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, 2019

or

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

For the transition period from to

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	ARNA	The Nasdaq Global Select Market

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 1, 2019:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	50,107,145

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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 170,884	$ 161,037
Short-term investments, available-for-sale	612,871	284,594
Accounts receivable	1,696	5,086
Prepaid expenses and other current assets	20,930	10,008
Total current assets	806,381	460,725
Investments, available-for-sale	389,980	82,412
Land, property and equipment, net	23,698	23,114
Deferred tax assets	—	110,333
Other non-current assets	21,989	10,319
Total assets	$ 1,242,048	$ 686,903
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 17,280	$ 16,181
Accrued clinical and preclinical study fees	15,860	10,454
Current portion of lease financing obligations	3,676	3,283
Total current liabilities	36,816	29,918
Other long-term liabilities	12,409	1,301
Lease financing obligations, less current portion	46,617	49,426
Commitments and contingencies		
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	2,159,445	2,106,960
Accumulated other comprehensive income (loss)	1,442	(155)
Accumulated deficit	(1,014,686)	(1,500,552)
Total stockholders' equity	1,146,206	606,258
Total liabilities and stockholders' equity	$ 1,242,048	$ 686,903

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,	
	2019	2018	2019	2018
Revenues:				
United Therapeutics revenue	$ —	$ —	$ 800,000	$ —
Royalty revenue	811	3,210	2,725	4,798
Collaboration and other revenue	539	363	704	4,524
Total revenues	1,350	3,573	803,429	9,322
Operating Costs and Expenses:				
Research and development	60,257	28,811	156,864	77,139
General and administrative	20,428	10,766	55,373	32,322
Transaction costs	—	—	14,573	—
Total operating costs and expenses	80,685	39,577	226,810	109,461
Income (loss) from operations	(79,335)	(36,004)	576,619	(100,139)
Interest and Other Income (Expense):				
Interest income	6,889	2,524	20,971	5,800
Interest expense	(1,203)	(1,423)	(3,666)	(4,344)
Other income	784	589	2,275	1,403
Total interest and other income (expense), net	6,470	1,690	19,580	2,859
Income (loss) from continuing operations before income taxes	(72,865)	(34,314)	596,199	(97,280)
Income tax provision	—	—	(110,333)	—
Income (loss) from continuing operations	(72,865)	(34,314)	485,866	(97,280)
Loss from discontinued operations	—	—	—	(830)
Net income (loss)	$ (72,865)	$ (34,314)	$ 485,866	$ (98,110)
Net income (loss) per share, basic:				
Continuing operations	$ (1.46)	$ (0.70)	$ 9.78	$ (2.10)
Discontinued operations	—	—	—	(0.02)
	$ (1.46)	$ (0.70)	$ 9.78	$ (2.12)
Net income (loss) per share, diluted:				
Continuing operations	$ (1.46)	$ (0.70)	$ 9.39	$ (2.10)
Discontinued operations	—	—	—	(0.02)
	$ (1.46)	$ (0.70)	$ 9.39	$ (2.12)
Shares used in calculating net income (loss) per share, basic:	49,864	49,368	49,667	46,243
Shares used in calculating net income (loss) per share, diluted:	49,864	49,368	51,763	46,243
Comprehensive Income (Loss):				
Net income (loss)	$ (72,865)	$ (34,314)	$ 485,866	$ (98,110)
Foreign currency translation gain (loss)	(33)	65	(45)	32
Unrealized gain on available-for-sale investments	168	93	1,642	62
Comprehensive income (loss)	$ (72,730)	$ (34,156)	$ 487,463	$ (98,016)

See accompanying notes to unaudited condensed consolidated financial statements.

ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	**49,422,991**	**$ 5**	**$ 2,106,960**	**$ (155)**	**$ (1,500,552)**	**$ 606,258**
Issuance of common stock upon exercise of options	125,655		3,364	—	—	3,364
Share-based compensation expense	—	—	13,024	—	—	13,024
Unrealized gain on available-for-sale investments	—	—	—	676	—	676
Translation loss	—	—	—	(19)	—	(19)
Net income	—	—	—	—	620,134	620,134
Balance at March 31, 2019	**49,548,646**	**$ 5**	**$ 2,123,348**	**$ 502**	**$ (880,418)**	**$ 1,243,437**
Issuance of common stock upon exercise of options	229,565	—	4,722	—	—	4,722
Issuance of common stock upon vesting of restricted stock unit awards	24,362	—	—	—	—	—
Share-based compensation expense	—	—	13,428	—	—	13,428
Unrealized gain on available-for-sale investments	—	—	—	798	—	798
Translation gain	—	—	—	7	—	7
Net loss	—	—	—	—	(61,403)	(61,403)
Balance at June 30, 2019	**49,802,573**	**$ 5**	**$ 2,141,498**	**$ 1,307**	**$ (941,821)**	**$ 1,200,989**
Issuance of common stock upon exercise of options	181,908	—	4,602	—	—	4,602
Share-based compensation expense	—	—	13,345	—	—	13,345
Unrealized gain on available-for-sale investments	—	—	—	168	—	168
Translation loss	—	—	—	(33)	—	(33)
Net loss	—	—	—	—	(72,865)	(72,865)
Balance at September 30, 2019	**49,984,481**	**$ 5**	**$ 2,159,445**	**$ 1,442**	**$ (1,014,686)**	**$ 1,146,206**

See accompanying notes to unaudited condensed consolidated financial statements.

ARENA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	**39,280,687**	**$ 4**	**$ 1,698,543**	**$ (1,216)**	**$ (1,490,187)**	**$ 207,144**
Adoption of ASC Topic 606	—	—	—	1,102	19,034	20,136
Issuance of common stock to underwriters	9,775,000	1	383,147	—	—	383,148
Issuance of common stock upon exercise of options	112,550	—	1,919	—	—	1,919
Issuance of common stock upon vesting of restricted stock unit awards	28,448	—	(166)	—	—	(166)
Share-based compensation expense	—	—	4,044	—	—	4,044
Unrealized loss on available-for-sale investments	—	—	—	(144)	—	(144)
Translation gain	—	—	—	17	—	17
Net loss	—	—	—	—	(31,963)	(31,963)
Balance at March 31, 2018	**49,196,685**	**$ 5**	**$ 2,087,487**	**$ (241)**	**$ (1,503,116)**	**$ 584,135**
Issuance of common stock to underwriters, net	—	—	(5)	—	—	(5)
Issuance of common stock upon exercise of options	106,364	—	1,948	—	—	1,948
Issuance of common stock upon vesting of restricted stock unit awards	20,075	—	—	—	—	—
Share-based compensation expense	—	—	4,530	—	—	4,530
Unrealized gain on available-for-sale investments	—	—	—	113	—	113
Translation loss	—	—	—	(50)	—	(50)
Net loss	—	—	—	—	(31,833)	(31,833)
Balance at June 30, 2018	**49,323,124**	**$ 5**	**$ 2,093,960**	**$ (178)**	**$ (1,534,949)**	**$ 558,838**
Issuance of common stock upon exercise of options	68,805	—	1,469	—	—	1,469
Share-based compensation expense	—	—	5,167	—	—	5,167
Unrealized gain on available-for-sale investments	—	—	—	93	—	93
Translation gain	—	—	—	65	—	65
Net loss	—	—	—	—	(34,314)	(34,314)
Balance at September 30, 2018	**49,391,929**	**$ 5**	**$ 2,100,596**	**$ (20)**	**$ (1,569,263)**	**$ 531,318**

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,	
	2019	**2018**
Operating Activities:		
Net income (loss)	$ 485,866	$ (98,110)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Loss from discontinued operations	—	830
Depreciation and amortization	2,349	2,863
Non-cash collaboration consideration	—	(1,500)
Non-cash royalty revenue	—	(2,493)
Deferred income taxes	110,333	—
Share-based compensation	39,797	13,729
Amortization of prepaid financing costs	67	83
Amortization of original issue discounts, net of premiums, on available-for-sale investments	(5,000)	129
Changes in operating assets and liabilities:		
Accounts receivable	3,390	1,000
Prepaid expenses and other assets	(10,771)	(3,002)
Payables and accrued liabilities	5,205	2,015
Accrued litigation settlement	—	(11,975)
Deferred revenues	—	(846)
Deferred rent	(1,114)	(879)
Net cash provided by (used in) operating activities - continuing operations	630,122	(98,156)
Net cash used in operating activities - discontinued operations	—	(370)
Net cash provided by (used in) operating activities	630,122	(98,526)
Investing Activities:		
Purchases of available-for-sale investments	(1,248,644)	(25,579)
Proceeds from sale and maturity of available-for-sale investments	619,441	85,033
Purchases of property and equipment	(2,933)	(568)
Other non-current assets	—	1
Net cash provided by (used in) investing activities - continuing operations	(632,136)	58,887
Net cash provided by investing activities - discontinued operations	997	3,405
Net cash provided by (used in) investing activities	(631,139)	62,292
Financing Activities:		
Principal payments on lease financing obligations	(2,416)	(3,032)
Proceeds from issuance of common stock, net	12,688	388,479
Net cash provided by financing activities	10,272	385,447
Effect of exchange rate changes on cash	(45)	613
Net increase in cash, cash equivalents and restricted cash	9,210	349,826
Cash, cash equivalents and restricted cash at beginning of period	161,900	159,700
Cash, cash equivalents and restricted cash at end of period	$ 171,110	$ 509,526

