ARENA PHARMACEUTICALS INC
Form 10-Q
November 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 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. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	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 No

The number of shares of common stock outstanding as of the close of business on November 4, 2016:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	243,313,807

ARENA PHARMACEUTICALS, INC.

INDEX

TRADEMARKS AND CERTAIN TERMS

Arena Pharmaceuticals®, Arena® and our corporate logo are registered service marks of Arena. BELVIQ®, BELVIQ XR®, and VENESPRI® 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," "the Company," "we," "us" and "our" refer to Arena Pharmaceuticals, Inc., and our wholly owned subsidiaries on a consolidated basis, unless the context otherwise provides. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Lorcaserin has been approved in the United States, South Korea and Mexico for weight management in a twice-a-day dosage formulation. The twice-a-day dosage formulation is being commercialized in the United States and South Korea under the brand name BELVIQ, and is expected to be commercialized in Mexico under the brand name VENESPRI. Lorcaserin has also recently been approved in the United States in a once-a-day dosage formulation, which is BELVIQ XR. In this document, "BELVIQ" refers to each of the formulations of lorcaserin approved for weight management, unless the context otherwise indicates.

i

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands)

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 101,629	$ 156,184
Accounts receivable	18,304	4,934
Inventory	10,166	9,502
Prepaid expenses and other current assets	4,768	4,218
Total current assets	134,867	174,838
Land, property and equipment, net	64,980	71,828
Intangibles, net	7,518	7,775
Other non-current assets	2,883	2,351
Total assets	$ 210,248	$ 256,792
Liabilities and Equity		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 14,767	$ 8,334
Accrued clinical and preclinical study fees	6,532	3,286
Payable to Eisai	12,065	12,080
Accrued restructuring charges	1,244	1,793
Current portion of deferred revenues	22,522	21,425
Current portion of lease financing obligations	3,378	2,978
Total current liabilities	60,508	49,896
Other long-term liabilities	853	470
Deferred revenues, less current portion	82,132	87,617
Lease financing obligations, less current portion	62,678	65,267
Commitments and contingencies		
Equity:		
Common stock	24	24
Additional paid-in capital	1,439,745	1,430,917
Accumulated other comprehensive income (loss)	867	(1,179)
Accumulated deficit	(1,437,308)	(1,376,220)
Total equity attributable to stockholders of Arena	3,328	53,542
Equity attributable to noncontrolling interest in consolidated variable interest entity	749	0
Total equity	4,077	53,542
Total liabilities and equity	$ 210,248	$ 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.

1

ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share data)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Revenues:				
Net product sales	$3,323	$4,884	$11,104	$15,787
Other Eisai collaboration revenue	12,954	2,065	18,155	7,414
Toll manufacturing	1,228	1,463	3,276	3,199
Other collaboration revenue	1,737	726	6,066	4,175
Total revenues	19,242	9,138	38,601	30,575
Operating Costs and Expenses:				
Cost of product sales	882	1,635	4,161	6,129
Cost of toll manufacturing	1,930	1,584	4,876	3,798
Research and development	17,466	22,072	54,514	68,241
General and administrative	8,590	9,028	23,979	26,311
Restructuring charges	231	0	6,346	0
Total operating costs and expenses	29,099	34,319	93,876	104,479
Loss from operations	(9,857)	(25,181)	(55,275)	(73,904)
Interest and Other Income (Expense):				
Interest income	54	37	247	105
Interest expense	(1,609)	(1,683)	(4,907)	(5,133)
Gain from valuation of derivative liabilities	0	852	0	474
Other	(1,067)	(443)	(1,275)	938
Total interest and other expense, net	(2,622)	(1,237)	(5,935)	(3,616)
Net loss	(12,479)	(26,418)	(61,210)	(77,520)
Less net loss attributable to noncontrolling interest in consolidated variable interest entity	122	0	122	0
Net loss attributable to stockholders of Arena	$(12,357)	$(26,418)	$(61,088)	$(77,520)
Net loss attributable to stockholders of Arena per share:				
Basic	$(0.05)	$(0.11)	$(0.25)	$(0.32)
Diluted	$(0.05)	$(0.11)	$(0.25)	$(0.32)
Shares used in calculating net loss attributable to stockholders of Arena per share:				
Basic	243,254	242,257	243,069	240,033
Diluted	243,254	242,257	243,069	240,033
Comprehensive Loss:				
Net loss	$(12,479)	$(26,418)	$(61,210)	$(77,520)
Foreign currency translation gain (loss)	694	(2,881)	2,046	(2,499)

Comprehensive loss	(11,785)	(29,299)	(59,164)	(80,019)
Less comprehensive loss attributable to noncontrolling interest in				
consolidated variable interest entity	122	0	122	0
Comprehensive loss attributable to stockholders of Arena	$(11,663)	$(29,299)	$(59,042)	$(80,019)

See accompanying notes to unaudited condensed consolidated financial statements.

2

ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine months ended September 30,	
	2016	2015
Operating Activities		
Net loss	$(61,210)	$(77,520)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,005	7,401
Amortization of intangibles	104	147
Share-based compensation	9,261	11,795
Gain from valuation of derivative liabilities	0	(474)
Amortization of prepaid financing costs	102	102
Loss on disposal of property and equipment	798	1,007
Changes in assets and liabilities:		
Accounts receivable	(13,122)	116
Inventory	157	1,240
Prepaid expenses and other assets	(514)	(366)
Payables and accrued liabilities	8,820	(21,271)
Deferred revenues	(4,929)	4,506
Other long-term liabilities	62	78
Net cash used in operating activities	(53,466)	(73,239)
Investing Activities		
Purchases of property and equipment	(644)	(10,800)
Proceeds from sale of property and equipment	786	2,232
Other non-current assets	(659)	(55)
Net cash used in investing activities	(517)	(8,623)
Financing Activities		
Principal payments on lease financing obligations	(2,189)	(1,829)
Proceeds from issuance of common stock	288	102,934
Net cash provided by (used in) financing activities	(1,901)	101,105
Effect of exchange rate changes on cash	1,329	(1,172)
Net increase (decrease) in cash and cash equivalents	(54,555)	18,071
Cash and cash equivalents at beginning of period	156,184	163,209
Cash and cash equivalents at end of period	$101,629	$181,280

See accompanying notes to unaudited condensed consolidated financial statements.

3

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. 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 consolidated 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 consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The accompanying consolidated financial statements include the balances and activity of our wholly owned subsidiaries and Beacon Discovery, Inc., or Beacon, a variable interest entity for which we have the controlling financial interest (see Note 13). The equity attributable to the noncontrolling interest in Beacon is presented as a separate component from the equity attributable to stockholders of Arena in the equity section of the condensed consolidated balance sheet. The results of operations and comprehensive loss attributable to the noncontrolling interest in Beacon is presented as separate components from the results of operations and comprehensive loss attributable to the stockholders of Arena in the condensed consolidated statement of operations and comprehensive loss.

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.” ASU No. 2014-15 requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. Certain disclosures will be required if conditions give rise to substantial doubt about an entity’s ability to continue as a going concern. ASU No. 2014-15 applies to all entities and is effective for annual and interim periods ending after December 15, 2016, with early adoption permitted. 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 12 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.

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 September 30, 2016			
Balance	Quoted Prices in	Significant Other	Significant
	Active Markets	Observable	Unobservable Inputs

		(Level 1)	Inputs (Level 2)	(Level 3)
Assets:				
Money market funds[1]	$56,327	$ 56,327	$ 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:

	September 30, 2016	December 31, 2015
Raw materials	$ 2,692	$ 2,487
Work in process	2,969	2,781
Finished goods at Arena GmbH	727	165
Finished goods at Eisai	2,492	3,309
Finished goods at Ildong	1,286	760
Total inventory	$ 10,166	$ 9,502

4. Land, Property and Equipment

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

	September 30, 2016	December 31, 2015
Cost	$ 166,420	$ 172,729
Less accumulated depreciation and amortization	(101,440)	(100,901)
Land, property and equipment, net	$ 64,980	$ 71,828

5. Accounts Payable and Other Accrued Liabilities

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

	September 30, 2016	December 31, 2015
Accounts payable	$ 7,645	$ 2,078
Accrued compensation	5,663	5,118
Other accrued liabilities	1,459	1,138
Total accounts payable and other accrued liabilities	$ 14,767	$ 8,334

6. Collaborations

Please refer to our Annual Report on Form 10-K for the year ended December 31, 2015, for additional information regarding the collaborations described below.

Eisai.

We have a collaboration agreement with Eisai Inc. and Eisai Co., Ltd. (collectively with Eisai Inc., Eisai). Under this agreement, or Eisai Agreement, Eisai is the exclusive distributor of BELVIQ in the United States and most other countries in the world except for South Korea, Taiwan, Australia, New Zealand and Israel.

In July 2016, the US Food and Drug Administration approved the New Drug Application for our once-daily formulation of lorcaserin for chronic weight management under the brand name BELVIQ XR. Eisai will pay us a $10.0 million substantive milestone payment earned from this achievement. Eisai has the exclusive rights to distribute BELVIQ XR in the United States. In October 2016, Eisai announced the commercial launch of BELVIQ XR in the United States.

In July 2016, the Federal Commission for the Protection Against Sanitary Risk approved the Marketing Authorization Application in Mexico for our twice-daily formulation of lorcaserin for chronic weight management. The product will be sold under the brand name VENESPRI. Eisai will pay us a $1.0 million substantive milestone payment earned from this achievement. Eisai has the exclusive rights to distribute VENESPRI in Mexico.

Under the Eisai Agreement, in addition to the $11.0 million in milestones mentioned above and the other $86.5 million in milestones previously achieved since we entered the agreement in 2010, we are eligible to receive up to 16 substantive regulatory milestones totaling $165.0 million. These payments are based on 16 milestone events of which eight milestones with an aggregate value of $105.0 million are related to a second or third product approval.

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Net product sales	$1,868	$3,274	$7,179	$11,603
Milestone payments	11,000	0	11,000	0
Amortization of upfront payments	1,886	1,886	5,656	5,656
Reimbursement of development expenses	11	107	1,242	1,454
Reimbursement of patent and trademark expenses	57	72	257	304
Subtotal other Eisai collaborative revenue	12,954	2,065	18,155	7,414
Total	$14,822	$5,339	$25,334	$19,017

The following table summarizes the deferred revenues under the Eisai Agreement, in thousands:

	September 30, 2016	December 31, 2015
Upfront payments	$ 81,278	$ 86,933
Net product sales	7,331	10,754
Total deferred revenues attributable to Eisai	88,609	97,687
Less current portion	(14,872)	(18,295)
Deferred revenues attributable to Eisai, less current portion	$ 73,737	$ 79,392

Ildong Pharmaceutical Co., Ltd.

We and Ildong Pharmaceutical Co., Ltd., or Ildong, have an exclusive agreement, or Ildong Agreement, under which Ildong has 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. There are no milestones we are eligible to receive in the future under the Ildong Agreement.

CY Biotech Company Limited

We have an agreement with CY Biotech Company Limited, or CYB. Under this agreement, we granted CYB exclusive rights to commercialize BELVIQ in Taiwan for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the Taiwan Food and Drug Administration. We also provide certain services and will manufacture and sell BELVIQ to CYB. There are no material milestones we are eligible to receive in the future under this agreement.

Abic Marketing Limited (Teva)

We granted Teva exclusive rights to commercialize BELVIQ in Israel for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the Israeli Ministry of Health, or MOH. We also provide certain services and will manufacture and sell BELVIQ to Teva. There are no material milestones we are eligible to receive in the future under this agreement.

Axovant Sciences Ltd.

We and Axovant Sciences, Ltd., or Axovant, have an exclusive agreement, or Axovant Agreement, under which Axovant has exclusive worldwide rights to develop and commercialize nelotanserin, subject to regulatory approval. We also provide certain services and will manufacture and sell nelotanserin to Axovant.

Under the Axovant Agreement, we are eligible to receive up to an aggregate of $41.5 million in success milestones in case of full development and regulatory success of nelotanserin. Of these payments, two development milestones totaling $4.0 million are substantive and four regulatory milestones totaling $37.5 million are substantive.

Boehringer Ingelheim International GmbH.

We and Boehringer Ingelheim GmbH, or Boehringer Ingelheim, have an exclusive agreement, or Boehringer Ingelheim Agreement, to conduct joint research to identify drug candidates targeting an undisclosed G protein-coupled receptor, or GPCR, that belongs to the group of orphan central nervous system, or CNS, receptors.

Under the Boehringer Ingelheim Agreement, we are eligible to receive up to an aggregate of $251.0 million in success milestones in case of full commercial success of multiple drug products. Of these payments, three development milestones totaling $7.0 million are substantive, three development milestones totaling $30.0 million are non-substantive, nine regulatory milestones totaling $84.0 million are non-substantive and four commercial milestones totaling $130.0 million are non-substantive.

7. Share-based Activity

Share-based Compensation.

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Cost of product sales	$0	$0	$20	$0
Research and development	1,200	2,097	4,940	6,338
General and administrative	981	1,751	3,269	5,457
Restructuring charges	0	0	1,032	0
Total share-based compensation expense	$2,181	$3,848	$9,261	$11,795
Total share-based compensation expense capitalized into inventory	$64	$41	$149	$146

Share-based Award Activity.

