ARENA PHARMACEUTICALS INC
Form 10-Q
November 08, 2018

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, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

858.453.7200

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Small reporting company
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 2, 2018:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	49,406,452

ARENA PHARMACEUTICALS, INC.

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TRADEMARKS AND CERTAIN TERMS

Arena Pharmaceuticals ® and Arena ® are registered service marks of Arena. Any other brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective holders.

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 508,663	$ 158,837
Short-term investments, available-for-sale	52,961	88,240
Accounts receivable	1,329	2,357
Insurance recovery receivable	—	12,025
Prepaid expenses and other current assets	9,524	2,681
Assets of disposal group held for sale	—	17,140
Total current assets	572,477	281,280
Investments, available-for-sale	—	24,242
Land, property and equipment, net	27,836	30,131
Other non-current assets	9,721	3,622
Total assets	$ 610,034	$ 339,275
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 7,975	$ 7,916
Accrued clinical and preclinical study fees	9,793	7,706
Accrued litigation settlement	—	24,000
Current portion of deferred revenues	800	1,110
Current portion of lease financing obligations	3,384	4,000
Liabilities of disposal group held for sale	—	27,595
Total current liabilities	21,952	72,327
Other long-term liabilities	1,019	989
Deferred revenues, less current portion	415	1,067
Lease financing obligations, less current portion	55,332	57,748
Commitments and contingencies		
Stockholders' equity:		
Common stock	5	4
Additional paid-in capital	2,100,594	1,698,543
Accumulated other comprehensive loss	(20)	(1,216)
Accumulated deficit	(1,569,263)	(1,490,187)
Total stockholders' equity	531,316	207,144

Total liabilities and stockholders' equity	$ 610,034	$ 339,275

See accompanying notes to unaudited condensed consolidated financial statements.

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,	
	2018	2017	2018	2017
Revenues:				
Collaboration and other revenue	$363	$1,881	$4,524	$5,439
Royalty revenue	3,210	534	4,798	534
Total revenues	3,573	2,415	9,322	5,973
Operating Costs and Expenses:				
Research and development	28,811	17,233	77,139	50,277
General and administrative	10,766	7,418	32,322	22,088
Litigation settlement expense, net	—	11,975	—	11,975
Total operating costs and expenses	39,577	36,626	109,461	84,340
Loss from operations	(36,004)	(34,211)	(100,139)	(78,367)
Interest and Other Income (Expense):				
Interest income	2,524	13	5,800	63
Interest expense	(1,423)	(1,516)	(4,344)	(4,624)
Other income	589	444	1,403	1,344
Total interest and other income (expense), net	1,690	(1,059)	2,859	(3,217)
Loss from continuing operations	(34,314)	(35,270)	(97,280)	(81,584)
Income (loss) from discontinued operations	—	2,606	(830)	2,807
Net loss	(34,314)	(32,664)	(98,110)	(78,777)
Less net loss attributable to noncontrolling interest in consolidated variable interest entity	—	311	—	1,054
Net loss attributable to stockholders of Arena	$(34,314)	$(32,353)	$(98,110)	$(77,723)
Amounts attributable to stockholders of Arena:				
Loss from continuing operations	$(34,314)	$(34,959)	$(97,280)	$(80,530)
Income (loss) from discontinued operations	—	2,606	(830)	2,807
	$(34,314)	$(32,353)	$(98,110)	$(77,723)
Net income (loss) attributable to stockholders of Arena per share, basic and diluted:				
Continuing operations	$(0.70)	$(0.93)	$(2.10)	$(2.32)
Discontinued operations	—	0.07	(0.02)	0.08
	$(0.70)	$(0.86)	$(2.12)	$(2.24)

Shares used in calculating net income (loss) attributable to stockholders of Arena per share, basic and diluted:	49,368	37,766	46,243	34,692
Comprehensive Loss:				
Net loss	$(34,314)	$(32,664)	$(98,110)	$(78,777)
Foreign currency translation gain (loss)	65	(443)	32	2,271
Unrealized gain on available-for-sale investments	93	—	62	—
Comprehensive loss	(34,156)	(33,107)	(98,016)	(76,506)
Less comprehensive loss attributable to noncontrolling interest in consolidated variable interest entity	—	311	—	1,054
Comprehensive loss attributable to stockholders of Arena	$(34,156)	$(32,796)	$(98,016)	$(75,452)

See accompanying notes to unaudited condensed consolidated financial statements.

ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Operating Activities:		
Net loss	$(98,110)	$(78,777)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Income) loss from discontinued operations	830	(2,807)
Depreciation and amortization	2,863	3,234
Non-cash collaboration consideration	(1,500)	—
Non-cash royalty revenue	(2,493)	—
Share-based compensation	13,729	5,758
Litigation settlement expense, net	—	11,975
Amortization of prepaid financing costs	83	102
Amortization of original issue discounts, net of premiums, on available-for-sale investments	129	—
Gain on disposal of property and equipment	—	(379)
Changes in operating assets and liabilities:		
Accounts receivable	1,000	11,651
Prepaid expenses and other assets	(3,002)	(1,245)
Payables and accrued liabilities	2,015	(2,567)
Accrued litigation settlement	(11,975)	—
Deferred revenues	(846)	(3,207)
Other long-term liabilities	(879)	(303)
Net cash used in operating activities - continuing operations	(98,156)	(56,565)
Net cash used in operating activities - discontinued operations	(370)	(3,929)
Net cash used in operating activities	(98,526)	(60,494)
Investing Activities:		
Purchases of available-for-sale investments	(25,579)	—
Proceeds from sale and maturity of available-for-sale investments	85,033	—
Purchases of property and equipment	(568)	(26)
Proceeds from sale of property and equipment	—	789
Other non-current assets	1	(5)
Net cash provided by investing activities - continuing operations	58,887	758
Net cash provided by investing activities - discontinued operations	3,405	31
Net cash provided by investing activities	62,292	789
Financing Activities:		
Principal payments on lease financing obligations	(3,032)	(2,588)
Proceeds from issuance of common stock, net	388,479	248,329

Net cash provided by financing activities	385,447	245,741
Effect of exchange rate changes on cash	613	1,990
Net increase in cash, cash equivalents and restricted cash	349,826	188,026
Cash, cash equivalents and restricted cash at beginning of period	159,700	91,575
Cash, cash equivalents and restricted cash at end of period	$509,526	$279,601

See accompanying notes to unaudited condensed consolidated financial statements.

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, 2017, as filed with the Securities and Exchange Commission, or SEC, from which we derived our condensed consolidated balance sheet as of December 31, 2017. The accompanying condensed 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 condensed consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying condensed 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.

Beacon Discovery, Inc., or Beacon, is a variable interest entity in which we had a controlling financial interest until December 2017. The results of operations and comprehensive loss attributable to the noncontrolling interest in Beacon are 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 for the three and nine months ended September 30, 2017. We deconsolidated Beacon in December 2017 (see Note 13).

Liquidity.

As of September 30, 2018, we had cash, cash equivalents and available-for-sale investments of approximately $561.6 million. We believe our cash and cash equivalents and available-for-sale investments will be sufficient to fund our operations for at least the next 12 months.

We will require substantial cash to achieve our objectives of discovering, developing and commercializing drugs, as this process typically takes many years and potentially 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, programs or patent portfolios, or from other potential sources of liquidity, which may include the sale of equity, issuance of debt or other transactions.

Changes in Accounting Policies - Revenue Recognition.

Effective January 1, 2018, we adopted Accounting Standard Codification 606, Revenue from Contracts with Customers, or ASC 606, issued by the Financial Accounting Standards Board, or FASB. As a result, we have changed our accounting policy for revenue recognition as detailed below.

We implemented ASC 606 using the modified retrospective method by recognizing the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of our accumulated deficit at January 1, 2018. Therefore,

the comparative period information has not been adjusted.

We applied ASC 606 using a practical expedient for contracts that were modified before the implementation date, which allowed us to determine an aggregate effect of all modifications that occurred before January 1, 2018, when determining the satisfied and unsatisfied performance obligations, the transaction price, and allocating that transaction price to the performance obligations instead of retrospectively restating the contracts for such contract modifications.

The cumulative impact to our accumulated deficit balance at January 1, 2018, as a result of the adoption of ASC 606 was a decrease of $19.0 million. The decrease arose primarily from a reduction of deferred revenue balances related to upfront payments received from customers and recognition of contract assets due to a combination of (i) the effects of applying the practical expedient for contract modifications and our conclusions related to satisfied and unsatisfied performance obligations, which resulted in a relatively higher portion of the total transaction price recognized as revenue in periods prior to our adoption of ASC 606, (ii) the effect of the bill-and-hold accounting guidance for inventory in ASC 606 and (iii) the inclusion of estimated future royalty payments related to our intellectual property in the total transaction price to the extent such intellectual property was legally sold to our customer rather than licensed. The cumulative effect adjustment is net of an impairment loss of $13.1 million which was a direct effect of the adoption

of ASC 606 on the asset group of the Manufacturing Operations, which was classified as assets of disposal group held for sale since December 2017.

The following table summarizes the impacts of adopting ASC 606 on our condensed consolidated financial statements, in thousands.

	Impact of Changes in Accounting Policies		
Three months ended September 30, 2018	As reported	Adjustments	Balances without adoption of ASC 606
Collaboration and other revenue	$363	$ 5	$368
Royalty revenue	3,210	(2,142)	1,068
Total revenue	3,573	(2,137)	1,436
Loss from operations	(36,004)	(2,137)	(38,141)
Loss from continuing operations	(34,314)	(2,137)	(36,451)
Net loss	(34,314)	(2,137)	(36,451)
Net loss attributable to stockholders of Arena	(34,314)	(2,137)	(36,451)
Nine months ended September 30, 2018			
Collaboration and other revenue	$4,524	$ 49	$4,573
Royalty revenue	4,798	(1,454)	3,344
Total revenue	9,322	(1,405)	7,917
Loss from operations	(100,139)	(1,405)	(101,544)
Loss from continuing operations	(97,280)	(257)	(97,537)
Income (loss) from discontinued operations	(830)	13,660	12,830
Net loss	(98,110)	13,403	(84,707)
Net loss attributable to stockholders of Arena	(98,110)	13,403	(84,707)
As of September 30, 2018			
Prepaid expenses and other current assets	$9,524	$ (1,310)	$8,214
Total current assets	572,477	(1,310)	571,167
Other non-current assets	9,721	(4,252)	5,469
Total assets	610,034	(5,562)	604,472
Current portion of deferred revenues	800	15	815
Total current liabilities	21,952	15	21,967
Deferred revenues, less current portion	415	52	467
Accumulated deficit	(1,569,263)	(5,629)	(1,574,892)
Total stockholders' equity	531,316	(5,629)	525,687
Total liabilities and stockholders' equity	610,034	(5,562)	604,472

Our revenues to date have been generated primarily through collaboration agreements. Our collaboration agreements frequently contain multiple elements including (i) intellectual property licenses, (ii) product research, development and regulatory services and (iii) product manufacturing. Consideration we receive under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments, payments for

product sales and royalty payments. Our customers include Everest Medicines Limited, or Everest, Outpost Medicine, LLC, or Outpost, Eisai Inc. and Eisai Co., Ltd., or collectively, Eisai, Axovant Sciences GmbH, or Axovant, Boehringer Ingelheim International GmbH, or Boehringer Ingelheim, and Siegfried.

