaluate nelotanserin as a potential treatment for REM behavior disorder in patients with dementia with Lewy bodies
- Conducting joint research with Boehringer Ingelheim International GmbH, or Boehringer Ingelheim, under our collaboration to identify and advance drug candidates targeting a GPCR that belongs to the group of orphan central nervous system, or CNS, receptors

In general, developing drugs and obtaining marketing approval is a long, uncertain and expensive process, and our ability to execute on our plans and achieve our goals 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, support Eisai and our other collaborators in their efforts with respect to BELVIQ, continue our research efforts to discover and develop additional drug candidates, and manufacture BELVIQ for commercial sale and studies.

We expect our cash used in operations will be slightly lower in 2016 as compared to 2015 due to cost savings from the workforce reductions we effected at the end of 2015 and by continuing to implement cost control measures. However, 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 financings. 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 prioritization decisions, 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 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 March 31,	
Source of revenue	2016	2015
Arena's portion of Eisai net product sales	$2.5	$4.4
Amortization of upfront payments from Eisai	1.9	1.9
Collaborative agreement with Boehringer Ingelheim	1.3	0.0
Reimbursement of development expenses and patent and trademark expenses from Eisai	1.3	0.3
Arena's portion of Ildong net product sales	1.1	2.2
Toll manufacturing agreements	1.0	0.3
Other collaborative agreements	0.6	0.1
Amortization of upfront payment from Ildong	0.1	0.1
Milestone payment from Ildong	0.0	3.0
Total revenues	$9.8	$12.3

Research and development expenses

	Three months ended March 31,	
Type of expense	2016	2015
External clinical and preclinical study fees and internal non-commercial manufacturing costs	$8.4	$7.5
Salary and other personnel costs (excluding non-cash share-based compensation)	4.9	7.8
Facility and equipment costs	2.4	2.3
Non-cash share-based compensation	1.8	2.1
Research supply costs	0.8	1.9
Other	0.2	0.4
Total research and development expenses	$18.5	$22.0

General and administrative expenses

	Three months ended March 31,	
Type of expense	2016	2015
Salary and other personnel costs (excluding non-cash share-based compensation)	$2.9	$3.3
Legal, accounting and other professional fees	1.7	1.4
Non-cash share-based compensation	1.0	1.8
Facility and equipment costs	1.0	1.2
Other	0.3	0.7
Total general and administrative expenses	$6.9	$8.4

THREE MONTHS ENDED MARCH 31, 2016, AND 2015

Revenues. We recognized revenues of $9.8 million for the three months ended March 31, 2016, compared to $12.3 million for the three months ended March 31, 2015. This decrease was primarily due to a decrease of $3.1 million in our portion of net product sales of BELVIQ and the $3.0 million milestone payment from Ildong that we earned in

February 2015 for the approval of BELVIQ in South Korea, while no milestone payments were earned in the three months ended March 31, 2016. This decrease was partially offset by (i) $1.3 million earned in the three months ended March 31, 2016, under our collaborative agreement with Boehringer Ingelheim, or Boehringer Ingelheim Agreement, which commenced in December 2015, (ii) an increase of $1.0 million in reimbursements of development expenses and patent and trademark expenses from Eisai, (iii) an increase of $0.7 million in toll manufacturing revenue and (iv) $0.6 million earned in the three months ended

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March 31, 2016, under our collaborative agreement with Axovant that commenced in May 2015. The decrease in our portion of net product sales of BELVIQ was due to a decrease in the number of tablets sold in the United States and South Korea and a lower net sales price per tablet in the United States. The lower net sales price per tablet in the United States is primarily related to Eisai's January 2015 launch of a new savings card. The increase in toll manufacturing revenue was primarily due an increase in the volume of toll manufacturing performed.