The following table summarizes our stock option activity during the nine months ended September 30, 2016, in thousands (except per share data):

Options	Weighted-Average

		Exercise Price
Outstanding at January 1, 2016	16,407	$ 5.01
Granted	16,502	1.61
Exercised	(63)	1.57
Forfeited/cancelled/expired	(7,281)	3.70
Outstanding at September 30, 2016	25,565	$ 3.20

The following table summarizes activity with respect to our time-based restricted stock unit awards, or RSUs, during the nine months ended September 30, 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	(193)	4,51
Forfeited/cancelled	(9)	4.31
Unvested at September 30, 2016	71	$ 5.16

During the nine months ended September 30, 2016, the remaining Total Stockholder Return, or TSR, performance restricted stock unit, or PRSU, awards that we 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 granted in March 2014 and March 2015 are still outstanding at September 30, 2016.

8. 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. Eisai is also the exclusive distributor of BELVIQ XR in the United States. We also produce drug products for Siegfried AG, or Siegfried, and, to a lesser extent, another third party under toll manufacturing agreements.

Percentages of our total revenues are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Eisai Agreement (See Note 6)	77.0 %	58.4 %	65.6 %	62.2 %
Ildong Agreement	8.2 %	18.6 %	11.0 %	24.4 %
Toll manufacturing agreements	6.4 %	16.0 %	8.5 %	10.5 %
Boehringer Ingelheim Agreement (See Note 6)	5.6 %	0.0 %	10.0 %	0.0 %
Axovant Agreement (See Note 6)	2.4 %	6.1 %	4.3 %	2.2 %
Other collaborative agreements	0.4 %	0.9 %	0.6 %	0.7 %
Total percentage of revenues	100.0 %	100.0 %	100.0 %	100.0 %

9. Net Loss Per Share

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

Since we are in a net loss position, in addition to excluding potentially dilutive out-of-the money securities, we exclude from our calculation of diluted net loss attributable to stockholders of Arena 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 attributable to stockholders of Arena per share, in thousands:

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Stock options	28,559	17,462	24,791	17,033
RSUs and unvested restricted stock	175	690	242	576
Warrant	0	0	0	26
Total	28,734	18,152	25,033	17,635

Because the market conditions for the PRSUs were not satisfied at September 30, 2016, or September 30, 2015, such securities are excluded from the table above.

10. Legal Proceedings

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints 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 Ninth Circuit heard oral argument on the appeal on May 4, 2016. On October 26, 2016, the Ninth Circuit panel reversed the district court's dismissal of the second consolidated amended complaint and remanded the case back to the district court for further proceedings. 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.

On September 30, 2016, we and Eisai filed a patent infringement lawsuit against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively with Lupin Limited, Lupin) in the U.S. District Court for the District of Delaware. The lawsuit relates to a "Paragraph IV certification" notification we and Eisai received regarding an abbreviated new drug application, or ANDA, submitted to the FDA by Lupin requesting approval to engage in the commercial manufacture, use, importation, offer for sale or sale of a generic version of BELVIQ® (lorcaserin hydrochloride tablets, 10 mg). In its notification, Lupin alleged that no valid, enforceable claim of any of the patents which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for BELVIQ® will be infringed by Lupin's manufacture, importation, use, sale or offer for sale of the product described in its ANDA. The lawsuit claims infringement of U.S. Patent Nos. 6,953,787; 7,514,422; 7,977,329; 8,207,158; 8,273,734; 8,546,379; 8,575,149; 8,999,970 and 9,169,213. In accordance with the Hatch-Waxman Act, as a result of filing a patent infringement lawsuit within 45 days of receipt of Lupin's notification, the FDA cannot approve the ANDA any earlier than 7.5 years from NDA approval unless a District Court finds that all of the asserted claims of the patents-in-suit are invalid, unenforceable or not infringed. We and Eisai are seeking a determination from the court that, among other things, Lupin has infringed our patents, Lupin's ANDA should not be approved until the expiration date of our patents, and Lupin should be enjoined from commercializing a product that infringes our patents. We cannot predict the ultimate outcome of any proceeding.

11. Restructuring Charges

In the fourth quarter of 2015, we committed to a reduction in our US workforce of approximately 35%, or approximately 80 employees, which we substantially completed by the end of 2015. In the fourth quarter of 2015, we committed to a reduction in our Swiss workforce of approximately 17%, or approximately 14 employees, which we substantially completed 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, including severance and other benefits, of $4.0 million, and at September 30, 2016, all of this charge has been paid.

In the second quarter of 2016, we committed to a reduction in our US workforce of approximately 73%, or approximately 100 employees, which we substantially completed in the third quarter of 2016. As a result of this workforce reduction, we recorded a restructuring charge in the second quarter of 2016 of $6.1 million for termination benefits, including severance and other benefits. Included within this amount is non-cash, share-based compensation expense of $1.0 million related to the accelerated vesting of stock options and the extension of the exercise period of vested options for employees impacted by the workforce reduction. At September 30, 2016, $4.0 million of the cash portion of the restructuring charge has been paid, resulting in a remaining accrual of $1.1 million.

In the third quarter of 2016, we committed to a reduction of our manufacturing workforce in Zofingen, Switzerland of approximately 23%, or approximately 15 employees, which we plan to substantially complete by the end of the first quarter of 2017. As a result of this workforce reduction, we recorded a restructuring charge in the third quarter of 2016 of $0.2 million for cash termination benefits. At September 30, 2016, $0.1 million of this charge has been paid, resulting in a remaining accrual of $0.1 million.

12. Management Changes

Appointment of President and Chief Executive Officer.

In May 2016, our Board of Directors appointed Amit Munshi as our President and Chief Executive Officer, and he joined our Board of Directors in June 2016 following our 2016 Annual Stockholders' Meeting. Harry F. Hixson, Jr., Ph.D., who served as our interim Chief Executive Officer from October 2015 to May 2016, continues to serve on our Board of Directors.

In connection with Mr. Munshi's appointment as an officer, 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 in May 2016, to reserve an additional 3,800,000 shares of common stock for inducement awards. The nonstatutory stock options have 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.

Termination of Chief Medical Officer.

In June 2016, our Board of Directors terminated without cause our former Senior Vice President and Chief Medical Officer, William R. Shanahan, Jr., M.D., J.D. Under our Amended and Restated Severance Benefit Plan, as amended, or Severance Benefit Plan, Dr. Shanahan is entitled to receive the following termination benefits: (1) a cash severance payment of approximately $0.5 million (subject to applicable withholdings); (2) continuation of health insurance coverage for a period of 12 months; (3) acceleration of the stock options and RSUs (other than PRSUs) held by Dr. Shanahan that would otherwise have vested through the 12-month period following the date of his termination, provided that, for purposes of calculating such vesting acceleration, any unvested portion of such equity awards that were scheduled to vest in annual installments are treated as if the original grant provided for vesting in equal monthly installments rather than annually; and (4) continued stock option exercisability until the later of (i) the end of the original post-termination exercise period provided in the applicable stock option agreement or (ii) 12 months (but not beyond the original contractual life of the option). In addition, with respect to outstanding PRSUs, when our Board of Directors' Compensation Committee determines our relative performance for an applicable performance period, a pro-rata portion of the relevant PRSUs held by Dr. Shanahan is eligible to vest (based on the percentage of the performance period that Dr. Shanahan provided service prior to his termination). The pro-rata vesting may be accelerated if we undergo a change in control before the scheduled end of the performance period. We recorded a charge of $1.0 million in the second quarter of 2016 related to these benefits, including non-cash, share-based compensation expense of $0.4 million, which is included in research and development expenses in our condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2016. As of September 30, 2016, there are remaining accruals for these benefits of $0.6 million included in accounts payable and other accrued expenses, the majority of which we expect to pay in the fourth quarter of 2016.

In July 2016, we and Dr. Shanahan entered into a one-year services agreement whereby Dr. Shanahan performs services for us relating to our research and development programs. As compensation, Dr. Shanahan receives a fixed monthly fee along with reimbursement of certain pre-approved expenses and continued stock option exercisability until 24 months from the July 2016 effective date of this agreement (but not beyond the original contractual life of the option). We recorded a charge of $0.1 million in the third quarter of 2016 related to this compensation, including non-cash, share-based compensation expense, which is included in research and development expenses in our condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2016.

Appointment of Chief Financial Officer.

In June 2016, our Board of Directors appointed Kevin R. Lind as our Executive Vice President and Chief Financial Officer. In connection with such appointment, our Board's Compensation Committee approved an inducement stock option grant to Mr. Lind to purchase 800,000 shares of our common stock under our 2013 Long-Term Incentive Plan, as amended in May 2016 and June 2016, to reserve an additional 800,000 shares of common stock for inducement awards in addition to the 3,800,000 shares it previously reserved for such awards. The nonstatutory stock options have a seven-year term and will vest over 4 years, with 25% of the shares subject to vesting one year after grant and the remainder of the shares vesting monthly over the following three years in equal installments, subject to his continued service through the applicable vesting dates and possible acceleration in specified circumstances.

Appointment of Chief Business Officer.

In August 2016, our Board of Directors appointed Vincent Aurentz as our Executive Vice President and Chief Business Officer. In connection with such appointment, our Board's Compensation Committee approved an inducement stock option grant to Mr. Aurentz to purchase 800,000 shares of our common stock under our 2013 Long-Term Incentive Plan, as amended in May 2016, June 2016 and August 2016, to reserve an additional 800,000 shares of common stock for inducement awards in addition to the 4,600,000 shares it previously reserved for such awards. The nonstatutory stock options have a seven-year term and will vest over 4 years, with 25% of the shares subject to vesting one year after grant and the remainder of the shares vesting monthly over the following three years in equal installments, subject to his continued service through the applicable vesting dates and possible acceleration in specified circumstances.

Resignation of Chief Scientific Officer.

In September 2016, Dominic P. Behan, Ph.D., D.Sc., our former Executive Vice President and Chief Scientific Officer resigned from the Company, including from our Board of Directors, and became the Chief Executive Officer of Beacon (see Note 13). Dr. Behan's resignation follows our strategic shift in priorities to emphasize our proprietary clinical stage pipeline, which was announced on June 30, 2016. Dr. Behan’s resignation was for good reason under our Severance Benefit Plan resulting from Dr. Behan’s materially diminished duties and responsibilities following this strategic shift.

Following his resignation from the Company, Dr. Behan acts as the Chair of our Scientific Advisory Board and provides consulting services to us regarding our research and development program under a five-year consulting agreement, or Consulting Agreement, which may be terminated earlier by either party on 30 days advanced written notice. Dr. Behan receives a market rate hourly consulting fee, along with reimbursement of certain pre-approved expenses. In addition, Dr. Behan’s consulting services constitute continuous service with us, and as a result, the outstanding equity awards we previously granted to Dr. Behan continue to vest and/or be exercisable, as those services are provided in accordance with the applicable plan(s) and written grant instrument(s) for such awards.

Under the Severance Benefit Plan, Dr. Behan is entitled to receive the following termination benefits: (1) a cash severance payment of approximately $0.9 million (subject to applicable withholdings); (2) continuation of health insurance coverage for a period of 18 months; (3) acceleration of the stock options and RSUs (other than PRSUs) held by Dr. Behan that would otherwise have vested through the 18-month period following his Arena employee-status termination date, provided that, for purposes of calculating such vesting acceleration, any unvested portion of such equity awards that were scheduled to vest in annual installments are treated as if the original grant provided for vesting in equal monthly installments rather than annually; (4) for options that were vested as of his Arena employee-status termination date, including those for which vesting was accelerated upon his termination, continued stock option exercisability until the later of (i) the end of the original post-termination exercise period provided in the applicable stock option agreement measured from the date of cessation of services under the Consulting Agreement or (ii) 18 months following his Arena employee status termination date (but not beyond the original contractual life of the option) and (5) for options that were not vested as of his Arena employee-status termination date, continued stock option exercisability, to the extent vested as of the date of cessation of services under the Consulting Agreement, until the end of the original post-termination exercise period provided in the applicable stock option agreement measured from the date of cessation of services under the Consulting Agreement (but not beyond the original contractual life of the option).

We recorded a charge of $2.6 million in the third quarter of 2016 related to these benefits, including non-cash, share-based compensation expense of $1.6 million, which is included in research and development expenses in our condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2016. As of September 30, 2016, there are remaining accruals for these benefits of $0.9 million included in accounts payable and other accrued expenses, the majority of which we expect to pay in the first quarter of 2017.

13. Beacon Discovery, Inc.

In the third quarter of 2016, Beacon was formed. Beacon is a privately held drug discovery incubator which focuses on identifying and advancing molecules targeting GCPRs. Dr. Behan is the Chief Executive Officer of Beacon (see

Note 12). On September 1, 2016, we entered into various agreements with Beacon described in further detail below.