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that we expect to be entitled to receive in exchange for these services and excludes sales incentives and amounts collected on behalf of third parties. We analyze the nature of these performance obligations in the context of individual collaboration agreements in order to assess the distinct performance obligations. We apply the following five steps to recognize revenue:

i) Identify the contract with a customer. We consider the terms and conditions of our collaboration agreements to identify contracts within the scope of ASC 606. We consider that we have a contract with a customer when the contract is approved, we can identify each party's rights regarding the goods and services to be transferred, we can identify the payment terms for the goods and services, we have determined the customer has the ability and intent to pay and the contract has commercial substance. We use

judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers.

ii) Identify the performance obligations in the contract. Performance obligations in our collaboration agreements are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from us, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. Our performance obligations generally consist of intellectual property licenses, research, development and/or regulatory services and manufacturing and supply commitments.

iii) Determine the transaction price. We determine the transaction price based on the consideration to which we expect to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from our customers. None of our collaboration agreements contain consideration payable to our customer or a significant financing component.

iv) Allocate the transaction price to performance obligations in the contract. If the contract contains a single performance obligation, the entire transaction price is allocated to that performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price.

v) Recognize revenue when or as we satisfy a performance obligation. Revenue is recognized at the time the related performance obligation is satisfied by transferring the promised goods or services to a customer. We recognize revenue when we transfer control of the goods or services to our customers for an amount that reflects the consideration that we expect to receive in exchange for those services.

Performance Obligations.

The following is a description of principal goods and services from which we generate revenue.

Intellectual property licenses

We generate revenue from licensing our intellectual property including know-how and development and commercialization rights. These licenses provide customers with a term-based license to further research, develop and commercialize our internally-discovered drug candidates. The consideration we receive in the form of nonrefundable upfront consideration related to the functional intellectual property licenses is recognized when we transfer such license to the customer unless the license is combined with other goods or services into one performance obligation, in which case the revenue is recognized over a period of time based on our estimated pattern in which we satisfy the combined performance obligation. Our licensing agreements are generally cancelable. Customers have the right to terminate their contracts upon notice. We have the right to terminate the contracts generally only if the customer is in breach of the contract and fails to remedy the breach in accordance with the contractual terms.

Intellectual property sales

We generate royalty revenue from sales of our intellectual property. We estimate the future royalty payments and recognize revenue with a corresponding contract asset at a point in time when we transfer the intellectual property to the customer. We periodically reassess our estimate of the future royalty payments and recognize any estimate adjustments as revenue in the current period.

Research, development and regulatory services

We generate revenue from research, development and regulatory services we provide to our customers in connection with the licensed intellectual property. The services we provide to our customers primarily include scientific research activities, preparation for and management of clinical trials, and assistance during the regulatory approval application process. Revenue associated with these services is recognized based on our estimate of total consideration to be received for such services and the pattern in which we perform the services. The pattern of performance is generally determined to be the amount of incurred expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract.

Product manufacturing

We generate revenue from manufacturing and clinical supply promises to our customers in connection with securing a supply of drug products for development and clinical trial purposes. The drug products are generally manufactured by our contract manufacturing organizations. We used our product manufacturing facility in Zofingen, Switzerland for a portion of the product manufacturing requirements until we sold the Manufacturing Operations on March 31, 2018 (see Note 2). Revenue associated with product manufacturing obligations is recognized at a point in time as control of the related product is transferred to the customer.

Contracts with Multiple Performance Obligations.

Most of our collaboration agreements with customers contain multiple promised goods or services. Based on the characteristics of the promised goods and services we analyze whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. We determine standalone selling price based on our overall pricing and discounting objectives, taking into consideration the type of services, estimates of hourly market rates, and stage of the development and clinical trials.

Variable Consideration.

Our contracts with customers primarily include two types of variable consideration: (i) development and regulatory milestone payments, which are due to us upon achievement of specific development and regulatory milestones and (ii) one-time sales-based payments and sales-based royalties associated with sold or licensed intellectual property.

Due to uncertainty associated with achievement of the development and regulatory milestones, the related milestone payments are excluded from the contract consideration and the corresponding revenue is not recognized until we conclude it is probable that reversal of such milestone revenue will not occur.

Product sales-based royalties under licensed intellectual property and one-time payments are accounted for under the royalty exception. We recognize revenue for sales-based royalties under licensed intellectual property and one-time payments at the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

Disaggregation of Revenue.

We operate in one reportable business segment. We provide goods and services to our customers in collaboration agreements pursuant to various geographical markets. In the following table, revenue is disaggregated by major customers, timing of revenue recognition and revenue classification, in thousands.

Customers	Three months ended September 30, 2018	Nine months ended September 30, 2018
Eisai	$ 3,210	$ 6,300
Outpost	—	2,750
Axovant	200	968
Siegfried	—	942
Boehringer Ingelheim	163	785
Other	—	84
Total	$ 3,573	$ 11,829

Timing of revenue recognition		
Revenue recognized at a point in time	$ 2,493	$ 7,770
Revenue recognized over time	1,080	4,059
Total	$ 3,573	$ 11,829
Classification		
Revenue from continuing operations	$ 3,573	$ 9,322
Revenue reported under discontinued operations	—	2,507
Total	$ 3,573	$ 11,829

Contract Assets and Contract Liabilities.

We receive payments from customers based on contractual terms. Accounts receivable are recorded when the right to consideration becomes unconditional. For research and development services, we generally bill our customers monthly or quarterly as

the services are performed. Product sales are generally billed as completed. Payment terms on invoiced amounts are typically 30 days. Contract assets include amounts related to our contractual right to consideration for both completed and partially completed performance obligations that have not been invoiced and for which we do not yet have the right to payment. The current portion of contract asset is included in prepaid expenses and other current assets in the condensed consolidated balance sheet. The non-current portion of contract assets is included in other non-current assets in the condensed consolidated balance sheet. As of January 1, 2018, we recorded a contract asset of $4.1 million, of which $1.4 million is classified as current and $2.7 million is classified as non-current, related to future royalties associated with intellectual property patents previously sold to a customer which do not qualify for the royalty exception in ASC 606. We estimated the amount of the contract asset by applying the expected value method to our estimate of future royalty payments we will receive from this customer. Any future changes to this estimate will be recorded as an adjustment to revenue in the period in which the change in estimate is made.

Contract liabilities consist of deferred revenue and include payments received in advance of performance under the contract.

The following table provides detail of changes in our contract assets and deferred revenues, in thousands. The deferred revenue balances as of December 31, 2017, presented in the following table include balances classified as liabilities of disposal group held for sale:

	Contract Assets - Current	Contract Assets - Non-Current	Current Portion of Deferred Revenues	Deferred Revenues, Less Current Portion
Balances at December 31, 2017	$—	$ —	$ 26,560	$ 1,067
ASC 606 implementation adjustments	7,527	2,694	(25,526)	(40)
Reductions of contract assets	(2,096)	(659)	—	—
Impact of the disposal of the Manufacturing Operations (see Note 2)	(4,543)	—	—	—
Foreign currency translation adjustment	145	—	—	—
Recognized as revenue during the period	277	2,217	(234)	(612)
Balances at September 30, 2018	$ 1,310	$ 4,252	$ 800	$ 415

Cost to Obtain and Fulfill a Contract.

We generally do not incur costs to obtain new contracts. Costs to fulfill contracts are expensed as incurred.

Remaining Performance Obligations.

The following table provides detail of estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) pursuant to our existing collaboration agreements as of September 30, 2018, in thousands:

As of

	September 30, 2018
Rest of 2018	$ 678
2019	2,080
2020	686
2021 and thereafter	—
Total	$ 3,444

Under the royalty exception in ASC 606 for licensed intellectual property we do not recognize any revenue for the variable amounts related to sales-based royalties until the later of when the sales occur or the performance obligation is satisfied or partially satisfied. Accordingly, the revenue related to future royalties and sales-based milestones is not included in the table above.

Recent Accounting Pronouncements.

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.

The FASB has subsequently issued additional ASUs to clarify certain elements of the new lease accounting guidance. 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.

The new guidance requires a modified retrospective transition, with the cumulative effect of transition, including initial recognition by lessees of lease assets and liabilities for existing operating leases, as of either: (a) the effective date meaning the cumulative effect of applying the new guidance is recognized as an adjustment to the opening retained earnings balance for the year of implementation, or (b) the beginning of the earliest comparative period presented. We plan to adopt the new lease standard effective January 1, 2019, using the effective date method with the cumulative effect of the change reflected in retained earnings as of January 1, 2019, if any. We plan to elect the package of practical expedients available in the new lease standard, allowing us not to reassess: (a) whether expired or existing contracts contain leases under the new definition of a lease; (b) lease classification for expired or existing leases; and (c) whether previously capitalized initial direct costs would qualify for capitalization under the new lease standard.

We have continued to monitor FASB activity to assess certain interpretative issues and the associated implementation of the new standard. We are in the process of reviewing our lease arrangements, including our property leases and subleases, and are not yet able to estimate the anticipated impact to our consolidated financial statements from the implementation of the new standard as we continue to interpret the principles of the new standard.

In November 2016, the FASB issued ASU No. 2016-18, Restricted Cash. ASU No. 2016-18 requires that restricted cash be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown in the statement of cash flows. In accordance with ASU No. 2016-18, we adopted this standard in the first quarter of 2018 and retrospectively adjusted the condensed consolidated statement of cash flows for the nine months ended September 30, 2017, to conform to the current period's presentation. The adoption of this ASU did not have a material impact on our consolidated financial statements.

The following table provides a reconciliation of the components of cash, cash equivalents, and restricted cash reported in our condensed consolidated balance sheets to the total of the amount presented in the condensed consolidated statements of cash flows, in thousands:

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 508,663	$ 158,837
Restricted cash included in other non-current assets	863	863
Total cash, cash equivalents and restricted cash presented in the condensed consolidated statement of cash flows	$ 509,526	$ 159,700

The restricted cash relates to our property leases. The restriction will lapse when the related leases expire.

Use of Estimates.

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.

Contingencies.