When collaborators pay us before revenues are earned, we record such payments as deferred revenues. At March 31, 2016, we had a total of $110.6 million in deferred revenues. Of such amount, $85.0 million is attributable to upfront payments we received under our collaboration with Eisai, $9.7 million is attributable to product supply of BELVIQ and the remaining amount is primarily attributable to the upfront payments we received under our other collaborative agreements.

Absent any new collaborations, we expect that our 2016 revenues will primarily consist of (i) net product sales of BELVIQ, (ii) amortization of the upfront payments we have received from our collaborators, (iii) toll manufacturing, (iv) milestone payments from our collaborators and (v) reimbursements from collaborators for development expenses, patent and trademark expenses and research funding.

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 for us 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 savings cards or, to a lesser extent, vouchers.

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, among other things, whether and when BELVIQ receives regulatory approval and is commercialized in new territories, reimbursement coverage for BELVIQ, marketing efforts, and the results of the CVOT.

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 $2.4 million for the three months ended March 31, 2016, and $3.2 million for the three months ended March 31, 2015.

Cost of toll manufacturing. Cost of toll manufacturing consists of direct and indirect costs associated with manufacturing drug products, primarily for Siegfried AG, or Siegfried, under toll manufacturing agreements, including related salaries, other personnel costs, machinery depreciation costs, amortization expense related to our manufacturing facility production licenses, and material costs. Cost of toll manufacturing increased by $0.8 million to $1.2 million for the three months ended March 31, 2016, from $0.4 million for the three months ended March 31, 2015, primarily due to the increased volume of toll manufacturing performed for Siegfried, and to a lesser extent from a toll manufacturing agreement that we entered into in April 2015 with a third party. We 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 $3.5 million to $18.5 million for the three months ended March 31, 2016, from $22.0 million for the three months ended March 31, 2015. This decrease was primarily due to decreases of $2.9

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million in salary and other personnel costs and $1.1 million in research supply costs, primarily due to the recent reduction in the number of our employees. This decrease was partially offset by an increase of $0.9 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs. We expect to incur substantial research and development expenses in 2016, and for the aggregate amount in 2016 to be higher than in 2015. We expect our external clinical costs will be higher in 2016 than in 2015 due to our continuing Phase 2 clinical trials for APD334 and ralinepag, which is partially offset by internal research and development expenses that are expected to be lower primarily due to the recent reduction in the number of our employees. Our actual external and internal expenses may be higher or lower than anticipated due to various factors, including our focus, progress and results. For example, patient enrollment in our Phase 2 clinical trials for APD334 and ralinepag is competitive and challenging and has taken longer than initially projected. This has resulted in our related external expenses being lower at this point than anticipated, and may increase our long-term expenses for these trials.

Included in the $8.4 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 March 31, 2016, were the following:

- $4.0 million related to lorcaserin and non-commercial manufacturing costs,
- $2.8 million related to APD334 and
- $0.9 million related to ralinepag.

Included in the $7.5 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 March 31, 2015, were the following:

- $4.3 million related to lorcaserin and non-commercial manufacturing costs,
- $1.8 million related to ralinepag and
- $0.7 million related to APD334.

General and administrative expenses. General and administrative expenses decreased by $1.5 million to $6.9 million for the three months ended March 31, 2016, from $8.4 million for the three months ended March 31, 2015. This decrease was primarily due decreases of $0.8 million in non-cash share-based compensation expense and $0.4 million in salary and other personnel costs, primarily due to the recent reduction in the number of our employees. We expect that our 2016 general and administrative expenses will be lower than in 2015, primarily due to the recent workforce reductions and other cost control initiatives.

Interest and other expense, net. Interest and other expense, net, decreased by $0.2 million to $2.4 million for the three months ended March 31, 2016, from $2.6 million for the three months ended March 31, 2015, primarily due to (i) a $1.5 million loss from revaluation of our derivative liabilities related to our previously outstanding warrant for the three months ended March 31, 2015, with no revaluation recorded in the three months ended March 31, 2016, as the warrant expired in August 2015 according to its terms, (ii) a $0.1 million gain on sale of equipment for the three months ended March 31, 2016, and (iii) an increase of $0.1 million in interest income. This decrease was partially offset by $1.0 million in foreign currency transaction losses, net for the three months ended March 31, 2016, compared to $0.6 million in foreign currency transaction gains, net for the three months ended March 31, 2015.