We entered into a license and collaboration agreement with Beacon, pursuant to which we transferred certain equipment to Beacon and granted Beacon a non-exclusive, non-assignable and non-sublicensable license to certain database information relating to compounds, receptors and pharmacology, and transferred certain equipment to Beacon. Beacon will seek to engage global partners to facilitate discovery and development. Beacon has agreed to assign to us any intellectual property relating to our existing research and development programs developed in the course of performing research for us, and grant us a non-exclusive license to any intellectual property developed outside the course of performing work for us that is reasonably necessary or useful for developing or commercializing the products under our research and development programs. We are also entitled to rights of negotiation and rights of first refusal to potentially obtain licenses to compounds discovered and developed by Beacon. In addition, we are entitled to receive (i) a percentage of any revenue received by Beacon on or after the second anniversary of the effective date of the agreement from any third party pursuant to a third party license, including upfront payments, milestone payments and royalties; (ii) single-digit royalties on the aggregate net sales of any related products sold by Beacon and its affiliates; and (iii) in the event that Beacon is sold, a percentage of the consideration for such sale transaction.

We entered a master services agreement with Beacon, pursuant to which Beacon performs certain research services for us.

We also entered into a separate services agreement with Beacon, pursuant to which Beacon now performs our research obligations under the Boehringer Ingelheim Agreement. In consideration for performing these research obligations, Beacon is entitled to receive the applicable FTE payments that are paid to us by Boehringer Ingelheim for the research services and certain milestone payments.

We also entered into a sublease agreement, or Sublease, with Beacon, pursuant to which we sublease approximately 15,000 square feet of laboratory, office and meeting room space to Beacon for a period of five years. Beacon can defer payments due to us under the Sublease by increasing the outstanding principal amount under a secured promissory note, or Note, we issued to Beacon. The outstanding principal amount and all accrued or unpaid interest thereon (calculated at a simple interest rate of seven percent per annum) shall be due and payable on the earlier of (i) August 31, 2022 or (ii) Beacon receiving cumulative cash proceeds of $10,000,000 from the sale of equity, issuance of debt or third party license revenue.

As Beacon would not be able to finance its activities without the financial support we are providing pursuant to these agreements, Beacon is a variable interest entity. Arena does not own any equity in Beacon; however, as these agreements provide us the controlling financial interest in Beacon, we consolidate Beacon's balances and activity within our condensed consolidated financial statements. The noncontrolling interest attributable to Beacon presented on our condensed consolidated financial statements is comprised of Beacon's equity ownership interests as we do not own any voting interest in Beacon.

The following table presents a reconciliation of the equity attributable to the stockholders of Arena and the equity attributable to Beacon, in thousands:

	Equity Attributable to Stockholders of Arena	Equity Attributable to Noncontrolling Interest in Consolidated Variable Interest Entity	Total Equity
Balance at December 31, 2015	$ 53,542	$ 0	$53,542
Net loss	(61,088)	(122)	(61,210)
Translation gain	2,046	0	2,046
Contribution of equipment and other assets from Arena to Beacon	(871)	871	0
Other	9,699	0	9,699
Balance at September 30, 2016	$ 3,328	$ 749	$4,077

The following table presents the assets and liabilities of Beacon which are included in our condensed consolidated balance sheet at September 30, 2016, in thousands. The assets include only those assets that can be used to settle obligations of Beacon. The liabilities include third party liabilities of Beacon. As of September 30, 2016, Beacon had no creditors with recourse to the general credit of Arena. The assets and liabilities exclude intercompany balances that eliminate in consolidation:

Assets of Beacon that can only be used to settle obligations of Beacon	
Cash and cash equivalents	$288

Prepaid expense and other current assets	42
Land, property and equipment, net	793
Total assets of Beacon that can only be used to settle obligation of Beacon	$1,123
Liabilities of Beacon for which creditors do not have recourse to the general credit of Arena	
Accounts payable and other accrued liabilities	$8
Total liabilities of Beacon for which creditors do not have recourse to the general credit of Arena	$8

14. Subsequent Events

In October 2016, Eisai announced the commercial launch of BELVIQ XR in the United States (see Note 6).

See Note 10 for the update to our legal proceedings which occurred subsequent to September 30, 2016.

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

General

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.

Use of "BELVIQ" in this Quarterly Report

Lorcaserin has been approved in the United States, South Korea and Mexico for weight management in a twice-a-day dosage formulation. The twice-a-day dosage formulation is being commercialized in the United States and South Korea under the brand name BELVIQ, and will be commercialized in Mexico under the brand name VENESPRI. Lorcaserin has also been approved in the United States in a once-a-day dosage formulation, which is BELVIQ XR.

In this document, "BELVIQ" refers to each of the formulations of lorcaserin approved for weight management, unless the context otherwise indicates.

OVERVIEW AND RECENT DEVELOPMENTS

We are a biopharmaceutical company focused on developing novel, small–molecule drugs across a range of therapeutic areas, and are currently directing our efforts and resources primarily on the following activities:

- Advancing our proprietary clinical programs:
- Etrasimod (formerly known as APD334) – a selective, next generation $S1P_1$ modulator of the sphingosine 1-phosphate, or S1P, receptor – which we are evaluating in an ongoing Phase 2 clinical trial for ulcerative colitis, and will potentially explore in additional indications
- APD371 — an agonist of the cannabinoid-2, or CB_2 receptor – which we expect to evaluate this compound in a Phase 2 clinical trial for pain associated with Crohn's disease

- Ralinepag (formerly known as APD811) – an agonist of the prostacyclin receptor – which we are evaluating in an ongoing Phase 2 clinical trial for pulmonary arterial hypertension, or PAH
- We continue to explore additional indications for all of our clinical-stage programs

- Supporting our collaborations:
- Eisai Inc. and Eisai Co., Ltd., which we refer to collectively as Eisai, and other collaborators in their efforts with respect to BELVIQ
- Axovant Sciences Ltd., or Axovant, in their efforts with respect to 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
- Boehringer Ingelheim International GmbH, or Boehringer Ingelheim, targeting a G protein-coupled receptor, or GPCR, that belongs to the group of orphan central nervous system, or CNS, receptors, which is in preclinical development

In July 2016, the US Food and Drug Administration, or FDA, approved the New Drug Application for our once-daily formulation of lorcaserin for chronic weight management under the brand name BELVIQ XR. Eisai will pay us a $10.0 million milestone payment earned from this achievement. In July 2016, the Federal Commission for the Protection Against Sanitary Risk approved the Marketing Authorization Application in Mexico for our twice-daily formulation of lorcaserin for chronic weight management. The product will be sold under the brand name VENESPRI. Eisai will pay us a $1.0 million milestone payment earned from this achievement.

In the second quarter of 2016, we committed to a reduction of our US workforce of approximately 73%, or approximately 100 employees, which we substantially completed in the third quarter of 2016. As a result of this workforce reduction, we recorded estimated restructuring charges during the second quarter of 2016 of $6.1 million in connection with one-time employee termination costs, including severance and other benefits. Included within this amount is non-cash, share-based compensation expense of $1.0 million related to the accelerated vesting of stock options and the extension of the exercise period of vested options for employees impacted by the workforce reduction. We estimate that the reduction will decrease annualized cash expenditures for (i) personnel by approximately $17 million and (ii) related other operating expenses between $6-8 million.

In the third quarter of 2016, we committed to a reduction of our manufacturing workforce in Zofingen, Switzerland of approximately 23%, or approximately 15 employees, which we plan to substantially complete by the end of the first quarter of 2017. As a result of this workforce reduction, we recorded a restructuring charge in the third quarter of 2016 of $0.2 million in cash termination benefits. We estimate that the reduction will decrease annualized cash expenditures by approximately $2 million.

In May 2016, our Board of Directors appointed Amit Munshi as our President and Chief Executive Officer, and he joined our Board of Directors in June 2016 following our 2016 Annual Stockholders' Meeting. Harry F. Hixson, Jr., Ph.D., who served as our interim Chief Executive Officer from October 2015 to May 2016, continues to serve on our Board of Directors. In June 2016, our Board of Directors appointed Kevin R. Lind as our Executive Vice President and Chief Financial Officer. In August 2016, our Board of Directors appointed Vincent Aurentz as our Executive Vice President and Chief Business Officer.

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, and manufacture BELVIQ for commercial sale and studies.

We expect our cash used in operations will be lower in 2016 as compared to 2015 due to cost savings from the workforce reductions we effected at the end of 2015, in June 2016 and in July 2016 and by continuing to implement cost control measures. However, we will need to receive additional funds under our existing collaboration agreements, under any new collaboration 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.

Our US operations are located in San Diego, California. Our primary clinical operations are located in Zug, Switzerland, and our commercial manufacturing for BELVIQ is located in Zofingen, Switzerland.

RESULTS OF OPERATIONS

We are providing the following summary of our revenues, research and development expenses and general and administrative expenses to supplement the more detailed discussion below. The dollar values in the following tables are in millions.

Revenues

Source of revenue	Three months ended September 30, 2016	2015	Nine months ended September 30, 2016	2015
Milestone payments earned from Eisai	$ 11.0	$ 0.0	$ 11.0	$ 0.0
Arena’s portion of Eisai net product sales	1.9	3.3	7.2	11.6
Amortization of upfront payments from Eisai	1.9	1.9	5.7	5.7
Arena’s portion of Ildong net product sales	1.4	1.6	3.9	4.2
Toll manufacturing	1.2	1.5	3.3	3.2
Collaborative agreement with Boehringer Ingelheim	1.1	0.0	3.9	0.0
Other collaborative agreements	0.5	0.6	1.8	0.9
Reimbursement of development expenses and patent and trademark expenses from Eisai	0.1	0.2	1.5	1.8
Amortization of upfront payment from Ildong	0.1	0.0	0.3	0.2
Milestone payment earned from Ildong	0.0	0.0	0.0	3.0
Total revenues	$ 19.2	$ 9.1	$ 38.6	$ 30.6

Research and development expenses

Type of expense	Three months ended September 30, 2016	2015	Nine months ended September 30, 2016	2015
External clinical and preclinical study fees and internal non-commercial manufacturing costs	$ 10.0	$ 8.1	$ 25.6	$ 24.8
Salary and other personnel costs (excluding non-cash, share-based compensation)	3.6	7.3	14.4	23.1
Facility and equipment costs	2.0	2.7	6.7	7.5
Non-cash, share-based compensation	1.2	2.1	4.9	6.3
Research supply costs	0.4	1.5	2.1	5.3
Other	0.3	0.4	0.8	1.2
Total research and development expenses	$ 17.5	$ 22.1	$ 54.5	$ 68.2

General and administrative expenses

Type of expense	Three months ended September 30, 2016	2015	Nine months ended September 30, 2016	2015
Salary and other personnel costs (excluding non-cash, share-based compensation)	$ 3.0	$ 3.0	$ 9.3	$ 9.9
Legal, accounting and other professional fees	2.9	2.5	7.0	5.7
Facility and equipment costs	1.3	1.4	3.4	4.0
Non-cash, share-based compensation	1.0	1.8	3.3	5.5
Other	0.4	0.3	1.0	1.2
Total general and administrative expenses	$ 8.6	$ 9.0	$ 24.0	$ 26.3

THREE MONTHS ENDED SEPTEMBER 30, 2016, AND 2015

Revenues. We recognized revenues of $19.2 million for the three months ended September 30, 2016, compared to $9.1 million for the three months ended September 30, 2015. This increase was primarily due to (i) the $10.0 million milestone payment earned

16

from Eisai for the July 2016 approval of BELVIQ XR in the United States, (ii) $1.1 million earned in the three months ended September 30, 2016, under our collaboration agreement with Boehringer Ingelheim, or Boehringer Ingelheim Agreement, which commenced in December 2015 and (iii) the $1.0 million milestone payment earned from Eisai for the July 2016 approval of VENESPRI in Mexico. This increase was partially offset by a decrease of $1.6 million in our portion of net product sales of BELVIQ due to a decrease in the number of tablets sold 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 an increase in the gross-to-net discount attributable to the Eisai saving card programs.

When collaborators pay us before revenues are earned, we record such payments as deferred revenues. At September 30, 2016, we had a total of $104.7 million in deferred revenues. Of such amount, $81.3 million is attributable to upfront payments we received under our collaboration with Eisai, $10.0 million is attributable to product supply of BELVIQ and the remaining amount is primarily attributable to the upfront payments we received under our other collaboration agreements.

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

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. For example, 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 collaboration 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 the commercialization of BELVIQ in the United States, South Korea and Mexico, 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 ongoing BELVIQ cardiovascular outcomes trial, or CVOT, also known as the CAMELLIA study.

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. Cost of products sold decreased to $0.9 million for the three months ended September 30, 2016, from $1.6 million for the three months ended September 30, 2015, due to a decrease in the number of BELVIQ tablets sold in the United States and South Korea and a decrease in per tablet manufacturing costs.

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 $0.3 million to $1.9 million for the three months ended September 30, 2016, from $1.6 million for the three months ended September 30, 2015, primarily due to increased costs incurred on toll manufacturing performed for Siegfried. We may consider entering into additional toll manufacturing agreements in the future to increase revenues and the 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, 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 $4.6 million to $17.5 million for the three months ended September 30, 2016, from $22.1 million for the three months ended September 30, 2015. This decrease was primarily due to decreases of $3.7 million in salary and other personnel costs, $1.1 million in research supply costs, $0.9 million in non-cash, share-based compensation expense and $0.7 million in facility and equipment costs, primarily due to our recent workforce reductions. This decrease was partially offset by an increase of $1.9 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs.