See accompanying 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, 2018, as filed with the Securities and Exchange Commission, or SEC, from which we derived our condensed consolidated balance sheet as of December 31, 2018. 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.

Pursuant to an asset purchase agreement with Siegfried Pharma AG and Siegfried AG, or collectively and individually, Siegfried, in March 2018 we completed a transaction to sell and assign to Siegfried, and Siegfried purchased and assumed 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. In connection with this transaction, all of Arena GmbH's approximately 50 employees transferred to Siegfried. We have excluded from our continuing operations for the comparative 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, the loss from discontinued operations was $0.8 million.

Liquidity.

As of September 30, 2019, we had cash, cash equivalents and available-for-sale investments of approximately $1.2 billion. We believe our cash, 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 collaborations, 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 - Leases.

Effective January 1, 2019, we adopted Accounting Standard Codification Topic 842, *Leases*, or ASC 842, issued by the Financial Accounting Standards Board, or FASB. ASC 842 requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. The new standard established a right-of-use model that requires a lessee to recognize a right-of-use asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. As a result, we have changed our accounting policy for leases as detailed below.

We implemented ASC 842 using the modified retrospective transition approach by applying the new standard to leases existing at the date of initial application. We used the effective date as our date of initial application. Therefore, we did not update the financial information and did not provide the disclosures required under the new standard for dates and periods before January 1, 2019.

We applied ASC 842 using a package of practical expedients, which permitted us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. We did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us.

Upon adoption of ASC 842, we recorded an operating lease liability of $6.3 million based on the present value of the remaining minimum rental payments under the terms of our existing operating lease pertaining to one of our leased properties with a corresponding right-of-use asset of $5.9 million. Adoption of this standard did not have a material impact on our condensed consolidated statements of operations or cash flows.

The new standard also provides practical expedients for an entity's ongoing accounting. We elected the short-term lease recognition exemption for our office equipment leases and short-term office space leases. This means, for those leases that qualify, we do not recognize right-of-use assets or lease liabilities. See Note 10 for disclosures related to our leases.

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. 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.

Concentrations of Credit Risk.

Our 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 losses by holding our cash primarily in US dollars or placing our cash and investments in US government, agency or government-sponsored enterprise obligations and in corporate debt instruments that are rated investment grade.

2. Cash, cash equivalents and restricted cash

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

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 170,884	$ 161,037
Restricted cash included in other non-current assets	226	863
Total cash, cash equivalents and restricted cash presented in the condensed consolidated statement of cash flows	$ 171,110	$ 161,900

The restricted cash relates to our property leases. The restriction lapsed when the related leases expired.

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 Using			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2019:				
Assets:				
Money market funds(1)	$ 112,294	$ 112,294	$ —	$ —
US government and government agency notes(2)	477,046	477,046	—	—
Corporate debt instruments(2)	525,805	—	525,805	—
December 31, 2018:				
Assets:				
Money market funds(1)	$ 62,438	$ 62,438	$ —	$ —
US government and government agency notes(3)	171,278	171,278	—	—
Corporate debt instruments(3)	240,481	—	240,481	—

(1) Included in cash and cash equivalents in the accompanying condensed consolidated balance sheets.
(2) Included in available-for-sale investments in the accompanying condensed consolidated balance sheets.
(3) 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:

	Maturity in years	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
September 30, 2019:					
US government and government agency notes	< 1	$ 279,319	$ 292	$ (5)	$ 279,606
Corporate debt securities	< 1	332,846	420	(1)	333,265
Short-term investments, available-for-sale		$ 612,165	$ 712	$ (6)	$ 612,871
US government and government agency notes	1 – 5	$ 197,522	$ 85	$ (167)	$ 197,440
Corporate debt securities	1 – 5	191,768	826	(54)	192,540
Investments, available-for-sale		$ 389,290	$ 911	$ (221)	$ 389,980
December 31, 2018:					
US government and government agency notes	< 1	$ 139,274	$ —	$ (18)	$ 139,256
Corporate debt securities	< 1	145,468	—	(130)	145,338
Short-term investments, available-for-sale		$ 284,742	$ —	$ (148)	$ 284,594
US government and government agency notes	1 – 5	$ 16,998	$ 6	$ —	$ 17,004
Corporate debt securities	1 – 5	65,512	—	(104)	65,408
Investments, available-for-sale		$ 82,510	$ 6	$ (104)	$ 82,412

5. Land, Property and Equipment

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

	September 30, 2019	December 31, 2018
Cost	$ 72,476	$ 69,542
Less accumulated depreciation and amortization	(48,778)	(46,428)
Land, property and equipment, net	$ 23,698	$ 23,114

6. Accounts Payable and Other Accrued Liabilities

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

	September 30, 2019	December 31, 2018
Accounts payable	$ 4,068	$ 6,192
Accrued compensation	9,149	8,622
Accrued expenses	409	—
Other accrued liabilities	3,654	1,367
Total accounts payable and other accrued liabilities	$ 17,280	$ 16,181

7. Collaborations and License Agreements

We have collaborations or license agreements with the following companies: United Therapeutics Corporation, or United Therapeutics, Everest Medicines Limited, Eisai Co., Ltd. and Eisai Inc., or collectively, Eisai, Boehringer Ingelheim International GmbH, or Boehringer Ingelheim, Outpost Medicine, LLC, and Axovant Sciences GmbH, or Axovant. Previously, we had a toll manufacturing agreement with Siegfried. Refer to our Annual Report on Form 10-K for the year ended December 31, 2018, for more information on our significant collaboration and license agreements.

In the following table, revenue is disaggregated by major customers, timing of revenue recognition and revenue classification, in thousands.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Customers				
United Therapeutics	$ —	$ —	$ 800,000	$ —
Eisai	811	3,210	2,575	6,300
Outpost	500	—	500	2,750
Other	39	363	354	2,779
Total	$ 1,350	$ 3,573	$ 803,429	$ 11,829
Timing of revenue recognition				
Revenue recognized at a point in time	$ 520	$ 2,493	$ 800,670	$ 7,770
Revenue recognized over time	830	1,080	2,759	4,059
Total	$ 1,350	$ 3,573	$ 803,429	$ 11,829
Classification				
Revenue from continuing operations	$ 1,350	$ 3,573	$ 803,429	$ 9,322
Revenue reported under discontinued operations	—	—	—	2,507
Total	$ 1,350	$ 3,573	$ 803,429	$ 11,829

The following table provides detail of changes in our contract assets, in thousands:

	Contract Asset - Current	Contract Asset - Non-Current
Balances at December 31, 2018	$ 1,484	$ 4,471
Change in contract assets	(53)	(992)
Balances at September 30, 2019	$ 1,431	$ 3,479

United Therapeutics Corporation.

In November 2018, we entered into an exclusive license agreement with United Therapeutics. Under this agreement, we granted United Therapeutics an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize ralinepag in any formulation. This transaction was completed in January 2019. United Therapeutics is responsible for all development, manufacturing and commercialization of the licensed products globally. In connection with this transaction we incurred transaction fees of approximately $17.0 million, of which $14.6 million was incurred in 2019, and are presented as transaction costs in the accompanying condensed consolidated statement of operations.

We received an upfront payment of $800.0 million under the agreement in the first quarter of 2019. We are also eligible to receive up to an aggregate of $400.0 million in regulatory milestone payments related to ralinepag, consisting of a payment of $150.0 million upon first marketing approval of an oral formulation of ralinepag in a major non-U.S. market, and a payment of $250.0 million upon U.S. marketing approval of an inhaled formulation of ralinepag to treat pulmonary arterial hypertension, as well as low double-digit, tiered royalties on net sales of ralinepag products, subject to certain adjustments for third party license payments.