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 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 March 31, 2016, we had $139.5 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

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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) sale of equity, issuance of debt or other transactions.

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, Ildong is 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 lorcaserin will be approved for marketing in any of such territories or with respect to filing any additional applications. 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 for a purchase price that increases with increasing sales. We are also eligible to receive regulatory and development milestone payments and purchase price adjustment payments. In the short term, we do not expect to receive the majority (or potentially any) of the milestone payments or purchase price adjustment payments, the amount of BELVIQ sales to increase significantly or the purchase price percentages to increase beyond the starting percentage in any territory.

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 purchase price, and is subject to change on April 1 and October 1 of each year. The estimated purchase price paid to us for product that Eisai sold to their distributors is compared to the actual purchase price of such product, and the difference is either refunded back to Eisai (for overpayments) or paid to us (for underpayments). The actual purchase price for BELVIQ that Eisai has sold has generally been lower than the estimated purchase price that Eisai has paid us for such product. Subsequent to the end of Eisai's fiscal year that ends March 31, we refund to Eisai the portion of these excess payments related to sales made during such fiscal year. As of March 31, 2016, our accrued payable to Eisai is $13.6 million, a majority of which we expect to pay in the quarter ended June 30, 2016.

We also manufacture BELVIQ and sell the drug product to Ildong for Ildong's commercialization for a purchase price that increases with increasing sales. For the three months ended March 31, 2016, the purchase price to Ildong equaled the required minimum, which exceeded the amounts calculated using the applicable percentages for the applicable tiers of Ildong's annual net product sales. In the short term, we do not expect the purchase price to increase beyond the required minimum.

As part of the US approval of BELVIQ, the US Food and Drug Administration, or FDA, is requiring the evaluation of the effect of long-term treatment with BELVIQ on the incidence of 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, Eisai and we are responsible for 90% and 10%, respectively, of the cost for the FDA-required portion of the CVOT. The FDA-required portion of the CVOT is expected to continue during the next couple of years, and the remaining amount of our share of the cost for this portion is estimated to be approximately $14.0 million. This cost will be incurred over the remaining time that the FDA-required portion of the CVOT is conducted, and the actual amount of the cost will depend on how long it takes to complete this portion of the CVOT and other factors. As part of CAMELLIA and as described further below in "long term," we also expect to evaluate BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes. We are also obligated to share the cost of two remaining FDA-required studies in obese pediatric patients and for additional clinical studies in other territories.

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, CY Biotech Company Limited, or CYB, and Teva Pharmaceutical Industries Ltd.'s local Israeli subsidiary, Abic Marketing Limited, or 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.

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 to incur substantial research and development expenses in 2016, and for the aggregate amount in 2016 to be higher than in 2015. We expect our external clinical costs will be higher in 2016 than in 2015 due to our continuing Phase 2 clinical trials for APD334 and ralinepag, which is partially offset by internal research and development expenses that are expected to be lower primarily due to the recent reduction in the number of our employees. We may not have sufficient cash to

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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 or if we change our focus, we may determine 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 expect to incur additional expenses, which may be significant regardless of whether we share the expenses with Eisai. For example, Eisai and we will share equally the expenses for the portion of CAMELLIA not required by the FDA for up to an aggregate of $40.0 million each, and Eisai will be responsible for 100% of such expenses thereafter. We do not expect to incur the majority of the expenses for such portion of CAMELLIA in the short term, if ever.

Subject to applicable regulatory approval, we expect Eisai to commercialize lorcaserin in additional territories under the Eisai Agreement. Under our Teva collaboration, we are eligible to receive payments upon regulatory approval of BELVIQ for weight loss or weight management. Under our Teva and CYB collaborations, we are eligible to receive payments from net product sales of BELVIQ as well as additional milestone payments and/or purchase price adjustment payments.