Although we expect to incur substantial research and development expenses in 2016, we expect these expenses will be lower than in 2015, primarily due to our recent workforce reductions. Our actual 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 etrasimod and ralinepag is competitive and challenging and has taken longer than projected. This has resulted in our related external expenses being lower at this point than anticipated, and will likely increase our long-term expenses for these trials.

Included in the $10.0 million of total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the three months ended September 30, 2016, were the following:

- $6.3 million related to etrasimod,
- $2.1 million related to lorcaserin and non-commercial manufacturing costs and
- $1.1 million related to ralinepag.

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

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

General and administrative expenses. General and administrative expenses decreased by $0.4 million to $8.6 million for the three months ended September 30, 2016, from $9.0 million for the three months ended September 30, 2015. This decrease was primarily due to a decrease of $0.8 million in non-cash, share-based compensation expenses, primarily due to the recent reductions in the number of our employees. This decrease was partially offset by an increase of $0.4 million in legal, accounting and other professional fees. We expect that our 2016 general and administrative expenses will be lower than in 2015, primarily due to our recent workforce reductions and other cost control initiatives.

Restructuring charges. We recognized $0.2 million of restructuring charges for the three months ended September 30, 2016, in connection with employee termination costs related to the reduction of our manufacturing workforce in Zofingen, Switzerland to which we committed in July 2016, compared to no restructuring charges for the three months ended September 30, 2015.

Interest and other expense, net. Interest and other expense, net, increased by $1.4 million to $2.6 million for the three months ended September 30, 2016, from $1.2 million for the three months ended September 30, 2015. This increase was primarily due to (i) a $0.9 million gain from revaluation of our derivative liabilities related to our previously outstanding warrant for the three months ended September 30, 2015, with no revaluation recorded in the three months ended September 30, 2016, as the warrant expired in August 2015 according to its terms and (ii) $0.4 million in foreign currency transaction losses, net for the three months ended September 30, 2016, compared to $0.5 million in foreign currency transaction gains, net for the three months ended September 30, 2015.

NINE MONTHS ENDED SEPTEMBER 30, 2016, AND 2015

Revenues. We recognized revenues of $38.6 million for the nine months ended September 30, 2016, compared to $30.6 million for the nine months ended September 30, 2015. This increase was primarily due to (i) the $10.0 million milestone payment earned from Eisai for the July 2016 approval of BELVIQ XR in the United States, (ii) $3.9 million earned in the nine months ended September 30, 2016, under the Boehringer Ingelheim Agreement, which commenced in December 2015, (iii) the $1.0 million milestone payment earned from Eisai for the July 2016 approval of VENESPRI in Mexico and (iv) and increase of $1.0 million earned under our collaboration agreement with Axovant, which commenced in May 2015. This increase was partially offset by a decrease of $4.7 million in our portion of net product sales of BELVIQ and the $3.0 million milestone payment from Ildong Pharmaceutical Co., Ltd., or Ildong, that we earned in February 2015 for the approval of BELVIQ in South Korea, while no milestone payments were earned from Ildong in the nine months ended September 30, 2016. The decrease in our portion of net product sales of BELVIQ was due to a decrease in the number of tablets sold 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 an increase in the gross-to-net discount attributable to the Eisai voucher and saving card programs.

Cost of product sales. Cost of products sold decreased to $4.2 million for the nine months ended September 30, 2016, from $6.1 million for the nine months ended September 30, 2015, due to a decrease in the number of BELVIQ tablets sold in the United States and South Korea and a decrease in per tablet manufacturing costs.

Cost of toll manufacturing. Cost of toll manufacturing increased by $1.1 million to $4.9 million for the nine months ended September 30, 2016, from $3.8 million for the nine months ended September 30, 2015, primarily due to increased costs incurred on toll manufacturing performed for Siegfried and from a toll manufacturing agreement that we entered into in April 2015 with a third party.

Research and development expenses. Research and development expenses decreased by $13.7 million to $54.5 million for the nine months ended September 30, 2016, from $68.2 million for the nine months ended September 30, 2015. This decrease was primarily due to decreases of $8.8 million in salary and other personnel costs, $3.2 million in research supply costs, $1.4 million in non-cash, share-based compensation expense and $0.8 million in facility and equipment costs, primarily due to the recent reduction in the number of our employees. This decrease was partially offset by an increase of $0.8 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs.

Included in the $25.6 million of total external clinical and preclinical study fees and internal non-commercial manufacturing costs noted in the table above for the nine months ended September 30, 2016, were the following:

- $12.0 million related to etrasimod,
- $8.7 million related to lorcaserin and non-commercial manufacturing costs and
- $3.2 million related to ralinepag.

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

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

General and administrative expenses. General and administrative expenses decreased by $2.3 million to $24.0 million for the nine months ended September 30, 2016, from $26.3 million for the nine months ended September 30, 2015. This decrease was primarily due to decreases of $2.2 million in non-cash, share-based compensation expense, $0.6 million in salary and other personnel costs and $0.6 million in facility and equipment costs, primarily due to the recent reductions in the number of our employees. This decrease was partially offset by an increase of $1.3 million in legal, accounting and other professional fees.

Restructuring charges. We recognized $6.3 million of restructuring charges for the nine months ended September 30, 2016, in connection with employee termination costs, including severance and other benefits, related to the reduction of our US workforce to which we committed in June 2016 and the reduction of our manufacturing workforce in Zofingen, Switzerland to which we committed in July 2016, compared to no restructuring charges for the nine months ended September 30, 2015.

Interest and other expense, net. Interest and other expense, net, increased by $2.3 million to $5.9 million for the nine months ended September 30, 2016, from $3.6 million for the nine months ended September 30, 2015. This increase was primarily due to (i)

$0.9 million in foreign currency transaction losses, net for the nine months ended September 30, 2016, compared to $1.6 million in foreign currency transaction gains, net for the nine months ended September 30, 2015, and (ii) a $0.5 million gain from revaluation of our derivative liabilities related to our previously outstanding warrant for the nine months ended September 30, 2015, with no revaluation recorded in the nine months ended September 30, 2016, as the warrant expired in August 2015 according to its terms. This increase was partially offset by (i) a decrease in interest expense of $0.2 million, (ii) a decrease in fixed asset disposal losses, net of $0.2 million and (ii) an increase in interest income of $0.1 million.

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 weight management in the United States under the brand names BELVIQ and BELVIQ XR, in South Korea under the brand name BELVIQ and in Mexico under the brand name VENESPRI, and we refer to all such products as "BELVIQ" in this Form 10-Q, unless the context otherwise indicates. 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 the commercialization of BELVIQ in the United States, South Korea, Mexico or in any other territory in which BELVIQ may be approved. We expect to continue to incur substantial losses for at least the short term.

Short term.

At September 30, 2016, we had $101.6 million in cash and cash equivalents. In addition, in the fourth quarter of 2016, we expect to receive a total of $11.0 million in milestone payments under our collaboration agreement with Eisai for the approval of BELVIQ XR in the United States and for the approval of VENESPRI in Mexico. 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, fund 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 collaboration, 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 we expect Eisai will commercialize lorcaserin in Mexico, and, subject to applicable regulatory approval, 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, South Korea and Mexico, but there is no assurance of whether or when lorcaserin will be approved 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 Swiss manufacturing facility and sell the drug product to Eisai for 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 BELVIQ 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 September 30, 2016, our accrued payable to Eisai is $12.1 million.

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 and nine months ended September 30, 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 FDA is requiring the evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors (which is the FDA-required portion of the trial 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 $8.0 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 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 our collaboration. 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, under our collaboration agreements, 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 may not have sufficient cash to meet all of our objectives beyond the next 12 months, which include advancing certain of our clinical- and earlier-stage programs and maintaining our manufacturing capabilities. If we do not generate sufficient funding 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 developing and commercializing drugs, and this process carries substantial risk and 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 collaboration, 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 estimate that our share of the cost of CAMELLIA and other development activities could be in excess of $80 million over the next several years.

Subject to applicable regulatory approval, we expect Eisai to commercialize lorcaserin in additional territories under our collaboration. 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 $19.8 million to $53.5 million in the nine months ended September 30, 2016, compared to $73.2 million in the nine months ended September 30, 2015. This decrease was primarily the result of (i) a decrease of $9.0 million in payments made for external clinical and preclinical study fees, (ii) the $7.5 million payment we received from Boehringer Ingelheim, less $1.2 million of withholding taxes (which was refunded to us in October 2016), in February 2016 upon entering into the Boehringer Ingelheim Agreement, while we did not receive any similar upfront payment in the nine months ended September 30, 2015, and (iii) reduced cash expenditures of approximately $4.6 million for personnel costs primarily resulting from the workforce reductions we effected at the end of 2015. 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 nine months ended September 30, 2016, and (ii) net payments of $6.1 million we received for shipments of BELVIQ to Eisai and Ildong in the nine months ended September 30, 2016, compared to $8.8 million in the nine months ended September 30, 2015.

Net cash used in investing activities decreased by $8.1 million to $0.5 million in the nine months ended September 30, 2016, compared to $8.6 million in the nine months ended September 30, 2015. This decrease was primarily due to $0.6 million in purchases of property and equipment in the nine months ended September 30, 2016, compared to $10.8 million in the nine months ended September 30, 2015. This decrease was partially offset by $0.8 million in proceeds from the sale of property and equipment in the nine months ended September 30, 2016, compared to $2.2 million in the nine months ended September 30, 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 $1.9 million was used in financing activities in the nine months ended September 30, 2016, as a result of payments of $2.2 million on our lease financing obligations, which were partially offset by net proceeds of $0.3 million from stock option exercises and purchases under our employee stock purchase plan. Net cash of $101.1 million was provided by financing activities in the nine months ended September 30, 2015, as a result of net proceeds of $100.7 million from our January 2015 offering of 21,000,000 shares of common stock and net proceeds of $2.2 million from stock option exercises and purchases under our employee stock purchase plan, which were partially offset by payments of $1.8 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 nine months ended September 30, 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 President and Chief Executive Officer and our Executive Vice President and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our President and Chief Executive Officer and our Executive Vice President and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective at the reasonable assurance level. There was no change in our internal control over financial reporting that occurred during the quarter covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints were brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. The plaintiffs sought unspecified monetary damages and other relief. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. On March 28, 2013, the Court dismissed the consolidated amended complaint without prejudice. On May 13, 2013, the lead plaintiff filed a second consolidated amended complaint. On November 5, 2013, the Court dismissed the second consolidated amended complaint without prejudice as to all parties except for Robert E. Hoffman, who was dismissed from the action with prejudice. On November 27, 2013, the lead plaintiff filed a motion for leave to amend the second consolidated amended complaint. On March 20, 2014, the Court denied plaintiff's motion and dismissed the second consolidated amended complaint with prejudice. On April 18, 2014, the lead plaintiff filed a notice of appeal, and on August 27, 2014, the lead plaintiff filed his appellate brief in the US Court of Appeals for the Ninth Circuit. On October 24, 2014, we filed our answering brief in response to the lead plaintiff's appeal. On December 5, 2014, the lead plaintiff filed his reply brief. A panel of the Ninth Circuit heard oral argument on the appeal on May 4, 2016. On October 26, 2016, the Ninth Circuit panel reversed the district court's dismissal of the second consolidated amended complaint and remanded the case back to the district court for further proceedings. 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.

On September 30, 2016, we and Eisai filed a patent infringement lawsuit against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively with Lupin Limited, Lupin) in the U.S. District Court for the District of Delaware. The lawsuit relates to a "Paragraph IV certification" notification we and Eisai received regarding an abbreviated new drug application, or ANDA, submitted to the FDA by Lupin requesting approval to engage in the commercial manufacture, use, importation, offer for sale or sale of a generic version of BELVIQ® (lorcaserin hydrochloride tablets, 10 mg). In its notification, Lupin alleged that no valid, enforceable claim of any of the patents which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for BELVIQ® will be infringed by Lupin's manufacture, importation, use, sale or offer for sale of the product described in its ANDA. The lawsuit claims infringement of U.S. Patent Nos. 6,953,787; 7,514,422; 7,977,329; 8,207,158; 8,273,734; 8,546,379; 8,575,149; 8,999,970 and 9,169,213. In accordance with the Hatch-Waxman Act, as a result of filing a patent infringement lawsuit within 45 days of receipt of Lupin's notification, the FDA cannot approve the ANDA any earlier than 7.5 years from NDA approval unless a District Court finds that all of the asserted claims of the patents-in-suit are invalid, unenforceable or not infringed. We and Eisai are seeking a determination from the court that, among other things, Lupin has infringed our patents, Lupin's ANDA should not be approved until the expiration date of our patents, and Lupin should be enjoined from commercializing a product that infringes our patents. We cannot predict the ultimate outcome of any proceeding.

Item 1A. Risk Factors.

RISK FACTORS

General

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

The risk factors set forth below with an asterisk (*) before the title are 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.