The promised goods and services under this agreement are accounted for as a single performance obligation consisting of a research, development and commercialization license. Our performance obligation under this agreement was satisfied upon the closing of the transaction in January 2019, and accordingly, the estimated total transaction price of the agreement was fully recognized as revenue during the three months ended March 31, 2019. The future potential milestone payments were excluded from the estimated total transaction price as they are considered constrained. Under the royalty exception in ASC 606 for licensed intellectual property, we do not include any variable amounts related to sales-based royalties in the transaction price until the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

Eisai.

In December 2016, we and Eisai amended and restated the terms of the previous 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 for finished drug product plus monthly manufacturing support payments through March 2018 totaling CHF 8.7 million.

We manufactured lorcaserin until March 2018, when we sold our Manufacturing Operations. 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. All other revenues earned under the Transaction Agreement, such as royalties, are classified within continuing operations in the condensed consolidated statements of operations.

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

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.

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 included previously received upfront payments, milestone payments, proceeds from net products sales, reimbursement of development expenses, reimbursement of patent expenses, manufacturing support payments received under the Supply Agreement, proceeds from the sale of inventory of bulk lorcaserin and the precursor material. The estimated future royalties that relate to intellectual property sold to Eisai do not qualify for the royalty exception and are included in the estimated total transaction price. We recognized a contract asset related to estimated future royalty payments from intellectual property sold to Eisai under the Transaction Agreement. We periodically adjust our estimate of future royalty payments from intellectual property sold to Eisai under the Transaction Agreement. The future royalties related to licensed intellectual property are excluded from the estimated total transaction price under the royalty exception. The future potential milestone payments are excluded from the estimated total transaction price as they are considered constrained due to our assessment of the probability of a significant revenue reversal.

For the three and nine months ended September 30, 2019, we recorded royalty revenue of $0.8 million and $2.6 million, respectively, related to the Transaction Agreement. 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. For the nine months ended September 30, 2018, we recognized as revenue $1.5 million, classified within discontinued operations, related to the Supply Agreement, all of which was recorded during the first quarter of 2018, primarily consisting of net product sales and other collaboration revenue with no such revenue recorded during 2019.

8. Income Taxes

We calculate the interim income tax provision in accordance with Accounting Standard Codification Topic 270, *Interim Reporting*, or ASC 270, and Topic 740, *Accounting for Income Taxes*, or ASC 740. At the end of each interim period, we estimate our annual effective tax rate and apply that rate to our ordinary quarterly earnings to calculate the tax related to ordinary income. Due to the full valuation allowance, we do not have an annual effective tax rate. The tax effects for other items that are excluded from ordinary income are discretely calculated and recognized in the period in which they occur. The income from the United Therapeutics Agreement recognized during the three months ended March 31, 2019 is a discrete item and not included in our annual effective tax rate based on the determination that it is significant, unusual and infrequent in nature as defined in ASC 270 and ASC 740. For the nine months ended September 30, 2019, we have recorded $110.3 million of income tax expense related to the treatment of the United Therapeutics income as a discrete item during the quarter ended March 31, 2019.

9. Share-based Compensation

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Research and development	$ 6,699	$ 2,269	$ 20,406	$ 5,836
General and administrative	6,646	2,898	19,391	7,894
Discontinued operations	—	—	—	11
Total share-based compensation expense	$ 13,345	$ 5,167	$ 39,797	$ 13,741

The following table summarizes our stock option activity during the nine months ended September 30, 2019, in thousands (except per share data):

	Options	Weighted-Average Exercise Price
Outstanding at January 1, 2019	6,541	$ 28.83
Granted	2,814	44.30
Exercised	(537)	23.62
Forfeited/cancelled/expired	(354)	33.99
Outstanding at September 30, 2019	8,464	$ 34.09