We disclose information regarding each material claim where the likelihood of a loss contingency is probable or reasonably possible. If a loss contingency is probable and the amount of the loss can be reasonably estimated, we record an accrual for the loss. In such cases, there may be an exposure to potential loss in excess of the amount accrued. The insurance recoveries are recorded in the period when the insurance reimbursement is deemed probable. The ability to predict the ultimate outcome of such matters involves judgments, estimates and inherent uncertainties. The actual outcome of such matters could differ materially from management's estimates.

2. Sale of Manufacturing Operations

In order to further focus our efforts and resources on our strategic objectives of developing our pipeline drug candidates, on March 9, 2018, we entered into an Asset Purchase Agreement, or Sale Agreement, with Siegfried Pharma AG and Siegfried AG,

(collectively and individually, Siegfried). Under the Sale Agreement, we agreed to sell and assign to Siegfried, and Siegfried agreed to purchase and assume from Arena GmbH, certain drug product finishing facility assets and know-how, including fixtures, equipment, other personal property and real estate assets located in Zofingen, Switzerland and related contracts and certain related liabilities, or collectively, the Manufacturing Operations. We refer to this transaction as the Siegfried Transaction. The Siegfried Transaction was completed on March 31, 2018. In connection with the Siegfried Transaction, all of Arena GmbH's approximately 50 employees transferred to Siegfried. We have excluded from our continuing operations for all periods presented in this report revenues and expenses associated with the disposed Manufacturing Operations, which are reported as discontinued operations. The total sales price for the Manufacturing Operations was approximately CHF 4 million of which approximately CHF 3 million was received in cash in March 2018 with the remaining portion to be received in March 2019, net of any qualifying claims by Siegfried. In the event Siegfried agrees to sell or transfer some or all of the transferred assets to certain third parties on or prior to December 31, 2018, for a consideration in excess of a specified amount, Arena GmbH will be entitled to percentage of such excess amount.

We have retrospectively revised the condensed consolidated statements of operations for the three and nine months ended September 30, 2017, and cash flows for the nine months ended September 30, 2017, to reflect the operations and cash flows of the disposed Manufacturing Operations as discontinued operations. The following table summarizes the results of discontinued operations for the periods presented in the condensed consolidated statements of operations, in thousands:

	Three months ended September 30,		Nine months ended September 30,	
Revenues	2018	2017	2018	2017
Net product sales	$—	$3,075	$1,129	$7,845
Other collaboration revenue	—	1,689	372	5,005
Toll manufacturing	—	769	1,006	2,241
Total revenues	—	5,533	2,507	15,091
Costs and expenses				
Cost of product sales	—	1,739	1,858	5,768
Cost of toll manufacturing	—	1,222	1,411	3,215
Research and development	—	74	—	463
General and administrative	—	373	329	1,103
Other (income) expenses, net	—	(481)	464	1,735
Total costs and expenses	—	2,927	4,062	12,284
Income (loss) from operations of discontinued operations	—	2,606	(1,555)	2,807
Gain on sale of discontinued operations	—	—	725	—
Income (loss) from discontinued operations	$—	$2,606	$(830)	$2,807

3. 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, 2018			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds(1)	$454,270	$ 454,270	$ —	$ —
Corporate debt instruments(2)	52,961	—	52,961	—

	Fair Value Measurements at December 31, 2017			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds(1)	$48,750	$ 48,750	$ —	$ —
US government and government agency notes(2)	50,335	50,335	—	—
Corporate debt instruments(2)	94,639	—	94,639	—

(1) Included in cash and cash equivalents in the accompanying condensed consolidated balance sheets.
(2) Included in either cash and cash equivalents or available-for-sale investments in the accompanying condensed consolidated balance sheets.

4. Investments, Available-for-Sale

Investments, available-for-sale, consisted of the following, in thousands:

September 30, 2018	Maturity	Amortized	Gross	Gross	Estimated

	in years	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	< 1	$ 53,032	$ —	$ (71)	$ 52,961
Short-term investments, available-for-sale		$ 53,032	$ —	$ (71)	$ 52,961

December 31, 2017	Maturity in years	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government and government agency notes	< 1	$ 34,873	$ —	$ (8)	$ 34,865
Corporate debt securities	< 1	53,438	—	(63)	53,375
Short-term investments, available-for-sale		$ 88,311	$ —	$ (71)	$ 88,240
Corporate debt securities	1 – 5	24,304	—	(62)	24,242
Investments, available-for-sale		$ 24,304	$ —	$ (62)	$ 24,242

5. Land, Property and Equipment

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

	September 30, 2018	December 31, 2017
Cost	$ 88,793	$ 88,244
Less accumulated depreciation and amortization	(60,957)	(58,113)
Land, property and equipment, net	$ 27,836	$ 30,131

6. Accounts Payable and Other Accrued Liabilities

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

	September 30, 2018	December 31, 2017
Accounts payable	$ 1,081	$ 1,599
Accrued compensation	5,732	5,255
Other accrued liabilities	1,162	1,062
Total accounts payable and other accrued liabilities	$ 7,975	$ 7,916

7. Collaborations

Refer to our Annual Report on Form 10-K for the year ended December 31, 2017, for more information on our significant collaboration agreements.

Outpost Medicine LLC.

In the second quarter of 2018, we and Outpost entered into a license agreement, or Outpost Agreement, under which Outpost has an exclusive right to advance an undisclosed, preclinical compound with potential utility in treating genitourinary disorders.

Under the Outpost Agreement, we received an upfront payment of $3.0 million, of which $1.5 million was in the form of an equity interest in Outpost. We are eligible to receive up to an aggregate of $96.5 million in success milestone payments in case of full commercial success of the potential drug product.

The promised goods and services under the Outpost Agreement are accounted for as a single performance obligation consisting of a research, development and commercialization license. Our performance obligation under the Outpost Agreement was fully satisfied as of June 30, 2018, and accordingly, the estimated total transaction price of the

Outpost Agreement was fully recognized as revenue in the second quarter of 2018. The future potential milestone payments were excluded from the estimated total transaction price as they are considered constrained.

Eisai.

In July 2010, we granted Eisai exclusive commercialization rights for lorcaserin (branded as BELVIQ and BELVIQ XR) solely in the United States and its territories and possessions. In May 2012, we and Eisai entered into the first amended and restated agreement, which expanded Eisai's exclusive commercialization rights to include most of North and South America. In November 2013, we and Eisai entered into the second amended and restated agreement, which expanded Eisai's exclusive commercialization rights for lorcaserin to all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel.

In December 2016, we and Eisai amended and restated the terms of the marketing and supply agreement for lorcaserin with Eisai by entering into a Transaction Agreement and a Supply Agreement (collectively, the Eisai Agreement) with Eisai. Under the Transaction Agreement, Eisai acquired an exclusive royalty-bearing license or transfer of intellectual property to global commercialization and manufacturing rights to lorcaserin, including in the territories retained by us under the prior agreement, with control over global development and commercialization decisions. Eisai is responsible for all lorcaserin development expenses going forward. We also assigned to Eisai our rights under the commercial lorcaserin distribution agreements with Ildong Pharmaceutical Co., Ltd., or Ildong, for South Korea; CY Biotech Company Limited, or CYB, for Taiwan; and Teva Pharmaceuticals Ltd.'s Israeli subsidiary, Abic Marketing Limited, or Teva, for Israel.

Under the Supply Agreement, Eisai paid us $10.0 million in December 2016 to acquire our entire on-hand inventory of bulk lorcaserin and the precursor material for manufacturing lorcaserin. Eisai also paid us for finished drug product plus monthly manufacturing support payments through September 2018 totaling CHF 8.7 million.

Until March 31, 2018, when we sold the Manufacturing Operations, including the assignment of the Supply Agreement, to Siegfried (see Note 2), we manufactured lorcaserin at our manufacturing facility in Zofingen, Switzerland. Revenues earned for (i) lorcaserin sold by us to Eisai under the manufacturing and supply commitment within the Supply Agreement and (ii) the manufacturing support payments are classified within discontinued operations as part of the Manufacturing Operations in the condensed consolidated statements of operations (see Note 2). All other revenues earned under the Transaction Agreement, such as royalties, are classified within continuing operations in the condensed consolidated statements of operations.

Royalty payments.

Pursuant to the Transaction Agreement, we are eligible to receive royalty payments from Eisai based on the global net sales of lorcaserin. The royalty rates are as follows:

- 9.5% on annual net sales less than or equal to $175.0 million
- 13.5% on annual net sales greater than $175.0 million but less than or equal to $500.0 million
- 18.5% of annual net sales greater than $500.0 million

Upfront payments.

Prior to the Transaction Agreement, we received from Eisai total upfront payments of $115.0 million under prior lorcaserin collaboration agreements and $7.5 million from the prior commercial lorcaserin distribution agreements with Ildong, CYB, and Teva. Revenues from these upfront payments were previously deferred, as we determined that the exclusive rights did not have standalone value without our ongoing development and regulatory activities. Accordingly, these payments were recognized ratably as revenue over the periods in which we expected the services to be rendered.

Milestone payments.

Prior to the Transaction Agreement, we received a total of $102.1 million in milestone payments from Eisai, Ildong, CYB, and Teva. These payments were recognized as revenue upon the achievement of the milestones.

We are eligible to receive an additional sales-based milestone of $25.0 million upon the achievement of global net sales of lorcaserin for a calendar year first exceeding $250.0 million.

Accounting for Eisai Agreement under ASC 606.

Upon implementation of ASC 606 on January 1, 2018, we applied a practical expedient for contract modifications applicable to contracts that were modified before the implementation date. The promised goods and services under the Eisai Agreement were assessed in combination with promised goods and services under our previous agreements with Eisai and commercial lorcaserin distribution agreements with Ildong, CYB, and Teva. The total estimated transaction price of these contracts at the implementation date was $344.4 million, which included previously received upfront payments, milestone payments, proceeds from net products sales, reimbursement of development expenses, reimbursement of patent expenses, manufacturing support payments received and expected to be received under the Supply Agreement, proceeds from the sale of on-hand inventory of bulk lorcaserin and the precursor material, royalty payments received through December 31, 2017, and estimated future royalty payments related to intellectual property sold to Eisai. The future potential milestone payments were excluded from the estimated total transaction price as they

are considered constrained due to our assessment of the probability of a significant revenue reversal. The future royalties related to licensed intellectual property were excluded from the estimated total transaction price under the royalty exception in ASC 606. The estimated future royalties that relate to intellectual property sold to Eisai do not qualify for the royalty exception in ASC 606 and were included in the estimated total transaction price.