Use of “BELVIQ” in this Quarterly Report

In this document, “BELVIQ” refers to once-a-day and twice-a-day formulations of lorcaserin for weight management, and, unless the context otherwise indicates, the risks identified for BELVIQ also apply to VENESPRI, BELVIQ XR and lorcaserin.

Risks Relating to Our Business

*We will need to further collaborate or obtain additional funds to execute on our corporate strategy, and we may not be able to do so; 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.

It takes many years and potentially hundreds of millions of dollars to successfully develop a compound into a marketed drug, and we have accumulated a large deficit since inception that has primarily resulted from the significant expenditures we have made with respect to lorcaserin and in seeking to research and develop other compounds. Our efforts may not result in any additional marketed drugs, and we expect that our losses and operating expenses will continue to be substantial.

While we intend to advance drug candidates and potentially earlier-stage compounds in our pipeline, we may not have adequate funds to develop our compounds into marketed drugs. Cash we have generated from sales of BELVIQ has been substantially lower than initially anticipated, and cash we may generate in the future from BELVIQ or otherwise is uncertain and difficult to predict. All of our other programs are in the research or development stage.

In June 2016, we announced a strategic shifting of priorities to emphasize our proprietary clinical-stage pipeline, and the implementation of cost reductions to streamline the organization to support our internal programs and collaborations. Such cost reductions include a substantial reduction of our workforce, primarily in areas of research, manufacturing and general and administrative, or G&A. In addition to these and possibly other cost reduction measures, we are hiring new personnel, primarily to support development, and revising our systems, processes and vendors. We cannot guarantee that we will be able to realize sufficient cost savings and other anticipated benefits from such reorganization, prioritization or other efforts, that our workforce reductions, other cost-control measures, and revisions to our systems and processes will not interfere with our ability to achieve our business objectives or have other negative consequences, or that we will not have to undertake future restructuring and cost-control measures.

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 activities. We may enter into collaboration or other agreements with other entities 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 any such agreement for any of our programs or drug candidates may depend on the outcomes of additional testing or regulatory applications for marketing approval, and we do not control these outcomes.

We may seek to obtain additional funding through the capital markets or other financing sources or we may eliminate, scale back or delay some or all of our research and 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.

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

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in research and development. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the US Food and Drug Administration, or FDA, and similar non-US regulatory authorities, and the FDA or other regulatory authority may require us to, or we or others may decide to, conduct additional research and development of any of our approved drugs. Clinical trials and preclinical studies are expensive and uncertain processes that may take years to complete. Failure can occur at any stage of the process, and successful early preclinical studies or clinical trials do not ensure that later studies or trials will be successful. In addition, the commencement or completion of our preclinical studies or clinical trials could be substantially delayed or prevented by several factors, including the following:

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

For example, recruitment for ulcerative colitis and pulmonary arterial hypertension studies is competitive and challenging. As part of the restructuring we announced in June 2016, we made significant changes in staffing, process, procedures and strategy, including with respect to the group overseeing our ongoing Phase 2 clinical trials in these therapeutic areas. We transferred much of the oversight of these clinical trials to recently hired employees in Switzerland. We plan to further modify the staffing of our clinical group, and there is no guarantee that we can hire qualified personnel in a timely manner or retain such personnel. It is unknown how our staffing and other changes will impact these clinical trials, and it is difficult to predict when these trials (or any future trials in these therapeutic areas) will be fully enrolled or data will be available.

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

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;

- delays in obtaining regulatory approvals to commence a study, or “clinical holds,” or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;

- unfavorable results from ongoing clinical trials or preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials at one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data;
- lack of sufficient funding to continue clinical trials or preclinical studies; or
- changes in business priorities or perceptions of the value of the program.

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

*Our efforts will be seriously jeopardized if we are unable to retain and attract key and other employees.

Our success depends on the continued contributions of our principal management, development and scientific personnel, and the ability to hire and retain key and other personnel. We face competition for such personnel, and we believe that risks and uncertainties related to our business may impact our ability to hire and retain key and other personnel, including with respect to the timing and risks associated with research, development and commercialization, the regulatory process, our available and anticipated cash resources, workforce reductions, subsequent departures of additional employees, threatened or actual litigation involving us and the volatility of our stock price. If we do not recruit and retain effective management and other key employees, particularly our executive officers, our operations, ability to generate or raise additional capital, and our business in general may be adversely impacted. For example, to execute our clinical programs, our strategy is to maintain a sufficient and robust clinical expertise and program management function. We are in the process of modifying and building this function, and we may not be able to establish the function we believe necessary to support our clinical goals and meet our corporate objectives.

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

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

The process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of technical and financial resources and personnel. We cannot be certain that we will have sufficient technical or financial resources or personnel, that results sufficiently favorable to justify commencement of new clinical trials will be obtained in preclinical studies or our current clinical trials, or that we will further develop a drug candidate at any stage of development. Even if favorable results are obtained from preclinical studies or clinical trials, our financial resources may not allow us to advance a drug candidate. If we are unable to identify our drug candidates, we may not be able to maintain a clinical development pipeline or generate additional revenues.

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

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

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

Our competitors, particularly large pharmaceutical companies, may have substantially greater research, development and marketing and sales capabilities and greater financial, scientific and human resources than we do. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before we do for the same indication may achieve a significant competitive advantage, including certain patent and marketing exclusivity rights. In addition, our competitors' drugs may have fewer side effects, more desirable characteristics (such as efficacy, route of administration or frequency of dosing), or be viewed more favorably by patients, healthcare providers, healthcare payers, the medical community, the media or others than our drug candidates or drugs, if any, for the same indication. Our competitors may also market generic or other drugs that compete with our drugs at a lower price than our drugs, which may negatively impact our drug sales, if any. Any results from our research and development efforts, or from our joint efforts with our existing or any future collaborators, may not compete successfully with existing or newly discovered products or therapies.

*We believe that our revenues 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.

BELVIQ has received regulatory approval for weight management in only the United States, South Korea and Mexico. We believe our revenues are substantially dependent on the success of BELVIQ, which was our first drug approved by any regulatory agency. 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 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, Mexico 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 approval from any other regulatory agency or be commercialized in any other territories.

Revenues generated by BELVIQ may constitute the majority of our revenues over the next several years, which will substantially depend on product sales of BELVIQ and, to a lesser extent, 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 treated with BELVIQ and their results;
- market acceptance and use of BELVIQ, which may depend on the public's view of BELVIQ, economic changes, national and world events, potentially seasonal and other fluctuations in demand, the timing and impact of current or new competition, and BELVIQ's perceived advantages or disadvantages over alternative treatments (including relative convenience, ease of administration, and prevalence and severity of any adverse events, including any unexpected adverse events);
- the actual and perceived safety and efficacy of BELVIQ on both a short- and long-term basis among actual or potential patients, healthcare providers and others in the medical community, regulatory agencies and insurers and other payers, including related decisions by any such entity or individual;

- incidence and severity of any side effects, including as a result of off-label use or in combination with one or more drugs;
- new data relating to lorcaserin, including as a result of additional studies, trials or analyses of lorcaserin or related drugs or drug candidates;
- the willingness of physicians to prescribe and of patients to use BELVIQ notwithstanding that results from our required postmarketing studies are not yet available and other long-term efficacy and safety data does not yet exist;
- 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 collaborators' 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 initially anticipated. If BELVIQ does not achieve sufficient market acceptance in the United States, South Korea and Mexico, 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.

In July 2016, the FDA approved our once-daily formulation of BELVIQ, which is called BELVIQ XR. In October, Eisai announced the commercial launch of BELVIQ XR in the United States. We do not know whether or how the availability of a once-daily formulation will impact product sales or our revenues.

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

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

Our and our collaborators' ability to successfully commercialize any of our drugs that have been or may be approved will depend, in part, on government regulation and the availability of coverage and adequate reimbursement from third-party payers, including private health insurers and government payers, such as the Medicaid and Medicare programs, increases in government-run, single-payer health insurance plans and compulsory licenses of drugs. We expect government and third-party payers will continue their efforts to contain healthcare costs by limiting coverage and reimbursement levels for new drugs. In addition, many countries outside of the United States have nationalized healthcare systems in which the government pays for all such products and services and must approve product pricing.

A government or third-party payer decision not to approve pricing, or provide adequate coverage and reimbursements, for our drugs, if any, could limit market acceptance of and demand for our drugs.

It is increasingly difficult to obtain coverage and adequate reimbursement levels from third-party payers, and significant uncertainty exists as to the coverage and reimbursement of newly approved prescription drug products. We or our collaborators also face competition in negotiating for coverage from pharmaceutical companies and others with competitive drugs or other treatment, and these competitors may have significantly more negotiating leverage or success with respect to individual payers than we or our collaborators may have.

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

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, 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 uncertainties 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 weight-management drugs, in general;
- actual sales to patients may significantly differ from expectations based on sales to wholesalers;
-

our collaborators control the commercialization of BELVIQ in most of the world, including related strategy and their allocation of resources, and we expect that any future collaborators for BELVIQ will similarly control the commercialization in the applicable territory; and

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

We expect that our revenues from BELVIQ will continue to be based in part on estimates, judgment and accounting policies, and incorrect estimates or regulators' or others' disagreement regarding such estimates or accounting policies may result in changes to guidance, projections or previously reported results. For example, with respect to the commercialization of BELVIQ in the United States, our revenues are based on information we receive from Eisai, including their estimates of deductions for certain items, such as taxes, credits, allowances, discounts, rebates, chargebacks and returns, which are subject to significant judgment and may change from time to time. We expect to continue to recognize revenues upon Eisai's sales to wholesalers. As BELVIQ is sold through to patients, if the actual level of deductions differs 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 and Mexico, 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 current marketing authorizations 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, South Korea and Mexico. 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 additional regulatory approvals of lorcaserin. 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, or MACE (non-fatal myocardial infarction, non-fatal stroke and cardiovascular death), 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 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 up to four more years, but the duration could be longer or shorter depending on the actual number of events observed. 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, South Korea and Mexico, 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 lorcaserin carries many risks and uncertainties, and our or others' lorcaserin regulatory submissions may not be satisfactory to the applicable regulatory authorities, including with regard to demonstrating adequate safety and efficacy for regulatory approval. We have made, and expect to make in the future, assumptions, estimations, calculations and decisions as part of our analyses of data and regulatory submissions, and the applicable regulatory authorities may not accept or agree with our assumptions, estimations, calculations, decisions or analyses, may interpret or weigh the importance of data differently or require additional information for approval.

Furthermore, as was the case with FDA approval, other regulatory approvals, even if obtained, may be limited to specific indications, limit the type of patients in which the drug may be used, or otherwise require specific warning or labeling language, any of which might reduce the commercial potential of lorcaserin. As with the FDA's approval of BELVIQ, regulatory authorities in other territories may condition marketing approval of lorcaserin on the conduct of specific postmarketing studies to further evaluate safety and efficacy, in either particular or general patient populations or both. The results of these studies, discovery of previously unknown issues involving safety or efficacy or failure to comply with post-approval regulatory requirements, including requirements with respect to manufacturing practices, reporting of adverse effects, advertising, promotion and marketing, may result in restrictions on the marketing of lorcaserin or the withdrawal of lorcaserin from the market.

With respect to the European Union, in 2013, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, identified major objections related to nonclinical and clinical issues, including tumors in rats, valvulopathy and psychiatric events, and the CHMP requested that we further justify lorcaserin's overall benefit-risk balance taking these issues into consideration with respect to the proposed indication of weight control. The major objections needed to be addressed before the CHMP could have recommended lorcaserin for marketing approval for weight control in the European Union. We did not believe we could resolve the major objections related to the results of nonclinical studies prior to the time we expected the CHMP to issue its final opinion, and, therefore, we withdrew the lorcaserin MAA for the European Union. We also previously received feedback with respect to regulatory applications in other territories that included major objections. We expect Eisai to submit for regulatory approval of lorcaserin in Europe and in other territories in the future, but such submissions may not occur when expected or ever. With respect to activities related to regulatory efforts and strategy, Eisai and we expect to continue to generate data from new studies and trials, as well as to continue analyzing existing data from previously conducted studies and trials, including for potential use in applications for the marketing approval of lorcaserin in Europe and other territories. As part of such efforts, Eisai and we may further analyze data from one of our long-term preclinical carcinogenicity studies for lorcaserin. While Eisai and we believe that such studies and analysis may be helpful with respect to regulatory applications, it is unknown whether any new data, or the results of such analysis, will be viewed favorably or if any data or results will positively or negatively impact any regulatory approvals, applications or strategy.

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

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

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

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

We developed lorcaserin to more selectively stimulate the serotonin 2C receptor than did fenfluramine or dexfenfluramine because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as “fen-phen”). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. In in vitro studies examining affinity, activity and serotonin receptor subtype specificity, lorcaserin demonstrated affinity for, and activity at, serotonin 2A, 2B and 2C receptors, but demonstrated greater affinity, activity and selectivity for the serotonin 2C receptor than for the serotonin 2A and 2B receptors. Activation of the latter two receptors has been associated with undesirable effects. Activation of the 2A receptor has been associated with central nervous system, or CNS, effects, including altered perception, mood and abuse potential, and activation of the 2B receptor has been associated with cardiac valvulopathy.