In January 2019, a total of 297,000 target Performance-Based Restricted Stock Units, or PRSUs, were granted to the employees in a company-wide grant. The PRSUs vest upon the closing price of our common stock, or the Closing Price, reaching certain price thresholds during the three-year performance period beginning January 4, 2019, and ending January 3, 2022, or the Performance Period, and the participant's subsequent satisfaction of a continuing service requirement of generally 90 calendar days. If, on five consecutive trading days or ten non-consecutive trading days during the Performance Period, the Closing Price equals or exceeds $60.00, $67.50 or $75.00, and the participant thereafter satisfies a continuing service requirement, then the PRSUs are deemed vested at 50%, 100% or 200%, respectively, of the participant's respective target PRSU amount. The shares may be issued following achievement of each price threshold, and the maximum number of common shares that may be issued pursuant to each PRSU grant equals 200% of the number of PRSUs granted. As these awards contain a market condition, we used a Monte Carlo simulation model to estimate the grant-date fair value, which totaled $18.1 million. The grant-date fair value is recognized as compensation expense over the requisite service period of approximately 1.2 years which was derived from the Monte Carlo simulation; no compensation expense is recognized for service not provided in case of separation from the Company. There is no adjustment of compensation expense recognized for service performed regardless of the number of PRSUs, if any, that ultimately vest. The $60.00 market condition threshold was achieved in the third quarter of 2019. As a result, a total of 140,710 shares were issued to employees in October 2019 upon the satisfaction of the continuing service requirement.

During the nine months ended September 30, 2018, 32,322 shares were issued to the holders of the performance restricted stock units 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. Leases

We have three properties in San Diego, California, under sale and leaseback agreements. The terms of these leases contain a purchase option and stipulate annual increases in monthly rental payments of 2.5%. We account for our sale and leaseback transactions using the financing method. Under the financing method, the book value of the properties and related accumulated depreciation remain on our balance sheet and no sale is recognized. The adoption of ASC 842 did not result in a change to our current accounting policy for our sale and leaseback agreements. The sales price of the properties is recorded as a financing obligation, and a portion of each lease payment is recorded as interest expense. For the three and nine months ended September 30, 2019, we recorded interest expense of $1.2 million, and $3.7 million, respectively. For the three and nine months ended September 30, 2018, we recorded interest expense of $1.4 million, and $4.3 million, respectively. We expect interest expense related to our facilities to total $26.0 million from December 31, 2018, through the remaining terms of the leases until their expiration in May 2027. The aggregate residual value of the facilities at the end of the lease terms is $5.0 million.

We lease an additional property in San Diego, California, under an operating lease, which expires in May 2027, contains a purchase option and stipulates annual increases in monthly rental payments of 2.5%. Upon adoption of ASC 842, we recorded an operating lease liability of $6.3 million based on the present value of the remaining minimum lease payments under the terms of our existing operating lease with a corresponding right-of-use asset of $5.9 million. As our leases do not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available at effective date of adoption in determining the present value of remaining minimum lease payments. The weighted-average discount rate we used was 7.25%.

In the second quarter of 2019, we entered into an additional lease in Zug, Switzerland, for approximately 10,500 square feet of office space with the lease inception date of June 1, 2019. This lease expires in May 2024. At the lease inception, we recorded an operating lease liability of $1.4 million based on the present value of the remaining minimum lease payments under the terms of this operating lease with a corresponding right-of-use asset of $1.5 million. As this lease did not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available as of the lease inception in determining the present value of remaining minimum lease payments. The weighted-average discount rate we used was 7.25%.

In the third quarter of 2019, we entered into a new lease agreement for approximately 12,755 square feet of office space in Boston, Massachusetts with the lease inception date of September 1, 2019. This lease is classified as an operating lease and expires in December 2026. The lease stipulates annual increases in monthly rental payments of 2.0%. At the lease inception date, we recorded an operating lease liability of $5.2 million based on the present value of the remaining minimum lease payments under the terms of this lease with a corresponding right-of-use asset of $5.2 million. As this lease did not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available at effective date of adoption in determining the present value of remaining minimum lease payments. The weighted-average discount rate we used was also 7.25%.

We also lease a shared office space in Boston, Massachusetts, under a short-term lease arrangement, and an office space in Zug, Switzerland, under an operating lease which expires in September 2020.

As of September 30, 2019, the balance of the right-of-use asset associated with the leases described above was $12.0 million and is included in other non-current assets in the accompanying condensed consolidated balance sheet. As of September 30, 2019, the current portion of the corresponding lease liability of $1.0 million is included in accounts payable and other accrued liabilities and the non-current portion of the lease liability of $11.8 million is included in other long-term liabilities in the accompanying condensed consolidated balance sheet. The operating lease costs and cash paid for the amounts included in the measurement of lease liabilities are classified as operating activities in the accompanying condensed consolidated cash flow statement. For the three and nine months ended September 30, 2019, we recorded rent expense of $0.6 million and $1.3 million, respectively. For the three and nine months ended September 30, 2018, we recorded rent expense of $0.3 million, and $0.9 million, respectively. The weighted-average remaining lease term for all operating leases as of September 30, 2019 was 7.1 years.