The estimated total transaction price was allocated between satisfied and unsatisfied performance obligations based on the relative standalone selling prices of the identified performance obligations. The remaining manufacturing and supply obligations under the Supply Agreement was the only unsatisfied performance obligation. As a result of this allocation, on January 1, 2018, we reduced the balance of deferred revenues associated with the Eisai Agreement at the implementation date by $25.5 million, recognized a contract asset of $6.1 million related to future manufacturing support payments under the Supply Agreement and recognized a contract

asset of $4.1 million related to estimated future royalty payments from intellectual property sold to Eisai under the Transaction Agreement. In connection with the sale of the Manufacturing Operations on March 31, 2018, we derecognized the remaining portion of the contract asset associated with the Supply Agreement. During the third quarter of 2018, we adjusted our estimate of future royalty payments from intellectual property sold to Eisai under the Transaction Agreement based on the positive CVOT study results reported by Eisai and recorded associated royalty revenue of $2.5 million.

Based on the bill-and-hold accounting guidance in ASC 606, effective January 1, 2018, we derecognized $3.6 million of inventory of bulk lorcaserin and the precursor material previously sold to Eisai for which the revenue recognition criteria were met on the implementation date under ASC 606.

For the three and nine months ended September 30, 2018, we recorded royalty revenue of $3.2 million and $4.8 million related to the Transaction Agreement compared to royalty revenue of $0.5 million recorded for the three and nine months ended September 30, 2017. For the nine months ended September 30, 2018, we recognized as revenue $1.5 million related to the Supply Agreement (classified under discontinued operations), all of which was recorded during the first quarter of 2018 and primarily consisting of net product sales and other collaboration revenue. For the three and nine months ended September 30, 2017, we recognized as revenue $4.8 million and $12.9 million (classified under discontinued operations), respectively, related to the Supply Agreement and primarily consisting of net product sales and other collaboration revenue.

In the condensed consolidated balance sheet at December 31, 2017, the deferred revenues of $25.5 million relating to the Eisai Agreement (primarily comprised of the deferred portion of the previously received upfront payments and the $10.0 million payment received from Eisai in December 2016) were classified as liabilities of disposal group held for sale.

Axovant Sciences GmbH.

We and Axovant have a development, marketing and supply agreement, or Axovant Agreement, under which Axovant has exclusive worldwide rights to develop and commercialize nelotanserin, subject to regulatory approval.

Under the Axovant Agreement, we received an upfront payment of $4.0 million in May 2015. We will receive payments from potential sales of nelotanserin under the Axovant Agreement and are eligible to receive purchase price adjustment payments based on Axovant’s annual net product sales. We are eligible to receive up to an aggregate of $41.5 million in success milestone payments in case of full development and regulatory success of nelotanserin.

The promised goods and services under the Axovant Agreement are accounted for as two separate performance obligations: (i) a combined performance obligation consisting of commercialization rights and development and regulatory services and (ii) a manufacturing and supply commitment. As of September 30, 2018, the estimated total transaction price was $9.9 million, of which $3.3 million is associated with performance obligations to be satisfied in the future. The future potential purchase price adjustment payments and milestone payments were excluded from the estimated total transaction price as they are considered constrained. We recognize revenue for the combined performance obligation consisting of commercialization rights and development and regulatory services based on the amount of incurred development expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract.

For the three and nine months ended September 30, 2018, we recorded revenue of $0.2 million and $1.0 million, respectively, related to the Axovant Agreement. For the three and nine months ended September 30, 2017, we recorded revenue of $0.5 million and $1.6 million, respectively, related to the Axovant Agreement.

Boehringer Ingelheim International GmbH.

We and Boehringer Ingelheim have a collaboration and license 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. The Boehringer Ingelheim Agreement was in effect through January 2018. We and Boehringer Ingelheim agreed to extend the original term of the Boehringer Ingelheim Agreement by twelve months through January 2019.

In partial consideration of the exclusive rights to our intellectual property necessary or useful to conduct the joint research under the Boehringer Ingelheim Agreement, we received from Boehringer Ingelheim an upfront payment of $7.5 million in 2016. Under the Boehringer Ingelheim Agreement, we are eligible to receive up to an aggregate of $251.0 million in success milestone payments in case of full commercial success of multiple drug products.

The promised goods and services under the Boehringer Ingelheim Agreement are accounted for as a single combined performance obligation consisting of a research license, a development and commercialization license and research services. Our performance obligation under the original term of the Boehringer Ingelheim Agreement was fully satisfied as of January 2018, and accordingly the estimated total transaction price of the Boehringer Ingelheim Agreement under the original contractual term of $10.5 million was fully recognized as revenue over the period from January 2016 through January 2018. As of September 30, 2018, the estimated total transaction price associated with the extended term of the Boehringer Ingelheim Agreement was $0.7 million, of which $0.2 million is associated with performance obligations to be satisfied in the future. The future potential milestone payments were excluded from the estimated total transaction price as they are considered constrained. We recognize revenue for the combined performance obligation based on the amount of incurred development expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract.

For the three and nine months ended September 30, 2018, we recorded revenue of $0.2 million and $0.8 million, respectively, related to the Boehringer Ingelheim Agreement. For the three and nine months ended September 30, 2017, we recorded revenue of $1.3 million and $3.8 million, respectively, related to the Boehringer Ingelheim Agreement.

8. Stockholders' Equity

In March 2018, we completed the sale of an aggregate of 9,775,000 shares of our common stock under an underwritten public offering. Net proceeds from the offering were approximately $383.1 million after deducting underwriting discounts and commissions and offering expenses payable by us.

9. Share-based Compensation

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Research and development	$2,269	$380	$5,836	$1,335
General and administrative	2,898	1,497	7,894	4,423
Discontinued operations	—	13	11	100
Total share-based compensation expense	$5,167	$1,890	$13,741	$5,858

The following table summarizes our stock option activity during the nine months ended September 30, 2018, in thousands (except per share data):

	Options	Weighted-

		Average Exercise Price
Outstanding at January 1, 2018	3,755	$ 20.00
Granted	3,075	37.64
Exercised	(288)	18.54
Forfeited/cancelled/expired	(326)	33.69
Outstanding at September 30, 2018	6,216	$ 28.08

During the nine months ended September 30, 2018, 32,322 shares were issued to the holders of the remaining performance restricted stock units, or PRSUs, granted in March 2015 based on the Total Stockholder Return, or 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, 2015.

10. Concentrations of Credit Risk

Financial instruments, which potentially subject us to concentrations of credit risk, consist primarily of cash, cash equivalents and available-for-sale investments. 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 or 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.

11. Income (Loss) Per Share

We calculate basic and diluted loss from continuing operations, income (loss) from discontinued operations and net loss per share using the weighted-average number of shares of common stock outstanding during the period.

Since we have a loss from continuing operations for the three and nine months ended September 30, 2018, and 2017, in addition to excluding potentially dilutive out-of-the money securities, we have excluded from our calculation of diluted income (loss) per share all potentially dilutive in-the-money (i) stock options, (ii) restricted stock unit awards, or RSUs, (iii) PRSUs and (iv) unvested restricted stock in our deferred compensation plan, and our diluted net income (loss) per share is the same as our basic net income (loss) per share.

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Stock options	5,918	3,862	5,669	3,667
RSUs and unvested restricted stock	24	3	18	3
Total	5,942	3,865	5,687	3,670

Because the market condition for the outstanding PRSUs was not satisfied at September 30, 2017, such securities are excluded from the table above. There are no outstanding PRSUs at September 30, 2018.

12. Legal Proceedings

Beginning in September 2010, a number of complaints were filed in the US District Court for the Southern District of California, or District Court, 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. In August 2011, the District Court consolidated the actions and appointed a lead plaintiff and lead counsel. In November 2017, we and the lead plaintiff signed a stipulation and agreement of settlement, or Stipulation, to resolve the consolidated class action. Under the terms of the Stipulation, and in exchange for a release of all claims by class members and a dismissal of the consolidated class action with prejudice, we have agreed that (i) our insurers would pay class members and their attorneys a total of approximately $12.025 million and (ii) Arena would pay class members and their attorneys approximately $11.975 million in either shares of our common stock or cash at our election. Accordingly, in the third quarter of 2017, we recognized $11.975 million of net expense for the portion of the

settlement that we agreed to pay in either common stock or cash. On April 12, 2018, the District Court entered its final approval order approving the settlement and the plan of allocation and request for attorneys' fees and expense. In the second quarter of 2018, we and our insurer made settlement payments in cash to the class members and their attorneys to settle our liability under the Stipulation.

On September 30, 2016, we and Eisai Inc. filed a patent infringement lawsuit against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, Lupin) in the U.S. District Court for the District of Delaware. The lawsuit relates to a “Paragraph IV certification” notification that we and Eisai Inc. 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 that are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, or 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 for 10 mg lorcaserin hydrochloride tablets. Lupin is accused of infringing U.S. Patent Nos. 6,953,787; 7,514,422; 7,977,329; 8,207,158 and 8,273,734. 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 Lupin’s 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. On January 11, 2017, Lupin filed an answer, defenses and counterclaims to the September 30, 2016 complaint. We and Eisai Inc. filed an answer to Lupin’s counterclaims on February 1, 2017. We and Eisai Inc. are seeking a determination from the court that, among other things, Lupin has infringed our patents, Lupin’s ANDA for 10 mg lorcaserin hydrochloride tablets should not be approved until the expiration date of our patents, and Lupin should be enjoined from commercializing a product that infringes our patents. Trial is currently scheduled for April 15, 2019. The parties have completed the fact discovery phase of the case, and are now in the expert discovery phase of the case.

On March 6, 2017, we and Eisai Inc. filed a patent infringement lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) in the U.S. District Court for the District of Delaware. The lawsuit also relates to a “Paragraph IV certification” notification that we and Eisai Inc. received regarding an ANDA submitted to the FDA by Teva requesting approval to engage in the commercial manufacture, use, importation, offer for sale or sale of a generic version of BELVIQ XR (lorcaserin hydrochloride extended-release tablets, 20 mg). In its notification, Teva alleged that no valid, enforceable claim of any of the patents that are listed in the Orange Book for BELVIQ XR will be infringed by Teva’s manufacture, importation, use, sale or offer for sale of the product described in its ANDA. Teva is accused of infringing U.S. Patent Nos. 6,953,787; 7,514,422; 7,977,329; 8,207,158 and 8,273,734. In accordance with the Hatch-Waxman Act, as a result of filing a patent infringement lawsuit within 45 days of receipt of Teva’s notification, the FDA cannot approve Teva’s 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. On April 18, 2017, Teva filed an amended answer, defenses and counterclaims to the March 6, 2017, complaint. We and Eisai Inc. are seeking a determination from the court that, among other things, Teva has infringed our patents, Teva’s ANDA should not be approved until the expiration date of our patents, and Teva should be enjoined from commercializing a product that infringes our patents. On May 1, 2017, the Teva and Lupin actions were consolidated for all purposes and will follow the case schedule that was previously entered in the Lupin action. We and Eisai Inc. filed an answer to Teva’s amended counterclaims on May 3, 2017. On or about October 16, 2017, we and Eisai Inc. received a “Paragraph IV certification” notification from Teva alleging that no valid, enforceable claim of U.S. Patent No. 9,770,455, which was listed in the Orange Book for BELVIQ and BELVIQ XR after the patent issued on September 26, 2017, will be infringed by Teva’s manufacture, importation, use, offer for sale or sale of the product described in its ANDA. On October 25, 2017, we and Eisai Inc. filed a first amended complaint against Lupin and Teva, adding infringement of U.S. Patent No. 9,770,455 by their respective ANDA products to the consolidated lawsuit. On or about November 6, 2017, we and Eisai Inc. received a “Paragraph IV certification” notification from Lupin alleging that no valid, enforceable claim of U.S. Patent No. 9,770,455 will be infringed by Lupin’s manufacture, importation, use, offer for sale or sale of the product described in its ANDA for 10 mg lorcaserin hydrochloride tablets.