We may not be correct in our belief that more selectively stimulating the serotonin 2C receptor will avoid these undesired side effects, or lorcaserin’s selectivity profile may not be adequate to avoid these side effects. Lorcaserin’s selectivity profile and the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased

FDA or other regulatory scrutiny of the safety of lorcaserin, may raise potential adverse publicity and may affect enrollment of any future clinical trials or product sales. In addition, we cannot guarantee that any other regulatory authority will find our safety data to be sufficient to approve lorcaserin for marketing.

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

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

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

- our collaborators may not comply with applicable regulatory guidelines with respect to lorcaserin, which could adversely impact the commercialization or development of lorcaserin;
- there could be disagreements regarding the agreements or the study or development of lorcaserin that delay or terminate the commercialization, research, study or development of lorcaserin, delay or eliminate potential payments under the agreements or increase our costs under or outside of the agreements;
- our collaborators may not effectively allocate adequate resources or otherwise support lorcaserin or may have limited experience in a particular territory; and
- our collaborators may not perform as expected, including with regard to making any required payments, and the agreements may not provide adequate protection or may not be effectively enforced.

We and our collaborators have the right to terminate our agreements in certain circumstances. We could also agree with a collaborator to amend the terms of our agreement, and we or others, including investors and analysts, may not view any amendments as favorable. If any of our marketing and supply agreements for lorcaserin is terminated early, we may not be able to find another company to further develop and commercialize lorcaserin in the covered territory on acceptable terms, if at all, and even if we elected to pursue further development or commercialization of lorcaserin on our own, we might not have the funds or otherwise be able to do so successfully.

We may enter into additional agreements for the commercialization of BELVIQ or one or more of our drug candidates, and may be similarly dependent on the performance of third parties with similar and potentially company-specific risks.

We are responsible for supplying lorcaserin and certain drug candidates under our marketing and supply agreements, including for commercial sale. We do or will rely on other companies, including third-party manufacturers and sole-source suppliers, and we or such other companies may encounter failures or difficulties or not receive or provide adequate supply, which could adversely affect the commercial production of BELVIQ or the clinical development or regulatory approval of our drug candidates.

Under each of our marketing and supply agreements for lorcaserin, we are the exclusive supplier of lorcaserin. Our drug product manufacturing facility in Switzerland is currently our only source for finished drug product of lorcaserin. Without this facility, we would need to rely on third-party manufacturers for such production or develop or acquire such facilities, which, in either case, would require substantial time and funds. We estimate that it would take a year or longer and a substantial amount of financial and other resources to secure a second source for finished drug product of lorcaserin, and we may not be successful in securing a second source for such finished drug product.

In addition, we do not own or operate manufacturing facilities that can produce active pharmaceutical ingredient, or API, intermediates and other material required to make BELVIQ and our drug candidates, or finished drug product for all of our drug candidates. Instead, we currently contract with other companies to supply API, intermediates and other materials. Certain of these materials are available from only one or a small number of suppliers, and using a new supplier, if available, could result in substantial delay and greater cost. We expect Siegfried AG, or Siegfried, will be the only source of API for BELVIQ for at least the short term. Our dependence on one source of finished drug product and API, as well as our dependence on other third parties in the supply chain, may adversely affect our ability to develop and deliver drug products on a timely and competitive basis, or at all.

Any performance failure on the part of us or a third-party manufacturer could result in a product recall or seizure, delay or otherwise adversely affect the sales of BELVIQ or the clinical development or regulatory approval of lorcaserin or one or more of our other drug candidates. We or third-party manufacturers may encounter difficulties involving production yields, regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. For example, in December 2014, Eisai and we discovered that a small number of bottles of BELVIQ in a limited number of lots had a missing or incomplete label, and, as a precautionary measure, Eisai voluntarily initiated a recall from wholesalers of the involved lots for inspection.

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

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

In addition, we or our third-party manufacturers may encounter delays and problems in manufacturing our drug candidates or drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental unrest or changes, social unrest, intentional misconduct or other factors inherent in operating complex manufacturing facilities. Commercially available starting materials, reagents and excipients may be or become scarce or more expensive to procure, and we may not be able to obtain favorable terms in agreements with subcontractors. We or our third-party manufacturers may not be able to operate our respective manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If we or our third-party manufacturers cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

We may not be able to enter into or maintain agreements for the manufacture of BELVIQ or one or more of our drug candidates with manufacturers whose facilities and procedures comply with applicable law. Manufacturers are subject to ongoing periodic inspection (which may be unannounced) by the FDA, the DEA, corresponding state and foreign authorities and other regulatory authorities to ensure strict compliance with Current Good Manufacturing Practices, or cGMPs, regulations and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer's compliance with these regulations and standards. In addition, we have contracted with Siegfried to provide to us certain business and technical services, including safety, health and environmental services. We are, therefore, relying at least in part on Siegfried's judgment, experience and expertise. We intend to reduce or eliminate our dependence on Siegfried for such business and technical services, and any changes may result in increased cost, additional risk or otherwise negatively impact our operations. If we or one of our manufacturers fail to maintain compliance or otherwise experience setbacks, we or they could be subject to civil or criminal penalties, the production of BELVIQ or one or more of our drug candidates could be interrupted or suspended, or our product could be recalled or withdrawn, resulting in delays, additional costs and potentially lost revenues.

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

The results and timing of clinical trials and preclinical studies, as well as related decisions, can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies, which are sometimes referred to as nonclinical studies, include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies, including adverse effects, as well as related analyses of such results, of BELVIQ or one or more of our drug candidates (including development programs related to lorcaserin) may not be viewed favorably by us or third parties, including investors, analysts, current or potential collaborators, the academic and medical communities, and regulators. The same may be true of decisions regarding the focus and prioritization of our research and development efforts, how we design individual studies, trials and development programs of lorcaserin as well as for any of our drug candidates, and regulatory decisions (including by us or regulatory authorities) affecting our programs. Stock prices of companies in our industry have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate or product did not otherwise meet expectations.

We regularly have drug programs in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our drug candidates and those under collaboration agreements.

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

In addition, results of completed or new preclinical and clinical studies can be interpreted differently by regulatory agencies, us or others, and can negatively impact even approved products such as lorcaserin. Unfavorable results or delays with respect to studies, trials or analyses for lorcaserin could negatively impact market acceptance of lorcaserin, limit the revenues we generate from sales, negatively impact regulatory agencies' views or restrictions on lorcaserin, result in lorcaserin's withdrawal from the market and preclude us from being profitable.

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

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

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

We expect our collaborators to commercialize lorcaserin for at least weight management, subject to any applicable regulatory approval. We may not be able to maintain our marketing and supply agreements for lorcaserin or enter into new agreements for lorcaserin on acceptable terms, if at all. If we are unable to maintain or enter into agreements to commercialize lorcaserin and we develop or acquire our own capabilities to commercialize lorcaserin in any territory independently, we may require additional capital to develop such capabilities, and the marketing and sale of lorcaserin in such territory may be delayed or otherwise impeded by our lack of resources. We may not be successful in developing the requisite capabilities to commercialize lorcaserin without a collaborator. Even if we were able to do so, we have not previously commercialized a drug, and our limited experience may make us less effective at commercial planning, marketing and selling than a more experienced pharmaceutical company. Our lack of corporate experience and adequate resources may impede our efforts to successfully commercialize lorcaserin independently.

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

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

The preclinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to BELVIQ and our drug candidates are, and any other resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies. We are subject to periodic inspections (which may be unannounced) by the FDA, the DEA and other regulatory agencies, including inspections at Arena Pharmaceuticals GmbH, or Arena GmbH, by the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions that may negatively impact the commercialization of BELVIQ or approval of one or more of our drug candidates or otherwise negatively impact our business. Regulatory agencies have in the past inspected certain aspects of our business in the United States and Switzerland, and we were provided with observations of objectionable conditions or practices with respect to our business in the United States. We believe we satisfactorily addressed such observations, but there is no assurance that regulatory agencies will not provide us with observations in future inspections or that we satisfactorily addressed observations provided to us in past inspections.

Neither collaborators nor we are permitted to market a drug candidate in the United States until the particular drug candidate is approved for marketing by the FDA. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate. Following its review of an NDA or a response to a Complete Response Letter, or CRL, the FDA may approve the NDA or issue a CRL.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The FDA’s review goals are subject to change, and it is unknown whether any particular FDA review will be completed within the FDA’s review goals or will be delayed. Moreover, the duration of the FDA’s review may depend on the number and types of other submissions made to the FDA around the same time period.

As with BELVIQ, any drug that acts on the CNS has the potential to be scheduled as a controlled substance by the DEA. DEA scheduling is a separate process that can delay when a drug may become available to patients beyond the issuance of an NDA approval letter, and the timing and outcome of such DEA process is uncertain. For example, the FDA approved the NDA for BELVIQ in June 2012, subject to the final scheduling of BELVIQ by the DEA. The DEA’s final rule placing BELVIQ into Schedule IV of the Controlled Substances Act was not effective until June

2013. Although the Improving Regulatory Transparency for New Medical Therapies Act was signed into law in November 2015 in part to reset the effective date of FDA approval to coincide with DEA scheduling for applicable drugs, the FDA has taken the position that this change in the law does not apply to benefit BELVIQ. The scheduling designation can also change after it has been finalized. DEA scheduling ranges from I to V, with I being the most tightly controlled category. If BELVIQ were to be rescheduled into a different category, such scheduling could negatively impact the ability or willingness to prescribe or dispense BELVIQ, the likelihood that patients will use it and other aspects of our and Eisai's ability to commercialize it.

Regulatory approval of an NDA is not guaranteed, and our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval. The number and types of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. Despite the time and expense exerted in preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials.

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

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

We cannot predict when or whether, or assure you that, our collaborators' or our past or any future regulatory submissions or responses will be sufficient to the applicable regulatory authority or others, that the applicable regulatory authority or others will consider data or our analyses, interpretations or procedures related to any of our drug candidates as sufficient or persuasive, or that any regulatory authority will ever approve any of our drug candidates in the future.

To market any drugs outside of the United States, we and our current or future collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional risks, some of which may be unanticipated.

For example, the EMA guidelines provide that clinical trials assessing drug candidates intended for weight control should subject patients to a weight reducing diet run-in period, and our Phase 3 clinical trials of BELVIQ did not include a run-in period. Such EMA guidelines also provide primary and alternative primary efficacy criteria for weight-loss drug candidates. We believe BELVIQ will satisfy the EMA's alternative primary efficacy criterion, which is the proportion of responders achieving more than 10% weight loss at the end of a 12-month period. However, we do not believe BELVIQ meets the more stringent EMA primary efficacy criterion, which requires demonstrating weight loss of at least 10% of baseline weight that is also at least 5% greater than that associated with placebo. Also, with respect to our previously filed MAA for lorcaserin for weight management in the European Union, the EMA raised questions regarding the dropout rate in our clinical trials and how this affects the analysis of efficacy in those trials. We also previously received feedback with respect to regulatory applications in other territories that included major objections.

Regulatory approval of a drug in one territory does not ensure additional regulatory approval in such territory (such as approval of the drug in combination with other drugs, for other indications or using different formulations) or regulatory approval in another territory, but a failure or delay in obtaining regulatory approval may negatively impact other regulatory processes. Failure to obtain regulatory approval in a territory, any delay or setback in obtaining such approval, or our regulatory strategy or decisions could adversely affect the regulatory approval or commercialization of our drug candidates in other territories, including that our drug candidates may not be approved for all indications requested, that such approval may be subject to limitations on the indicated uses for which the drug may be marketed, and with regard to the pricing or reimbursement of any approved drugs.

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

Our drugs will still be subject to extensive postmarketing regulation if approved.

Following regulatory approval of any of our drug candidates, we and our collaborators will be subject to ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements. As with BELVIQ, there may also be additional postmarketing obligations imposed by the FDA or other regulatory agencies. These obligations may result in significant expense and limit the ability to commercialize such drugs.

The FDA or other regulatory agencies may also require that the sponsor of the NDA or foreign equivalent, as applicable, conduct additional clinical trials to further assess approved drugs after approval under a post-approval commitment. Such additional studies may be costly and may impact the commercialization of the drug. For example, as part of the approval of BELVIQ, the FDA required the conduct of the CVOT described above as well as postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric and adolescent patients. Along with being costly and time consuming, a delay or unfavorable results from these trials could negatively impact market acceptance of BELVIQ; limit the revenues we generate from sales; result in BELVIQ's withdrawal from the market; negatively impact the potential approval of lorcaserin in other territories for weight management, for other indications, in combination with other agents or using different formulations; and preclude us from being profitable.

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

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

If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, such noncompliance could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions, including:

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

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

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

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

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

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

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

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

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

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

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

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

Setbacks and consolidation in the pharmaceutical and biotechnology industries could make entering into agreements with pharmaceutical companies to collaborate or commercialize our drugs more difficult and diminish our revenues.

Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to drugs or drug candidates, as well as competition from generic drugs, litigation and industry consolidation, may have an adverse effect on us, including by making it more difficult to enter into agreements with pharmaceutical companies to collaborate or commercialize our drugs and diminishing our revenues. For example, the FDA may be more cautious in approving our drug candidates based on safety concerns relating to these or other drugs or drug candidates, or pharmaceutical companies may be less willing to enter into new collaborations or continue existing collaborations if they are integrating a new operation as a result of a merger or acquisition or if their therapeutic areas of focus change following a merger.