At September 30, 2019, the future lease payments under our existing financing obligations and non-cancellable operating leases were as follows, in thousands:

Year ending December 31,	Financing Obligations	Operating Leases
Remainder of 2019	$ 1,356	$ 342
2020	8,254	2,520
2021	8,461	2,479
2022	8,672	2,522
2023	8,889	2,566
2024	9,111	2,273
Thereafter	22,941	4,667
Total minimum lease payments	67,684	$ 17,369
Less amounts representing interest	(22,341)	
Add amounts representing residual value	4,950	
Lease financing obligations	50,293	
Less current portion	(3,676)	
	$ 46,617	

At December 31, 2018, the future minimum lease payments under our existing financing and operating lease obligations were as follows, in thousands:

Year ending December 31,	Financing Obligations	Operating Leases
2019	$ 7,391	$ 1,050
2020	8,254	1,100
2021	8,461	976
2022	8,672	1,000
2023	8,889	1,025
Thereafter	32,052	3,698
Total minimum lease payments	73,719	$ 8,849
Less amounts representing interest	(25,960)	
Add amounts representing residual value	4,950	
Lease financing obligations	52,709	
Less current portion	(3,283)	
	$ 49,426	

In 2016 and 2017, we entered into agreements to sublease several of our California properties. All our subleases expire in May 2027. The terms of the subleases stipulate annual increases in monthly rental payments. For the three and nine months ended September 30, 2019, we recognized rent income from our subleases of $0.7 million and $2.2 million, respectively. For the three and nine months ended September 30, 2018, we recognized rent income from our subleases of $0.7 million, and $1.8 million, respectively. At September 30, 2019, the expected minimum rental payments to be received under our subleases were as follows:

Year ending December 31,	
Remainder of 2019	$ 416
2020	1,873
2021	2,477
2022	3,487
2023	3,794
2024	3,896
Thereafter	9,839
Total	$ 25,782

11. Income (Loss) Per Share

We calculate basic and diluted income (loss) from continuing operations, loss from discontinued operations and net income (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 months ended September 30, 2019 and the three and nine months ended September 30, 2018, 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, and (iii) PRSUs, 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 because they were anti-dilutive, in thousands:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Stock options	5,811	5,918	3,809	5,669
RSUs and unvested restricted stock	276	24	—	18
Total	6,087	5,942	3,809	5,687

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, 2018, or 2018 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," "potential," "continue," "likely," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report was filed with the SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, the risk factors identified in our SEC reports, including this Quarterly Report. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements.

OVERVIEW AND RECENT DEVELOPMENTS

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

Our most advanced investigational clinical programs are:

- **Etrasimod,** which we are evaluating in late-stage clinical programs for the treatment of inflammatory bowel disease, or IBD, a Phase 2 for atopic dermatitis, or AD, as well as progressing programs for other potential indications; and
- **Olorinab,** which we are evaluating in a Phase 2 trial for the treatment of abdominal pain associated with irritable bowel syndrome, or IBS, as well as progressing in other visceral pain conditions.

We continue to assess other research and development stage drug candidates, including APD418, a potential first-in-class beta-3 AdrR antagonist and cardiac myotrope, which we are studying in a preclinical program for the treatment of decompensated heart failure.

Additionally, we have collaborations or license agreements with various companies, including:

- United Therapeutics with respect to ralinepag
- Everest with respect to etrasimod in Greater China and select countries in Asia
- Outpost Medicine with respect to OP-352, which is in Phase 1 development
- 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, and
- Eisai with respect to BELVIQ/BELVIQ XR, which are marketed products.

In October 2019, we announced that the first subject has been dosed in the Phase 2 ADVISE trial evaluating two dose levels etrasimod in development for the treatment of AD. ADVISE is a multicenter, randomized, double-blinded, placebo-controlled 16-week study (with a 52-week open-label extension) to assess the safety and efficacy of once-daily etrasimod in approximately 120 subjects with moderate-to-severe AD.

In October 2019, Everest announced that the first subject has been dosed in a Phase 3 trial evaluating etrasimod in development for the treatment of UC in Greater China and South Korea. Everest will pay us a $5.0 million milestone payment earned from this achievement.