In addition to potential payments from our 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.

We evaluate from time to time potential acquisitions, 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 $5.4 million to $17.6 million in the three months ended March 31, 2016, compared to $23.0 million in the three months ended March 31, 2015. This decrease was primarily the result of (i) the $7.5 million payment we received from Boehringer Ingelheim, less $1.2 million of withholding taxes (which are refundable to us), in February 2016 upon entering into the Boehringer Ingelheim Agreement, while we did not receive any similar upfront payment in the three months ended March 31, 2015, (ii) reduced cash expenditures for personnel and research supply costs resulting from the workforce reductions we effected at the end of 2015 and (iii) a decrease of $1.2 million in payments made for external clinical and preclinical study fees. These decreases in net cash used in operations were partially offset by (i) the $3.0 million milestone payment we received from Ildong, less withholding taxes, in March 2015 for the marketing approval of BELVIQ in South Korea, while we did not receive any similar milestone payment in the three months ended March 31, 2016, and (ii) net payments of $2.3 million we

received for shipments of BELVIQ to Eisai and Ildong in the three months ended March 31, 2016, compared to $5.0 million in the three months ended March 31, 2015.

Net cash used in investing activities decreased by $1.0 million to $0.1 million in the three months ended March 31, 2016, compared to $1.1 million in the three months ended March 31, 2015. This decrease was primarily due to $0.2 million in purchases of property and equipment in the three months ended March 31, 2016, compared to $1.1 million in the three months

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ended March 31, 2015. We expect that our capital expenditures will be lower in 2016 compared to 2015 primarily due to the payment in July 2015 of CHF 8.2 million for our acquisition of additional space in our Swiss manufacturing facility.

Net cash of $0.6 million was used in financing activities in the three months ended March 31, 2016, as a result of payments of $0.7 million on our lease financing obligations, which were partially offset by net proceeds of $0.1 million from stock option exercises and purchases under our employee stock purchase plan. Net cash of $101.4 million was provided by financing activities in the three months ended March 31, 2015, as a result of net proceeds of $100.7 million from our January 2015 offering of 21,000,000 shares of common stock and net proceeds of $1.3 million from stock option exercises and purchases under our employee stock purchase plan, which were partially offset by payments of $0.6 million 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, 2015, and there have been no material changes during the three months ended March 31, 2016.

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, 2015.

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 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. A panel of the US Court of Appeals for the Ninth Circuit heard oral argument on the appeal on May 4, 2016. 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 BELVIQ, lorcaserin or the investigational once-daily formulation of BELVIQ (currently known as BELVIQ XR) also apply to the others.

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, 2015, as filed with the Securities and Exchange Commission, or SEC.

Risks Relating to Our Business

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; 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 substantially 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. While we intend to advance compounds in our pipeline, we may not have adequate funds to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a drug candidate or preclinical compound into a marketed drug, and our efforts may not result in any additional marketed drugs.

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We cannot assure you that any additional amounts paid to us for BELVIQ or any of our other drug candidates or programs 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.

Around the end of 2015, we committed to a workforce reduction, and we plan to continue implementing cost control measures 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.

We may seek to obtain additional funding from the capital markets or otherwise 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.

We believe that our revenues for at least the short term are substantially 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, is being marketed for weight management by our collaborators in United States and South Korea under the brand name BELVIQ. We believe our revenues for at least the short term are substantially 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 and 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., Ltd. (collectively, 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;
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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);

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- 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.

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 have filed a regulatory submission with the US Food and Drug Administration, or FDA, for the approval 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 with respect to BELVIQ or lorcaserin 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

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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, the ACA, 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.

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

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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 Pharmaceutical Co., Ltd., or 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 for several more 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 development, 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.

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 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 Marketing Authorization Application, or 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

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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 anal