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

In the course of our discovery, preclinical testing and clinical trials, we and our collaborators may from time to time rely on third parties, including laboratories, investigators, clinical research organizations and manufacturers, to perform critical services. For example, we rely on third parties to conduct our clinical trials and many of our preclinical studies. Clinical research organizations are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as Good Clinical Practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our preclinical studies or clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with regulatory requirements and our protocols, our preclinical studies or clinical trials may not meet regulatory requirements or may need to be repeated. As a result of our dependence on third parties, we may face delays or failures outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

We may participate in new strategic transactions that could impact our liquidity, increase our expenses, present significant distractions to our management and be viewed as unfavorable.

From time to time we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. Additional potential transactions we may consider include a variety of different business arrangements, such as strategic collaborations, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transaction may be viewed as unfavorable by our stockholders or others and may require us to incur non-recurring or other charges, may create potential liabilities, may increase our near- and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or business, which could harm our operations and financial results.

As part of an effort to enter into significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from any transaction we may consummate, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected.

We may incur substantial liabilities for any product liability claims or otherwise as a drug product manufacturer.

We develop, test, manufacture and expect to commercialize drugs for use by humans. We face an inherent risk of product liability exposure related to the testing of our drug candidates in clinical trials, and face an even greater risk with the commercialization of BELVIQ as well as any other drug that may be approved for marketing. In addition, under the marketing and supply agreement with Eisai, Arena GmbH and Eisai will, in general, share equally in losses resulting from third-party product liability claims, with certain limited exceptions.

Whether or not we are ultimately successful in any product liability or related litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. In addition, damages awarded in a product liability action could be substantial and could have a negative impact on our financial condition.

An individual may bring a liability claim against us if one of our drugs or drug candidates causes, or merely appears to have caused, an injury. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our drug;
- injury to our reputation;
- increased difficulty to attract, or withdrawal of, clinical trial subjects;
- costs of related litigation;
- substantial monetary awards to subjects or other claimants;
- loss of revenues; and
- the inability to commercialize our drug candidates.

We will have limited product liability insurance that covers our clinical trials and products. We may not be able to maintain or obtain insurance coverage at a reasonable cost, and we may not have insurance coverage that will be adequate to satisfy any liability that may arise, which could have an adverse effect on our results of operations and financial condition.

We expect that Arena GmbH will, from time to time, manufacture BELVIQ for commercialization and lorcaserin and other drug candidates for clinical trials or other studies and potentially commercialization. Arena GmbH will also, from time to time, manufacture certain drug products for other companies. Arena GmbH is subject to liability for non-performance, product recalls and breaches of the agreements with our collaborators and other third parties.

*We have significant contractual obligations, which may adversely affect our cash flow, cash position and stock price.

We have long-term leases on real properties and other contractual obligations. In addition, under our marketing and supply agreement with Eisai, we are obligated to pay 10% of the required portion of the ongoing CVOT, and to share costs for the non-required portion of the CVOT and any future clinical studies in territories outside the United States. If we are unable to generate cash from operations sufficient to meet our financial obligations, we will need to obtain additional funds from other sources, which may include one or more financings. However, we may be unable to obtain sufficient additional funds when we need them on favorable terms or at all. The sale of equity or convertible debt securities or other financing transaction in the future may be dilutive to our stockholders, and some financing arrangements may require us to enter into covenants that would further restrict certain business activities or our ability to incur additional indebtedness or conduct other financing transactions, and may contain other terms that are not favorable to our stockholders or us.

Also, if we are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet our contractual obligations, or we need to use existing cash to fund our contractual obligations, we may have to delay or curtail some or all of our development and commercialization programs, sell or license some or all of our assets on terms that you or others may view as unfavorable, or default under our agreements. Our contractual obligations could have significant additional negative consequences, including, without limitation:

- increasing our vulnerability to general adverse economic conditions;
- limiting our ability to obtain additional funds;
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources; and
- litigation or other disagreements.

We may be subject, directly or indirectly, to federal and state healthcare laws, including but not limited to fraud and abuse and false claims laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties and prosecution.

In the United States, drug manufacturers and marketers are subject to various state and federal fraud and abuse laws, including, without limitation, the Federal Anti-Kickback Statute and Federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the research, manufacturing, sales, marketing and education programs for our drugs.

The Federal Anti-Kickback Statute prohibits persons and entities from knowingly and willingly soliciting, offering, receiving or providing any remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the purchase, lease, order or the furnishing or arranging for, a good, item, facility or service, for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Federal Anti-Kickback Statute is broad and, despite a series of narrow statutory exceptions and regulatory safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Moreover, the ACA, among other things, amended the intent requirement of the Federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. The ACA also provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal Civil False Claims Act. Many states have also adopted laws similar to the Federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The Federal Civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the Federal Civil False Claims Act can be brought by any individual on behalf of the government, known as "qui tam" actions, and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The filing of qui tam actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend a Federal Civil False Claims Act action. When an entity is determined to have violated the Federal Civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim, in addition to other penalties that may apply. Various states have also enacted laws modeled after the Federal Civil False Claims Act, some of which are broader in scope and may apply regardless of payer.

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

The Federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the US Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information.

Additionally, the Drug Supply Chain Security Act imposes obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We are unable to predict whether we could be subject to actions under any of these fraud and abuse or other laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil, criminal and/or administrative penalties, damages, fines, individual imprisonment, disgorgement, possible exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

*We may not be able to effectively integrate, manage or maintain our international operations, and such difficulty could adversely affect our business operations, financial condition, results of operations and stock price.

The headquarters of our operations outside of the United States is in Switzerland. Activities conducted in Switzerland include clinical operations and regulatory, manufacturing, quality control, quality assurance, development of manufacturing processes, qualifying suppliers and otherwise managing aspects of the supply chain, regulatory compliance, distribution of finished products, alliance management, and strategic planning and development. We also have drug candidates in clinical trials outside of the United States. There are significant risks associated with foreign operations, including, but not limited to, compliance with local laws and regulations, the protection of our intellectual property, the ability to integrate our corporate culture with local customs and cultures, the distraction to our management, foreign currency exchange rates and the impact of shifts in the United States and local economies on those rates, and integration of our policies and procedures, including disclosure controls and procedures and internal control over financial reporting, with our international operations.

With respect to local laws and regulations, the European Union, Switzerland and certain other foreign territories have restrictions on the transfer, use and maintenance of certain personal data, including providing that transfers of personal data outside of their territories may only take place if the country to which the personal data is transferred ensures an "adequate" level of privacy protection. The European Commission has previously found that the United States did not provide adequate levels of protection. Any restrictions on our data transfers may negatively impact our ability and increase our costs to maintain international operations, including our Swiss manufacturing facility and clinical trials and other studies.

In October 2015 and July 2016, we initiated measures to reduce our expenditures and streamline our operations in Switzerland, including changes with respect to the staffing, process, procedures and strategy relating our Swiss manufacturing facility and our ongoing Phase 2 clinical trials. These staffing and other changes may increase risks related to our international operations as well as our operations in general.

We use biological materials, hazardous materials, chemicals and radioactive compounds.

Our research, development and manufacturing activities involve the use of potentially harmful biological materials, as well as materials, chemicals and various radioactive compounds that could be hazardous to human health and safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. We cannot completely eliminate the risk of contamination, which could cause:

- interruption of our research, development or manufacturing efforts;
- injury to our employees and others;
- environmental damage resulting in costly clean up; and
- liabilities under domestic or foreign laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

In such an event, we may be held liable for any resulting damages, and any such liability could exceed our resources. Although we carry insurance in amounts and type that we consider commercially reasonable, we cannot be certain that the coverage or coverage limits of our insurance policies will be adequate, and we do not have insurance coverage for losses relating to an interruption of our research and development efforts caused by contamination.

*Our business and operations might be adversely affected by business disruptions and security breaches, including any cybersecurity incidents.

Our US operations are located in a business park in San Diego. We also have a drug product manufacturing facility in Zofingen, Switzerland, and we expect that, at least for the near-term, this facility will be the sole location for the manufacturing of BELVIQ finished drug product. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in Europe and Asia. Natural disasters or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, disruption in transportation networks or delivery services, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors.

We depend on the efficient and uninterrupted operation of our computer and communications systems, which we use for, among other things, sensitive company data, including our financial data, intellectual property and other proprietary business information.

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

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

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

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

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

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

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

Negative US and global economic conditions may pose challenges to our business strategy, which relies on funding from collaborators or the financial markets, and creates other financial risks for us.

Negative conditions in the US or global economy, including financial markets, may adversely affect our business and the business of our current and prospective collaborators, distributors and licensees, which we sometimes refer to generally as our collaborators, and others with which we do or may conduct business. The duration and severity of these conditions is uncertain. If negative economic conditions persist or worsen, we may be unable to secure funding to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our research and development or business development efforts. Such negative conditions could also impact commercialization of BELVIQ or any other drugs we develop as well as our financial condition.

From time to time, we may maintain a portfolio of investments in marketable debt securities, which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, we rely on credit rating agencies to help evaluate the riskiness of investments, and such agencies may not accurately predict such risk. In addition, such agencies may reduce the credit quality of our individual holdings, which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

Currency fluctuations may negatively affect our financial condition.

We primarily spend and generate cash in US dollars, and present our consolidated financial statements in US dollars. However, a portion of our expected and potential payments and receipts under our agreements are in foreign currencies, including Swiss francs. For example, payments and receipts under our agreements with Siegfried are required to be paid in Swiss francs. A fluctuation of the exchange rates of foreign currencies versus the US dollar may, thus, adversely affect our financial results, including cash balances, expenses and revenues. We may in the future enter into hedging transactions to try to reduce our foreign currency exposure, but there is no assurance that such transactions will occur or be successful.

Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers; our disclosure controls and procedures and our internal control over financial reporting may not prevent potential errors and fraud.

Laws and regulations affecting public companies, including rules adopted by the SEC and by NASDAQ, as well as the laws and regulations of foreign governments, may result in increased costs to us, particularly as we continue to develop the required capabilities in the United States and abroad to commercialize our products. These laws, rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all potential errors and fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. There are inherent limitations in all control systems, and no system of controls can provide absolute assurance that all control issues and instances of fraud, if any, or misstatements due to error, if any, within the company have been detected. While we believe that our disclosure controls and procedures and internal control over financial reporting are and have been effective at the reasonable assurance level, we intend to continue to examine and refine our disclosure controls and procedures and internal control over financial reporting and to monitor ongoing developments in these areas.

Risks Relating to Our Intellectual Property

Our success is dependent on intellectual property rights held by us and third parties and our interest in these rights is complex and uncertain.

Our success will depend on our own and on current or future collaborators' abilities to obtain, secure and defend patents. In particular, the patents directed to BELVIQ and our drug candidates are important to commercializing drugs. We have numerous US and foreign patent applications pending for our technologies. There is no assurance that any of our patent applications will issue, or that any of the patents will be enforceable or will cover a drug or other commercially significant technology or method, or that the patents will be held to be valid for their expected terms.

The procedures for obtaining a patent in the United States and in most foreign countries are complex. These procedures require an analysis of the scientific technology related to the invention and many sophisticated legal issues. Obtaining patent rights outside the United States often requires the translation of highly technical documents and an improper translation may lead to the loss of, or otherwise jeopardize, the patent protection of our inventions. Ensuring adequate quality of translators and foreign patent attorneys is often very challenging. Consequently, the process for having our pending patent applications issue as patents will be difficult, complex and time consuming. Our patent position is very uncertain and we do not know when, or if, we will obtain additional patents for our technologies, or if the scope of the patents obtained will be sufficient to protect our drugs, or be considered sufficient by parties reviewing our patent positions pursuant to a potential marketing, licensing or financing transaction.

In addition, other entities may challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. Even the issuance of a patent is not conclusive as to its validity or enforceability. We cannot make assurances as to how much protection, if any, will be given to our patents if we attempt to enforce them or they are challenged. It is possible that a competitor or a generic pharmaceutical provider may successfully challenge our patents and those challenges may result in reduction or elimination of our patents' coverage.

We also rely on confidentiality agreements and trade secrets to protect our technologies. However, such information is difficult to protect. We require our employees to contractually agree not to improperly use our confidential information or disclose it to others, but we may be unable to determine if our employees have conformed or will conform to their legal obligations under these agreements. We also enter into confidentiality agreements with prospective collaborators, collaborators, service providers and consultants, but we may not be able to adequately protect our trade secrets or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of this information. Many of our employees and consultants were, and many of them may currently be, parties to confidentiality agreements with other pharmaceutical and biotechnology companies, and the use of our technologies could violate these agreements. In addition, third parties may independently discover our trade secrets or proprietary information.

Some of our academic institution licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries before we have the opportunity to file patent applications on such discoveries. In some of our collaborations, we do not control our collaborators' ability to disclose their own discoveries under the collaboration and in some of our academic collaborations we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain the confidentiality of our technologies and other confidential information in connection with our collaborations, our ability to receive patent protection or protect our proprietary information will be impaired.