We and Eisai Inc. also received a “Paragraph IV certification” notification from Lupin alleging that no valid, enforceable claim of any of the patents that are listed in the Orange Book for BELVIQ and BELVIQ XR will be

infringed by Lupin's manufacture, importation, use, sale or offer for sale of the product described in its ANDA for 20 mg lorcaserin hydrochloride extended-release tablets. Because Lupin is not the first applicant to submit a substantially complete application containing a Paragraph IV certification for approval of a generic equivalent of BELVIQ XR, absent extenuating circumstances, Lupin would not be able to launch its 20 mg lorcaserin hydrochloride extended-release tablets before Teva was able to launch its respective product. On March 23, 2018, we and Eisai Inc. filed a second amended complaint against Lupin and Teva, adding infringement of U.S. Patent Nos. 6,953,787, 7,514,422, 7,977,329, 8,207,158, 8,273,734, and 9,770,455 by Lupin's generic equivalent of BELVIQ XR. This consolidated action against Lupin and Teva is currently in expert discovery. We cannot predict the ultimate outcome of any proceeding.

13. Beacon Discovery, Inc.

On September 1, 2016, we entered into a series of agreements with Beacon. Beacon, a privately held drug discovery incubator which focuses on identifying and advancing molecules targeting GCPRs, was founded and is owned by several of our former employees.

As Beacon's equity investment at risk is not sufficient to permit Beacon to finance its activities without subordinated financial support, Beacon is considered a variable interest entity in which we hold a significant variable interest pursuant to the agreements with Beacon. We do not own any equity interest in Beacon; however, as the agreements provided us the controlling financial interest in Beacon until December 2017, we consolidated Beacon's balances and activity within our consolidated financial statements until December 2017 as we were determined to be the primary beneficiary of Beacon. Pursuant to a contract Beacon entered into with a third party in December 2017 which provided Beacon with a certain amount of upfront funding, we determined we no longer held the controlling financial interest as of that date and, therefore, deconsolidated Beacon from our consolidated financial statements as we were no longer deemed to be the primary beneficiary. Our condensed consolidated financial statements for the three and nine months ended September 30, 2017, include Beacon's results of operations and cash flows. As of September 30, 2018, Beacon's total assets of $6.7 million, total liabilities of $7.9 million and total stockholders' deficit of $1.2 million are excluded from our consolidated balance sheet.

For the three and nine months ended September 30, 2018, Beacon recognized revenues of $0.6 million and $4.7 million, respectively, of which none and $0.7 million, respectively was earned by Beacon from agreements with us. For the three and nine months ended September 30, 2018, Beacon reported net loss of $1.1 million and $0.5 million, respectively.

For the three and nine months ended September 30, 2017, Beacon recognized revenues of $0.7 million and $2.0 million, substantially all of which was earned by Beacon from agreements with us. For the three and nine months ended September 30, 2017, Beacon incurred a net loss of $0.3 million and $1.1 million which is fully presented as net loss attributable to noncontrolling interest in consolidated variable interest entity in our condensed consolidated statements of operations and comprehensive loss.

As of September 30, 2018, a note receivable from Beacon with a balance of $0.5 million is included in prepaid expenses and other current assets in our condensed consolidated balance sheet. We believe that our maximum exposure to loss as a result of our involvement with Beacon is limited to the note receivable due to us from Beacon.

14. Subsequent Events

In October 2018, the China Food and Drug Administration, or CFDA, approved the Investigational New Drug application submitted by Everest Medicines Limited, or Everest, for an oral formulation of ralinepag. Everest will pay us a $1.0 million milestone payment earned from this achievement.

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, 2017, or 2017 Annual Report, as filed with the Securities and Exchange Commission, or SEC. Operating results are not necessarily indicative of results that may occur in future periods.

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

OVERVIEW AND RECENT DEVELOPMENTS

We are focused on delivering novel, transformational medicines with optimized pharmacology and pharmacokinetics to patients globally. Our proprietary pipeline includes multiple potentially first- or best-in-class programs with broad clinical utility.

Our three most advanced investigational clinical programs are:

- Ralinepag, which we are evaluating in a Phase 3 program for pulmonary arterial hypertension, or PAH,
- Etrasimod, which we are preparing for a Phase 3 program for ulcerative colitis, as well as progressing programs for Crohn's disease, primary biliary cholangitis, atopic dermatitis and other indications, and
- Olorinab, for a broad range of visceral pain conditions and which we are evaluating in Phase 2 for the treatment of gastrointestinal pain.

We continue to explore additional indications for all of our clinical-stage programs. We have a preclinical program investigating APD418 for the treatment of decompensated heart failure.

Additionally, we have collaborations with the following pharmaceutical companies:

- Everest Medicines Limited, or Everest, in its efforts with respect to ralinepag and etrasimod in Greater China and select Asian countries,

Axovant Sciences GmbH, or Axovant, in its efforts with respect to nelotanserin, an orally available inverse agonist of the serotonin 2A receptor, which is in development for various neurological disorders,

- Boehringer Ingelheim International GmbH, or Boehringer Ingelheim, targeting a G protein-coupled receptor that belongs to the group of orphan central nervous system receptors, which is in preclinical development stage,
- Outpost Medicine, LLC, or Outpost, in its efforts with respect to a preclinical compound for the potential treatment of genitourinary disorders, and
- Eisai Co., Ltd. and Eisai Inc., or collectively, Eisai, in their efforts with respect to BELVIQ/BELVIQ XR, which are marketed products.

In October 2018, the China Food and Drug Administration, or CFDA, approved the Investigational New Drug application for an oral formulation of ralinepag. Everest will pay us a $1.0 million milestone payment earned from this achievement.

In October 2018, we announced positive data from a planned interim analysis of the ongoing open-label extension of the Phase 2 trial of ralinepag in development for the treatment of pulmonary arterial hypertension.

In October 2018, Eisai reported it provided Eurofarma Laboratórios S.A. the exclusive development and marketing rights for lorcaserin hydrochloride in 17 countries in Latin America and the Caribbean.

In September 2018, we announced positive topline results from our Phase 2a trial of olorinab in development for the treatment of pain associated with Crohn's disease.

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. We expect to continue to incur substantial net losses for at least the short term as we advance our clinical development programs and support our collaborators.

RESULTS OF OPERATIONS

We are providing the following summary of our research and development expenses and general and administrative expenses to supplement the more detailed discussion below. This summary excludes research and development expenses and general and administrative expenses associated with the disposed Manufacturing Operations, which are reported within income (loss) from discontinued operations. The dollar values in the following tables are in millions.

Research and development expenses

	Three months ended September 30,		Nine months ended September 30,	
Type of expense	2018	2017	2018	2017
External clinical and preclinical study fees	$16.9	$10.4	$46.1	$30.5
Salary and other personnel costs (excluding non-cash share-based compensation)	7.8	3.7	19.1	11.2
Non-cash share-based compensation	2.3	0.4	5.8	1.3
Facility and equipment costs	1.3	1.3	3.8	3.9
Other	0.5	1.4	2.3	3.4
Total research and development expenses	$28.8	$17.2	$77.1	$50.3

General and administrative expenses

	Three months ended September 30,		Nine months ended September 30,	
Type of expense	2018	2017	2018	2017

Legal, accounting and other professional fees	$ 3.0	$ 2.1	$ 10.4	$ 6.0
Salary and other personnel costs (excluding non-cash share-based compensation)	3.3	2.4	9.4	7.0
Non-cash, share-based compensation	2.9	1.5	7.9	4.4
Facility and equipment costs	1.1	1.1	3.4	3.7
Other	0.5	0.3	1.2	1.0
Total general and administrative expenses	$ 10.8	$ 7.4	$ 32.3	$ 22.1

THREE MONTHS ENDED SEPTEMBER 30, 2018, AND 2017

Revenues. We recognized revenues of $3.6 million for the three months ended September 30, 2018, compared to $2.4 million for the three months ended September 30, 2017. This increase was primarily due to a $2.5 million non-cash adjustment to our contract asset for an increase in estimated future royalty payments as a result of recent positive CVOT study results reported by Eisai. This increase was partially offset by a decrease of $1.2 million in collaboration revenue from Boehringer Ingelheim and a decrease of $0.4 million in collaboration revenue from Axovant.

Absent any new collaborations, we expect our 2018 revenues will primarily consist of (i) royalty revenues from Eisai based upon Eisai's sales of BELVIQ, (ii) upfront payments from our collaborators and (iii) reimbursements from collaborators for research funding. Revenues from royalties based on sales of BELVIQ are difficult to predict, and our overall revenues may vary from quarter to quarter and year to year.

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

Research and development expenses increased by $11.6 million to $28.8 million for the three months ended September 30, 2018, from $17.2 million for the three months ended September 30, 2017. This increase was primarily due to increases of $6.5 million in external clinical and preclinical study fees, $4.1 million in salary and other personnel costs and $1.9 million in non-cash, share-based compensation expense.

We expect to incur substantial research and development expenses in 2018 and for the aggregate amount in 2018 to be significantly greater than the amount incurred in 2017 due to increasing headcount and clinical trial costs related to advancing the ralinepag and etrasimod programs into Phase 3. Our actual expenses may be higher or lower than anticipated due to various factors, including our progress and results. For example, patient enrollment in our Phase 3 clinical programs are expected to be competitive and challenging, and could take longer than originally projected, which may result in our related external expenses being delayed or lower in 2018 than anticipated (but which might increase the overall costs for completing these multi-year programs).

Included in the $16.9 million of total external clinical and preclinical study fees noted in the table above for the three months ended September 30, 2018, were the following:

- $8.1 million related to ralinepag,
- $6.1 million related to etrasimod, and
- $1.0 million related to olorinab.