We believe that the United States is by far the largest single market for pharmaceuticals in the world. Because of the critical nature of patent rights to our industry, changes in US patent laws could have a profound effect on our future profits, if any. It is unknown which, if any, patent laws will change, how changes to the patent laws will ultimately be enforced by the courts and the impact on our business. For example, in September 2011, the America Invents Act was signed into US law, which changes include, among others, the awarding of a patent to the first inventor to file a patent as opposed to the first inventor to make an invention and the creation of new administrative procedures for challenging US patents. It may be several years before the impact of the America Invents Act on patent law is understood, and we cannot predict with certainty whether or to what extent the changes may impair our business.

*A dispute regarding the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be costly and result in delays or termination of our future research, development, manufacturing and sales activities.

Our commercial success depends upon our ability to develop and manufacture our drugs and drug candidates, market and sell drugs, and conduct our research and development activities without infringing or misappropriating the proprietary rights of others. There are many patents and patent applications filed, and that may be filed, by others relating to drug discovery and development programs that could be determined to be similar, identical or superior to ours or our licensors or collaborators. We may be exposed to future litigation by others based on claims that our drugs, drug candidates, technologies or activities infringe the intellectual property rights of others. Numerous US and foreign issued patents and pending patent applications owned by others exist in the area of G protein-coupled receptors, or GPCRs, including some which purport to allow the patent holder to control the use of all drugs that modulate a particular drug target or GPCR, regardless of whether the infringing drug bears any structural resemblance to a chemical compound known to the patent holder at the time of patent filing. Numerous US and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we are developing drugs. There are also numerous issued patents and patent applications to chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. These could materially affect our ability to develop our drug candidates or manufacture, import or sell drugs, and our activities, or those of our licensors or collaborators, could be determined to infringe these patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our drugs, drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our drug candidates or technologies may infringe. Further, there may be issued patents or pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe (i) are invalid, unenforceable, or we do not infringe; (ii) relate to immaterial portions of our overall drug discovery, development, manufacturing and commercialization efforts; or (iii) in the case of pending patent applications, the resulting patent would not be granted or, if granted, would not likely be enforced in a manner that would materially impact such efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, unenforceability, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

In addition, others may infringe or misappropriate our proprietary rights, and we may have to institute costly legal action to protect our intellectual property rights. We may not be able to afford the costs of enforcing or defending our intellectual property rights against others.

There could be significant litigation and other administrative proceedings in our industry that affect us regarding patent and other intellectual property rights. Any legal action or administrative action against us, or our collaborators, claiming damages or seeking to enjoin commercial activities relating to our drug discovery, development, manufacturing and commercialization activities could:

- require us, or our collaborators, to obtain a license to continue to use, manufacture or market the affected drugs, methods or processes, which may not be available on commercially reasonable terms, if at all;
- prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject us to potential liability for damages;
- consume a substantial portion of our managerial, scientific and financial resources; or
- be costly, regardless of the outcome.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

We are aware of third-party patents, as well as third-party patent applications, that could adversely affect the potential commercialization of etrasimod. For example, we are aware of a third-party patent, as well as third-party patent applications, with broad claims to administering an $S1P_1$ receptor agonist by starting with a lower dose and then increasing to a higher, standard daily dose. While we do not believe that any such claims that would cover the potential commercialization of etrasimod are valid and enforceable, we may be incorrect in this belief. In addition, other patents may issue from third-party patent applications with respect to certain dosing regimens, which could also adversely affect the potential commercialization of etrasimod, if etrasimod is approved with a specific dosing regimen.

We have been contacted from time to time by third parties regarding their intellectual property rights, sometimes asserting that we may need a license to use their technologies. For example, a third party has communicated that it believes its issued US patents include patent claims that cover BELVIQ or its use. We do not believe such patent claims are valid or, even if they were held valid, that they cover BELVIQ or its use. If we fail to obtain any required licenses or make any necessary changes to our technologies, we may become involved in expensive and time-consuming litigation or we may be unable to develop or commercialize some or all of our drugs or drug candidates.

We and Eisai have filed a patent infringement lawsuit against an ANDA filer relating to a “Paragraph IV certification.” While we intend to vigorously enforce our intellectual property rights relating to BELVIQ, we cannot predict the outcome of any litigation matter. For example, our existing patents could be invalidated, found unenforceable or found not to cover a generic form of BELVIQ. If an ANDA filer were to prevail in patent litigation and/or receive approval to sell a generic version of BELVIQ, BELVIQ would become subject to increased competition and our revenue would be adversely affected.

We cannot protect our intellectual property rights throughout the world.

Filing, prosecuting, defending and enforcing patents on all of our drug discovery technologies and all of our potential drug candidates throughout the world would be prohibitively expensive. Competitors may use our technologies to develop their own drugs in jurisdictions where we have not obtained patent protection. These drugs may compete with our drugs, if any, and may not be covered by any of our patent claims or other intellectual property rights. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to “work” the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our drug candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Risks Relating to Our Securities

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

Our stock price has fluctuated historically. From January 1, 2014, to November 4, 2016, the market price of our stock was as low as $1.30 per share and as high as $7.97 per share.

Very few drug candidates being tested will ultimately receive regulatory approval, and companies in our industry sometimes experience significant volatility in their stock price. Our stock price may fluctuate significantly depending on a variety of factors, including:

- regulatory actions or decisions or legislation affecting lorcaserin, including decisions of regulatory authorities relating to lorcaserin, or other drugs or drug candidates, including those of our competitors;
- the commercial availability and success or failure of BELVIQ (including perceptions of prescription trends or other information) or any of our drug candidates;
- the development and implementation of our continuing development and research plans, including outcome studies and other research and development for lorcaserin (including related development programs);

- the entrance into, or failure to enter into, a new collaboration or the modification or termination of an existing collaboration or other material transaction;
- the timing and receipt by us of milestone and other payments or failing to achieve and receive the same;
- fluctuation in prescriptions, sales or financial results (including with respect to revenue recognition) or inaccurate sales or cash forecasting;
- accounting restatements and changes;
- supply chain or manufacturing issues;
- discussions or recommendations affecting our drugs or drug candidates by FDA advisory committees or other reviewers of preclinical or clinical data or other information related to lorcaserin, drug candidates or other drugs;
- results or decisions affecting the development or commercialization of BELVIQ or any of our drug candidates, including the results of studies, trials and other analyses;
- the timing of the development of our drug candidates;
- changes in our research and development budget or the research and development budgets of our existing or potential collaborators;
- the introduction, development or withdrawal of drug candidates or drugs by others that target the same diseases and conditions that we or our collaborators target or the introduction of new drug discovery techniques;
- the success, failure or setbacks of our or a perceived competitor's drugs or drug candidates;
- expenses related to, and the results of, litigation, other disputes and other proceedings;
- financing strategy or decisions;
- the allocation of our resources;
- our ability, or the perception by investors of our ability, to continue to meet all applicable requirements for continued listing of our common stock on the The NASDAQ Stock Market, and the possible delisting of our common stock if we are unable to do so;
- developments in intellectual property rights or related announcements; and
- capital market conditions.

We are not able to control many of these factors. If our financial or scientific results in a particular period do not meet stockholders' or analysts' expectations, our stock price may decline and such decline could be significant.

Any future equity or debt issuances or other financing transactions may have dilutive or adverse effects on our existing stockholders.

We have been opportunistic in our efforts to obtain cash, and we expect to continue to evaluate various funding alternatives from time to time. We have primarily financed our operations, and we may continue to finance our operations, by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. We may issue additional shares of common stock or convertible securities that could dilute your ownership in our company and may include terms that give new investors rights that are superior to yours. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. In addition, we may also raise additional funds through the incurrence of debt or other financing transaction, and the investors may have rights superior to your rights in the event we are not successful and are forced to seek the protection of bankruptcy laws or the transaction may otherwise adversely affect our business prospects and existing stockholders.

*There are a substantial number of shares of our common stock that may become eligible for future sale in the public market, and the sale of our common stock could cause the market price of our common stock to fall.

As of November 4, 2016, there were (i) options to purchase 25,557,696 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of $3.20 per share, (ii) 582,349 restricted stock unit awards outstanding under our equity incentive plans, (iii) performance restricted stock unit awards outstanding under our equity incentive plans targeted at 931,667 shares (however, the actual number of shares that may be awarded ranges from 0% to 200% of such amount), (iv) 16,985,776 additional shares of common stock remaining issuable under our 2013 Long-Term Incentive Plan, as amended, (v) 1,126,635 shares of common stock remaining issuable under our 2009 Employee Stock Purchase Plan, as amended, and (vi) 62,501 shares of common stock remaining issuable under our Deferred Compensation Plan.

Once issued, the shares described above will be available for immediate resale in the public market. The market price of our common stock could decline as a result of such resales due to the increased number of shares available for sale in the market. As of November 4, 2016, there were 243,313,807 shares of our common stock outstanding.

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

A small number of stockholders may hold or acquire a significant amount of our outstanding stock. From time to time, there is a large short interest in our stock. These holders of such stock or positions may seek control of us, support transactions that we or you do not believe are favorable, and have interests that are different from yours. In addition, sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

We may also be involved in disagreements with the holders of our stock, warrants or other securities in the future. Such disagreements may lead to proxy contests or litigation, which may be expensive and consume management's time, involve settlements, the terms of which may not be favorable to us, or result in other negative consequences to our business.

Certain of our agreements, provisions in our charter documents, possible future agreements and Delaware law could delay or prevent a change in management or a takeover attempt that you may consider to be in your best interests.

There is a standstill provision in our marketing and supply agreement with Eisai, and we may enter into agreements with similar provisions. In addition, we may in the future adopt a stockholders' rights agreement, which would cause substantial dilution to any person who attempts to acquire us in a manner or on terms not approved by our board of directors. These provisions or agreements, as well as other provisions in our certificate of incorporation and bylaws and under Delaware law, could delay or prevent the removal of directors and other management and could make more difficult a merger, tender offer or proxy contest involving us that you may consider to be in your best interests. For example, our charter provisions:

- allow our board of directors to issue preferred stock without stockholder approval;
- limit who can call a special meeting of stockholders;
- eliminate stockholder action by written consent; and
- establish advance notice requirements for nomination for election to the board of directors or for proposing matters to be acted upon at stockholders' meetings.

Item 6. Exhibits.

EXHIBIT NO.	DESCRIPTION
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena’s quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena’s registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena’s registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Certificate of Amendment No. 3 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.4 to Arena’s registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
3.5	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena’s current report on Form 8-K filed with the Securities and Exchange Commission on October 9, 2014, Commission File No. 000-31161)
4.1	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to Arena’s registration statement on Form S-1, as amended, filed with the Securities and Exchange Commission on July 19, 2000, Commission File No. 333-35944)
10.1*	2013 Long-Term Incentive Plan, as amended in May, June and August 2016
10.2*	Amendment No. 2, effective August 15, 2016, to Amended and Restated Severance Benefit Plan, effective May 9, 2016 and amended on June 13, 2016, and, as amended, providing benefits for Drs. Audet, Behan and Shanahan and Messrs. Aurentz, Lind, Mezzino and Spector
10.3*	Employment Agreement, dated as of August 9, 2016, between Arena and Vincent E. Aurentz
10.4*	Consulting Agreement dated July 15, 2016, between Arena and William R. Shanahan, Jr.
10.5*	Consulting Agreement dated September 1, 2016, between Arena and Dominic P. Behan
31.1	Certification of principal executive officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of principal financial officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934

32.1	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan or arrangement.

SIGNATURES

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

Date:	November 9, 2016	ARENA PHARMACEUTICALS, INC.

By: /s/ Amit Munshi
Amit Munshi
President and Chief Executive Officer (principal executive officer)

By: /s/ Kevin R. Lind
Kevin R. Lind
Executive Vice President and Chief Financial Officer (principal financial and accounting officer)

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena’s quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena’s registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena’s registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Certificate of Amendment No. 3 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.4 to Arena’s registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
3.5	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena’s current report on Form 8-K filed with the Securities and Exchange Commission on October 9, 2014, Commission File No. 000-31161)
4.1	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to Arena’s registration statement on Form S-1, as amended, filed with the Securities and Exchange Commission on July 19, 2000, Commission File No. 333-35944)
10.1*	2013 Long-Term Incentive Plan, as amended in May, June and August 2016
10.2*	Amendment No. 2, effective August 15, 2016, to Amended and Restated Severance Benefit Plan, effective May 9, 2016 and amended on June 13, 2016, and, as amended, providing benefits for Drs. Audet, Behan and Shanahan and Messrs. Aurentz, Lind, Mezzino and Spector
10.3*	Employment Agreement, dated as of August 9, 2016, between Arena and Vincent E. Aurentz
10.4*	Consulting Agreement dated July 15, 2016, between Arena and William R. Shanahan, Jr.
10.5*	Consulting Agreement dated September 1, 2016, between Arena and Dominic P. Behan
31.1	Certification of principal executive officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of principal financial officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934

32.1	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan or arrangement.

53