Included in the $10.4 million of total external clinical and preclinical study fees noted in the table above for the three months ended September 30, 2017, were the following:

- $6.5 million related to etrasimod,
- $2.7 million related to ralinepag, and
- $0.7 million related to olorinab.

General and administrative expenses. General and administrative expenses increased by $3.4 million to $10.8 million for the three months ended September 30, 2018, from $7.4 million for the three months ended September 30, 2017. This increase was primarily due to an increase of $1.4 million in non-cash share-based compensation expenses, an increase of $0.9 million in legal, accounting and other professional fees, and an increase of $0.9 million in salary and other personnel costs. The increases in compensation costs are primarily due to an increase in the number of general and administrative employees. We expect that our 2018 general and administrative expenses will be higher than in 2017.

Interest and other income (expense), net. Interest and other income, net, was $1.7 million for the three months ended September 30, 2018, compared to interest and other expense, net of $1.1 million for the three months ended September 30, 2017. This change was primarily due to an increase of $2.5 million in interest income from our available-for-sale investments activity.

NINE MONTHS ENDED SEPTEMBER 30, 2018, AND 2017

Revenues. We recognized revenues of $9.3 million for the nine months ended September 30, 2018, compared to $6.0 million for the nine months ended September 30, 2017. This increase was primarily due to a $2.5 million non-cash adjustment to our contract asset for an increase in estimated future royalty payments as a result of recent positive CVOT study results reported by Eisai and $2.8 million in upfront fee revenue from our license agreement with Outpost. This increase was partially offset by a decrease of $3.1 million in collaboration revenue from Boehringer Ingelheim and a decrease of $0.6 million in collaboration revenue from Axovant.

Research and development expenses. Research and development expenses increased by $26.8 million to $77.1 million for the nine months ended September 30, 2018, from $50.3 million for the nine months ended September 30, 2017. This increase was primarily due to increases of $15.6 million in external clinical and preclinical study fees, $7.9 million in salary and other personnel costs and $4.5 million in non-cash, share-based compensation expense. The increases in compensation costs are primarily due to an increase in the number of research and development employees.

Included in the $46.1 million of total external clinical and preclinical study fees noted in the table above for the nine months ended September 30, 2018, were the following:

- $21.6 million related to ralinepag,
- $18.4 million related to etrasimod, and
- $2.9 million related to olorinab.

Included in the $30.5 million of total external clinical and preclinical study fees noted in the table above for the nine months ended September 30, 2017, were the following:

- $20.6 million related to etrasimod,
- $6.9 million related to ralinepag, and
- $1.6 million related to olorinab.

General and administrative expenses. General and administrative expenses increased by $10.2 million to $32.3 million for the nine months ended September 30, 2018, from $22.1 million for the nine months ended September 30, 2017. This increase was primarily due to an increase of $4.4 million in legal, accounting and other professional fees, an increase of $3.5 million in non-cash share-based compensation expenses, and an increase of $2.4 million in salary and other personnel costs. The increases in compensation costs are primarily due to an increase in the number of general and administrative employees.

Interest and other expense, net. Interest and other income, net was $2.8 million for the nine months ended September 30, 2018, compared to interest and other expense, net of $3.2 million for the nine months ended September 30, 2017. This change was primarily due to an increase of $5.8 million in interest income from our available-for-sale investments activity.

Discontinued operations. On March 31, 2018, Arena GmbH sold the Manufacturing Operations via the Siegfried Transaction. As a result of the Siegfried Transaction, we have excluded from our continuing operations for all periods presented in this report revenues and expenses associated with the disposed Manufacturing Operations, which are reported as discontinued operations. For the nine months ended September 30, 2018, loss from discontinued operations was $0.8 million. For the nine months ended September 30, 2017, income from discontinued operations was $2.8 million. See Note 2 to our condensed consolidated financial statements included in this Quarterly Report for additional information regarding the sale of our Manufacturing Operations.

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. We expect to continue to incur substantial losses for at least the short term.

To date, we have obtained cash and funded our operations primarily through equity financings, the issuance of debt and related financial instruments, payments from collaborators and customers, and sale leaseback transactions. We expect to continue to evaluate various funding alternatives on an ongoing basis. If we determine it is advisable to raise additional funds, there is no assurance that adequate funding will be available to us or, if available, that such funding will be available on terms that we or our stockholders view as favorable.

Short term liquidity.

At September 30, 2018, we had $561.6 million in cash, cash equivalents and available-for-sale investments. We believe our cash resources are sufficient to allow us to continue operations for at least the next twelve months from the date this Quarterly Report is filed with the SEC.

Long term liquidity.

It will require substantial cash to achieve our objectives of discovering, developing and commercializing drugs, and this process typically takes many years and potentially several hundreds of millions of dollars for an individual drug. We may not have adequate available cash, or assets that could be readily turned into cash, to meet these objectives in the long term. We will need to obtain significant funds under our existing collaborations, under new 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.

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 obtain regulatory approval to 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 and any other drug we or our collaborators obtain regulatory approval to market, regulatory decisions affecting our and our collaborator's drug candidates, 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 increased by $38.0 million to $98.5 million in the nine months ended September 30, 2018, compared to $60.5 million in the nine months ended September 30, 2017. This increase was primarily the result of (i) a class action litigation settlement payment of $12.0 million in the second quarter of 2018, (ii) an increase of $13.8 million in payments made for external clinical study fees, and (iii) an increase in cash expenditures of approximately $9.4 million for personnel costs resulting primarily from an increase in the number of employees.

Net cash provided by investing activities was $62.3 million in the nine months ended September 30, 2018, compared to $0.8 million in the nine months ended September 30, 2017. This change was primarily due to $59.5 million in net proceeds from the sale and maturity, net of purchases of available-for-sale investments in the nine months ended September 30, 2018, and $3.5 million in proceeds from the sale of the Manufacturing Operations during the nine months ended September 30, 2018, partially offset by an increase of $0.5 million purchases of property and equipment.

Net cash of $385.4 million was provided by financing activities in the nine months ended September 30, 2018, as a result of net proceeds of $388.5 million from the sale of shares of our common stock under a secondary offering financing and proceeds from stock option exercises, which were partially offset by payments of $3.0 million on our lease financing obligations. Net cash of $245.7 million was provided by financing activities in the nine months ended September 30, 2017, as a result of net proceeds of $243.3 million from the sale of shares of our common stock primarily under the secondary offering financings and our ATM facility and proceeds from stock option exercises of

$5.0 million, which were partially offset by payments of $2.6 million on our lease financing obligations.

CRITICAL ACCOUNTING POLICIES AND MANAGEMENT ESTIMATES

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Our discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with US generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from those estimates.

Our critical accounting policies and management estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, and there have been no material changes during the nine months ended September 30, 2018 except that effective January 1, 2018, we adopted Accounting Standard Codification 606, Revenue from Contracts with Customers, or ASC 606,

issued by the Financial Accounting Standards Board. As a result, we have changed our accounting policy for revenue recognition as detailed in Note 1 to the condensed consolidated financial statements included in this Quarterly Report.

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, 2017.

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 were no changes to our internal control over financial reporting that occurred during the quarter covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

See the first paragraph under Item 1 of Part II of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, as filed with the SEC on August 7, 2018.

On September 30, 2016, we and Eisai Inc. filed a patent infringement lawsuit against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, Lupin) in the U.S. District Court for the District of Delaware. The lawsuit relates to a “Paragraph IV certification” notification that we and Eisai Inc. 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 that are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, or 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 for 10 mg lorcaserin hydrochloride tablets. Lupin is accused of infringing U.S. Patent Nos. 6,953,787; 7,514,422; 7,977,329; 8,207,158 and 8,273,734. 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 Lupin’s 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. On January 11, 2017, Lupin filed an answer, defenses and counterclaims to the September 30, 2016 complaint. We and Eisai Inc. filed an answer to Lupin’s counterclaims on February 1, 2017. We and Eisai Inc. are seeking a determination from the court that, among other things, Lupin has infringed our patents, Lupin’s ANDA for 10 mg lorcaserin hydrochloride tablets should not be approved until the expiration date of our patents, and Lupin should be enjoined from commercializing a product that infringes our patents. Trial is currently scheduled for April 15, 2019. The parties have completed the fact discovery phase of the case, and are now in the expert discovery phase of the case.

On March 6, 2017, we and Eisai Inc. filed a patent infringement lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) in the U.S. District Court for the District of Delaware. The lawsuit also relates to a “Paragraph IV certification” notification that we and Eisai Inc. received regarding an ANDA submitted to the FDA by Teva requesting approval to engage in the commercial manufacture, use, importation, offer for sale or sale of a generic version of BELVIQ XR (lorcaserin hydrochloride extended-release tablets, 20 mg). In its notification, Teva alleged that no valid, enforceable claim of any of the patents that are listed in the Orange Book for BELVIQ XR will be infringed by Teva’s manufacture, importation, use, sale or offer for sale of the product described in its ANDA. Teva is accused of infringing U.S. Patent Nos. 6,953,787; 7,514,422; 7,977,329; 8,207,158 and 8,273,734. In accordance with the Hatch-Waxman Act, as a result of filing a patent infringement lawsuit within 45 days of receipt of Teva’s notification, the FDA cannot approve Teva’s 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. On April 18, 2017, Teva filed an amended answer, defenses and counterclaims to the March 6, 2017, complaint. We and Eisai Inc. are seeking a determination from the court that, among other things, Teva has infringed our patents, Teva’s ANDA should not be approved until the expiration date of our patents, and Teva should be enjoined from commercializing a product that infringes our patents. On May 1, 2017, the Teva and Lupin actions were consolidated for all purposes and will follow the case schedule that was previously entered in the Lupin action. We and Eisai Inc. filed an answer to Teva’s amended counterclaims on May 3, 2017. On or about October 16, 2017, we and Eisai Inc. received a “Paragraph IV certification” notification from Teva alleging that no valid, enforceable claim of U.S. Patent No. 9,770,455, which was listed in the Orange Book for BELVIQ and BELVIQ XR after the patent issued on September 26, 2017, will be infringed by Teva’s manufacture, importation, use, offer for sale or sale of the product described in its ANDA. On October 25, 2017, we and Eisai Inc. filed a first amended complaint against Lupin and Teva, adding infringement of U.S. Patent No. 9,770,455 by their respective ANDA products to the consolidated

lawsuit. On or about November 6, 2017, we and Eisai Inc. received a “Paragraph IV certification” notification from Lupin alleging that no valid, enforceable claim of U.S. Patent No. 9,770,455 will be infringed by Lupin’s manufacture, importation, use, offer for sale or sale of the product described in its ANDA for 10 mg lorcaserin hydrochloride tablets.

We and Eisai Inc. also received a “Paragraph IV certification” notification from Lupin alleging that no valid, enforceable claim of any of the patents that are listed in the Orange Book for BELVIQ and BELVIQ XR will be infringed by Lupin’s manufacture, importation, use, sale or offer for sale of the product described in its ANDA for 20 mg lorcaserin hydrochloride extended-release tablets. Because Lupin is not the first applicant to submit a substantially complete application containing a Paragraph IV certification for approval of a generic equivalent of BELVIQ XR, absent extenuating circumstances, Lupin would not be able to launch its 20 mg lorcaserin hydrochloride extended-release tablets before Teva was able to launch its respective product. On March 23, 2018, we and Eisai Inc. filed a second amended complaint against Lupin and Teva, adding infringement of U.S. Patent Nos. 6,953,787, 7,514,422, 7,977,329, 8,207,158, 8,273,734, and 9,770,455 by Lupin’s generic equivalent of BELVIQ XR. This consolidated action against Lupin and Teva is currently in expert discovery. We cannot predict the ultimate outcome of any proceeding.

Item 1A. Risk Factors.

RISK FACTORS

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

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, 2017, as filed with the Securities and Exchange Commission, or SEC.

Risks Relating to Our Business

We will need to obtain additional funds or enter into collaboration agreements to execute on our corporate strategy, and we may not be able to do so at all or on terms you view as favorable; 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. We have accumulated a large deficit that has primarily resulted from the significant expenditures we have made in research and development since our inception. We expect that our losses and operating expenses will continue to be substantial.

All of our current active development programs are in the development stage, and we currently do not have, and we may not have in the future, adequate funds to develop our compounds into marketed drugs.

We may seek to obtain additional funding through the capital markets or other financing sources. Additional funding may not be available to us or may not be available on terms we or others believe are favorable. Our ability to obtain additional funding may depend on many factors, including those outside our control. Should we obtain additional funding, your ownership interest may be diluted or otherwise negatively impacted.

We may enter into collaboration or other agreements with other entities to continue to develop and, if successful, commercialize one or more of our drug candidates. We may not be able to enter into any such agreements 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 depends on many factors, potentially including the outcomes of additional testing (including clinical trial results) or regulatory applications for marketing approval, and we do not control these outcomes.

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. We may also eliminate, scale back or delay some or all of our research and development programs, and any such reductions or failure to apply our resources effectively or to obtain additional funding could narrow, slow or otherwise adversely impact the development and commercialization of one or more of

our drug candidates, which could reduce our opportunities for success and have a material adverse effect on our business, our prospects and the market price of our common stock.

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 clinical and preclinical 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 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 even after a drug is approved. The commencement or completion of our clinical trials or preclinical studies 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 a meeting, 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 the indications in our planned clinical studies is competitive and challenging, and it is difficult to predict when such trials will be fully enrolled or when data will be available.

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 those listed above affecting the commencement or completion of trials and the following:

- 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;
- 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. In addition, even if the earlier-stage results of our development programs are favorable, these programs may take significantly longer than expected to complete or may not be completed at all. If we or our collaborators abandon or are delayed in our development efforts related to any drug or 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.

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.

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

The results and timing of clinical trials and preclinical studies, as well as related decisions by us, collaborators and regulators, can affect our stock price. Results of clinical trials and preclinical studies are uncertain and subject to different interpretations by regulatory agencies, us or others. The design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions), as well as related analyses of such results, including adverse effects, may not be viewed favorably by us or third parties, including investors, analysts, current or potential collaborators, the academic and medical communities, and regulators, which could adversely impact the development and opportunities for regulatory approval of drug candidates and commercialization (and even result in withdrawal from the market) of approved drugs. The same may be true of decisions regarding the focus and prioritization of our research and development efforts. 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.

The development, approval or commercialization of any of our drug candidates could be negatively affected by circumstances related to other drug candidates or approved products.

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 indicate potential risks related to the development of our drug candidates. For example, etrasimod is an orally available modulator of the S1P receptors. An approved drug that is also an orally available modulator of the S1P receptors, 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, a rare brain infection, 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.

Topline data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose topline or interim data from time to time, which are 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.

Our hypothesis that selectively targeting receptors can lead to more efficacious or safer drugs may not be correct.

In general, we have designed and optimized our drug candidates (including etrasimod, ralinepag and olorinab, formerly APD371) to selectively target certain receptors found on cells in humans. Our hypothesis is that selectivity may allow our drug

candidates to address diseases more efficaciously or without some of the negative effects associated with less selective drugs. In certain cases, we believe early research and, if available, early clinical testing, provides preliminary support for our hypothesis. However, our hypothesis may not be correct, early research and early phase clinical testing may not be predictive of efficacy or safety in later trials, and our drug candidates may not be approved or, if approved, have the desired efficacy or safety profile.

* 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 confirmed in later studies or trials, including preclinical studies that continue or that are initiated after earlier clinical trials and large-scale clinical trials, and our drug candidates or drugs in subsequent trials or studies may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. For example, we have announced positive topline Phase 2 results for ralinepag in patients with PAH and positive topline Phase 2 results for etrasimod in patients with ulcerative colitis, but these results may not be confirmed in any subsequent Phase 3 study. By way of another example, the impact of etrasimod on heart rate that was observed in completed clinical trials may not be observed in subsequent trials, and it could be viewed negatively by the FDA or other regulatory agencies.

Unfavorable results from clinical trials or preclinical studies could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a program. Clinical and preclinical 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 such trials or studies could cause a clinical trial to be delayed, repeated or terminated; a program to be abandoned; or negatively impact a related marketed drug, which could have a material adverse effect on our business, financial condition and results of operations.

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 etrasimod, there are other drugs that have a similar mechanism of action already in Phase 3 clinical development for the same indications that we are pursuing, such as ulcerative colitis. By way of another example, with regard to ralinepag, a competitor with the same mechanism of action, selexipag, is already currently approved in the United States, Europe and other countries. 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.

Our revenues in the future will be substantially dependent on the success of our or our collaborators' marketing of drugs we have discovered or developed. To the extent such drugs are 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.

We believe our revenues will be substantially dependent on the success of the drugs we or our collaborators successfully develop. We do not know whether or when such drug candidates will be approved by regulatory authorities for sale or commercialized. Even if approved and commercialization begins, we do not know if such commercialization will be successful or otherwise meet our, your, analysts' or others' expectations, and the market price of our common stock could decline significantly. For example, sales of lorcaserin to date have been less than we and others initially anticipated, and, because lorcaserin is the only approved and marketed drug in which we have a financial interest, our revenue for the near-term is substantially dependent on our Transaction Agreement with Eisai and sales of lorcaserin.

We cannot guarantee future product sales or achievement of any other milestones. In addition, our Transaction Agreement with Eisai for lorcaserin, and any of our other collaborations, 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 a drug 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 the drug and their results;
- market acceptance and use of the drug, which may depend on the public's view of the drug, economic changes, national and world events, potentially seasonal and other fluctuations in demand, the timing and impact of current or new competition, and the drug'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 the drug 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 the drug, including as a result of additional studies, trials or analyses of the drug or related drugs or drug candidates;
- the willingness of physicians to prescribe and of patients to use the drug;
- the claims, limitations, warnings and other information in the drug's current or future labeling;
- any current or future scheduling designation for the drug by the US Drug Enforcement Administration, or DEA, or any comparable foreign authorities;
- our or 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 the drug consistent with its approved labeling;
- the price and perceived cost-effectiveness of the drug, 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 the drug to their constituencies;
- introduction of counterfeit or unauthorized versions of the drug;
- to the extent the drug 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 of the drug into the higher-priced territory; and
- the availability of adequate commercial manufacturing and supply chain for the drug.

Our 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.

Federal and state healthcare reform measures that have been or 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. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, which was enacted in 2010, is one such healthcare reform measure that has made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. In the years since its enactment, there have been, and continue to be, significant developments in, and continued legislative activity around, attempts to repeal or repeal and replace the ACA, which leads to uncertainty regarding the future of the ACA, and its impact on our business and operations. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payers. For example, reimbursement has been challenging for BELVIQ, including because Medicare explicitly excludes coverage for drugs for weight loss. The implementation of additional 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. There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. Congress also could consider additional legislation to repeal or repeal and replace other elements of the ACA. At this time, the full effect that the ACA will have on our business in the future remains unclear.

There have also been several recent US Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, the Trump administration’s budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other

future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Cost control measures legislation has been enacted at the state level. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Forecasting potential sales for drugs will be difficult, and if our projections are inaccurate, our business may be harmed and our stock price may be adversely affected.

Our business planning requires us to forecast or make assumptions regarding demand and revenues for our drugs if they are approved despite numerous uncertainties. These uncertainties may be increased if we rely on our collaborators to conduct commercial activities and provide 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 other items that impact commercialization;
- lack of patient and physician familiarity with the drug;
- lack of patient use and physician prescribing history;
- lack of commercialization experience with the drug;
- actual sales to patients may significantly differ from expectations based on sales to wholesalers; and
- uncertainty relating to when the drug may become commercially available to patients and rate of adoption in other territories.

Revenues from drug sales may 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. Expected and actual product sales and quarterly and other results may greatly fluctuate, including in the near-term for lorcaserin, 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.

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. If we do not recruit and retain effective management and other key employees, particularly our executive officers, our operations, our 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.

* We may need to expand our organization and may experience difficulties in managing this growth, which could disrupt our operations.

We are seeking to expand our employee base to increase our managerial, scientific, operational, manufacturing supply, commercial, financial and other resources and to hire more consultants and contractors. Future growth will impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. Moreover, if our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize any approved products and compete effectively will depend, in part, on our ability to effectively manage any future growth.

* 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, regulatory action or litigation.

An NDA holder (or the equivalent outside the United States) is responsible for assessing and monitoring the safety of a drug that has been approved for marketing, including reviewing reports of adverse safety events. In addition, NDA holders often conduct additional studies or trials or analyze new or previous data related to an approved drug, including with respect to required postmarketing studies and in connection with seeking additional regulatory approvals in new territories.

For example, as a condition to obtaining FDA approval of lorcaserin, the FDA required the conduct of postmarketing studies, including evaluation of the effect of long-term treatment with lorcaserin 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 CVOT). Along with the FDA-required portion of the trial, the trial includes an 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. New data relating to lorcaserin, including from adverse event reports or required postmarketing, registration or other studies or trials, may result in label changes, adversely affect sales or development, result in withdrawal of lorcaserin from the market, or result in litigation. In addition, analyses of previous data can have similar risks. We expect Eisai 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. 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.

The 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 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 regulatory scrutiny of the safety of lorcaserin, may raise potential adverse publicity and may affect product sales or result in litigation.

If we license or otherwise partner our drugs, our failure to maintain such agreements or poor performance under such agreements could negatively impact our business.

Our collaborators may have primary responsibility for the regulatory approval and, ultimately, marketing and distribution of our drug candidate in the territory or territories under the applicable collaboration. We may have limited or no control over the amount and timing of resources that any of these collaborators will dedicate to such activities. This is the case for our ralinepag and etrasimod license agreement with Everest and for our lorcaserin Transaction Agreement with Eisai.

When we enter collaboration agreements, we are subject to a number of other risks, including:

- our collaborators may not comply with applicable regulatory guidelines, which could adversely impact the commercialization or development of the drug candidate;
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there could be disagreements regarding the agreements or the study or development that delay or terminate the commercialization, research, study or development, 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 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 or our collaborators might terminate our agreements in certain circumstances or amend the terms of our agreement, and investors and analysts may not view any termination or amendments as favorable.

* We rely on other companies, including third-party manufacturers and sole-source suppliers, to manufacture lorcaserin and certain other drugs, and we or such other companies may encounter failures or difficulties or not receive or provide adequate supply, which could adversely affect development or commercialization.

We do not own or operate manufacturing facilities that can produce active pharmaceutical ingredient, or API, intermediates and other material required to make our drug candidates or lorcaserin. Instead, we rely on 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. Our and our manufacturers' dependence on single or limited sources of materials may adversely affect our ability to develop and deliver drug products on a timely and competitive basis, or at all. For example, the drug product manufacturing facility in Switzerland which we sold effective March 31, 2018, is currently the only source for finished drug product of lorcaserin.

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 sales of an approved product 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 lorcaserin 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 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 or other company in the supply chain fail to maintain

compliance or otherwise experience setbacks, we or they could be subject to civil or criminal penalties, the production of one or more of our drug candidates or lorcaserin could be interrupted or suspended, or our product could be recalled or withdrawn, resulting in delays, additional costs and potentially lost revenues.

* 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.

Preclinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other activities relating to developing and manufacturing drugs are 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. 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 research and development or commercialization, 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. 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.

Regulatory approval of a drug candidate 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.

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. The approval by the FDA or any other regulatory authority does not assure or predict with any certainty that any other regulatory authority will approve the drug.

In addition, existing regulatory policies and laws may change. We cannot predict the likelihood, nature or extent of new government regulation, either in the United States or in other countries, or the impact on our drug candidates or drugs. For example, new FDA regulation could delay or prevent marketing approvals, increase the cost of research and development, and result in narrower product labeling and expensive post-marketing requirements.

Our activities and 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. 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 result in litigation.

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 Risk Evaluation and Mitigation Strategies, or REMS, study, 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 any of drug that receives 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.

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

Any drug 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.

Collaboration 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 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 a risk with the commercialization of lorcaserin as well as any other drug that may be approved for marketing.

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 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.

Arena GmbH manufactured BELVIQ and other products for commercialization or clinical trials, up until the sale of our manufacturing business to Siegfried effective March 31, 2018. Even after the sale, we could be subject to liability for manufacturing defect claims relating to our manufacturing activities that preceded the closing of the sale. For example, under our agreement with Eisai, we and Eisai will each bear 50% of losses arising from any alleged defective manufacturing of BELVIQ by Arena GmbH prior to the date of the sale to Siegfried.

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

We have long-term leases on real properties and other contractual obligations. If we are unable to generate cash from operations sufficient to meet 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 Payments 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. Further, we may also be subject to state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

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, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, 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.

We have certain clinical operations personnel in Switzerland, and we engage in clinical trials and manufacturing activities in many territories 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. In addition, the European Commission has approved a data protection regulation, known as the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. In the future we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation, including the GDPR, in the EU countries in which we operate, including restrictions on data transfers that may negatively impact our ability and increase our costs to maintain international operations.

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

Our 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 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, and certain of our clinical operations outside the US are located in single building in Zug, Switzerland. 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 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 conduct studies and clinical trials of our drug candidates, manufacture our drug candidates and lorcaserin, and warehouse, market and distribute lorcaserin, and similar events relating to these third parties' 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 drugs 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 our employees and directors may be named as defendants in litigation that could result in substantial costs and divert management's attention.

Securities class action litigation may be brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years.

For example, 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. These lawsuits in general included allegations that we and certain of our employees and directors violated the federal securities laws by making materially false and misleading statements regarding our BELVIQ trials, thereby artificially inflating the price of our common stock. In November 2017, we reached a settlement agreement regarding these lawsuits and the court entered its final approval order approving the settlement in April 2018. Under the terms of the settlement agreement, and in exchange for a release of all claims by class members and a dismissal of the consolidated class action with prejudice, (i) our insurers paid class members and their attorneys a total of approximately $12.025 million and (ii) we paid class members and their attorneys approximately $11.975 million.

While we carry liability insurance, any losses we incur in connection with any future lawsuits may not be covered by insurance in an amount sufficient to cover our losses or at all, and our assets may be insufficient to cover any amounts that exceed our insurance coverage. We may have to pay damage awards or otherwise may enter into settlement arrangements in connection with any future claims. A settlement of any of future lawsuit against us could also 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, any future lawsuit against us and/or our directors or executive officers could result in substantial costs and significantly and adversely impact our reputation and divert our management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition. In addition, any 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.

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. 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. These laws, rules and regulations 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2017, we had federal and state net operating loss carryforwards of $1,120.0 million. Our federal net operating loss carryforwards ($721.4 million) will begin to expire, if not utilized, beginning in 2023, and our state net operating loss carryforwards ($398.6 million) begin expiring in 2028. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

* Changes or modifications in financial accounting standards, including those related to revenue recognition, may harm our results of operations.

From time to time, the Financial Accounting Standards Board, or FASB, either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations or reported cash flows. In May 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU No. 2014-09 supersedes prior revenue

recognition guidance and establishes a comprehensive revenue recognition model with a broad principle that requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this principle, an entity identifies the contract with a customer, identifies the separate performance obligations in the contract, determines the transaction price, allocates the transaction price to the separate performance obligations and recognizes revenue when each separate performance obligation is satisfied. The FASB has subsequently issued additional ASUs to clarify certain elements of the new revenue recognition guidance. The new guidance (codified as Accounting Standards Codification, or ASC, 606) 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 the new guidance is recognized as an adjustment to the opening retained earnings balance for the year of implementation. We adopted the new revenue standard effective January 1, 2018, using the modified retrospective method. The cumulative impact to our accumulated deficit balance at January 1, 2018, as a result of the adoption of ASC 606 was a decrease of $19.0 million. Any difficulties in implementing this standard, adopting or implementing any other new accounting standard, or updating or modifying our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors’ confidence in us.

Finally, if we were to change our critical accounting estimates, including those related to the recognition of revenue, our operating results could be significantly affected.

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, maintain and defend patents. In particular, the patents directed to our drug candidates and drugs are important to developing and commercializing drugs and our revenue. We have numerous US and foreign patents issued and 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 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 jeopardize our patent protection. 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, 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 in litigation or administrative proceedings. We cannot make assurances as to how much protection, if any, our patents will provide 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 patent 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 other proprietary information.

Some of our research and development collaborators and scientific consultants have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators and consultants 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 relationships we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain confidentiality in connection with our collaborations and relationships, 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 how it would impact 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 issued patents and pending patent applications owned by others relating to research 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 issued patents and pending patent applications owned by others exist in the areas of our research and development, including some which purport to allow the patent holder to control the use of all drugs that modulate a particular drug

target 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 issued patents and pending patent applications owned by others also exist in the therapeutic areas in which we are developing drugs. There are also numerous issued patents and pending patent applications owned by others that are directed 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 owned by others, of which we are not aware, that our drug candidates or technologies may infringe. Further, there may be issued patents or pending patent applications owned by others 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 research and 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 and seek damages or enjoinment of our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert 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. We may have to institute costly legal action to protect our intellectual property rights, or may not be able to afford the costs of enforcing or defending our intellectual property rights.

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 research and development, manufacturing and commercialization activities could:

- require us, or our collaborators, to obtain a license 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. In addition, during the course of intellectual property 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 modulators 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 (one of which has subsequently expired) include patent claims that cover lorcaserin 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 patent infringement lawsuits against ANDA filers relating to “Paragraph IV certifications.” While we intend to vigorously enforce our intellectual property rights relating to lorcaserin, 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 lorcaserin. If an ANDA filer were to prevail in patent litigation and/or receive approval to sell a generic version of lorcaserin, lorcaserin 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 candidates throughout the world would be prohibitively expensive. 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 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, 2016, to November 2, 2018, the market price of our stock was as low as $11.30 per share and as high as $50.05 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:

- results or decisions affecting the development or commercialization of any of our drug candidates or drugs, including the results of studies, trials and other analyses;
- the success, failure or setbacks of our or a perceived competitor’s drugs or drug candidates;
- the timing of the development of our drug candidates;
- discussions or recommendations affecting our drugs or drug candidates by the FDA or other reviewers of preclinical or clinical data or other information related to our drug candidates or drugs;
- regulatory actions or decisions or legislation affecting drugs or drug candidates, including ours and those of our competitors;
- the commercial availability and success or failure of any of our drug candidates or lorcaserin;
- the development and implementation of our continuing development and research plans, including outcome studies for lorcaserin;
- 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;
- 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;
- 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 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.

We may be unable to comply with the applicable continued listing requirements of the Nasdaq Global Select Market.

Our common stock is currently listed on the Nasdaq Global Select Market, or Nasdaq. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards. There can be no assurance that we will be able to comply with the applicable listing standards. If we were not able to comply with applicable listing standards, our shares of common stock would be subject to delisting. In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

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. We have effective registration statements to sell shares of our common stock and certain other securities, and we may elect to sell shares pursuant to such registration from time to time, including pursuant to an Equity Distribution Agreement that we put in place in January 2017 with Citigroup Global Markets Inc. During the period from February through April 2017, we sold 489,023 shares for aggregate gross proceeds of $7.4 million under the Equity Distribution Agreement, which permits total sales of up to $50.0 million in the aggregate.

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.

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 SEC.

* 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 2, 2018, there were (i) options to purchase 6,190,662 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of $28.08 per share, (ii) 24,189 restricted stock unit awards outstanding under our equity incentive plans, and (iii) 6,272,597 additional shares of common stock remaining issuable under our Amended and Restated 2017 Long-Term Incentive 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 2, 2018, there were 49,406,452 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	Certificate of Amendment No. 4 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 15, 2017, Commission File No. 000-31161)
3.6	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 4.7 to Arena's registration statement on Form S-8, filed with the Securities and Exchange Commission on June 22, 2017, Commission File No. 333-218905)
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

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 8, 2018	ARENA PHARMACEUTICALS, INC.
		By: /s/ Amit D. Munshi Amit D. 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)