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 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	2019	2018	2019	2018
External clinical and preclinical study fees	$ 38.1	$ 16.9	$ 93.8	$ 46.1
Salary and other personnel costs (excluding non-cash share-based compensation)	11.8	7.8	33.1	19.1
Non-cash share-based compensation	6.7	2.3	20.4	5.8
Facility costs	1.4	1.3	4.1	3.8
Other	2.3	0.5	5.5	2.3
Total research and development expenses	$ 60.3	$ 28.8	$ 156.9	$ 77.1

General and administrative expenses

	Three months ended September 30,		Nine months ended September 30,	
Type of expense	2019	2018	2019	2018
Non-cash share-based compensation	$ 6.6	$ 2.9	$ 19.4	$ 7.9
Legal, accounting and other professional fees	6.0	3.0	14.9	10.4
Salary and other personnel costs (excluding non-cash share-based compensation)	5.3	3.3	14.4	9.4
Facility and equipment costs	1.6	1.1	4.3	3.4
Other	0.9	0.5	2.4	1.2
Total general and administrative expenses	$ 20.4	$ 10.8	$ 55.4	$ 32.3

THREE MONTHS ENDED SEPTEMBER 30, 2019, AND 2018

Revenues. We recognized revenues of $1.4 million for the three months ended September 30, 2019, compared to $3.6 million for the three months ended September 30, 2018. This decrease was primarily due to a $2.5 million non-cash revenue in the third quarter of 2018 related to an increase in estimated future royalty payments from Eisai as a result of positive CVOT study results reported by Eisai.

Absent any new collaborations, we expect our revenues for the remainder of 2019 to primarily consist of royalty payments from Eisai based upon Eisai’s sales of BELVIQ to its distributors and potential milestone payments from our existing collaborations and license agreements.

Revenues from royalties are difficult to predict, and our overall revenues will likely continue to vary from quarter to quarter and year to year. In the short term, we expect the amount of revenue we earn to fluctuate.

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 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 $31.5 million to $60.3 million for the three months ended September 30, 2019, from $28.8 million for the three months ended September 30, 2018. This increase was primarily due to increases of $21.2 million in external clinical and preclinical study fees, $4.4 million in non-cash share-based compensation expense, and $4.0 million in salary and other personnel costs. The increases in compensation costs are primarily due to an increase in the number of research and development employees, and an incremental expense associated with performance-based restricted stock units granted in 2019, which is reflected in the non-cash share-based compensation expense.

We expect to incur substantial research and development expenses in 2019 and for the aggregate amount in 2019 to be greater than the amount incurred in 2018. We expect our internal costs to be higher primarily due to increasing headcount and higher external clinical trial costs in connection with advancing the etrasimod and olorinab programs. 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 program for etrasimod is expected to be competitive and challenging, and could take longer than originally projected, which may result in our related external expenses being lower in 2019 than anticipated (but which might increase the overall costs for completing this multi-year program).

Included in the $38.1 million of total external clinical and preclinical study fees noted in the table above for the three months ended September 30, 2019, were the following:

- $31.8 million related to etrasimod, and
- $4.4 million related to olorinab.

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.

General and administrative expenses. General and administrative expenses increased by $9.6 million to $20.4 million for the three months ended September 30, 2019, from $10.8 million for the three months ended September 30, 2018. This increase was primarily due to an increase of $3.7 million in non-cash share-based compensation expenses, an increase of $3.0 million in legal, accounting and other professional fees, and an increase of $2.0 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, and an incremental expense associated with performance-based restricted stock units granted in 2019, which is reflected in the non-cash share-based compensation expense. We expect that our 2019 general and administrative expenses will be higher than in 2018.

Interest and other income (expense), net. Interest and other income, net increased by $4.8 million to $6.5 million for the three months ended September 30, 2019, from $1.7 million for the three months ended September 30, 2018. This increase was primarily due to an increase of $4.3 million in interest income primarily from our available-for-sale investments activity.

NINE MONTHS ENDED SEPTEMBER 30, 2019, AND 2018

Revenues. We recognized revenues of $803.4 million for the nine months ended September 30, 2019, compared to $9.3 million for the nine months ended September 30, 2018. This increase resulted primarily from the revenue associated with the upfront payment of $800.0 million we received in January 2019 pursuant to the United Therapeutics Agreement partially offset by a decrease of $3.7 million in revenues from Eisai primarily due to a non-cash revenue in the third quarter of 2018 related to an increase in estimated future royalty payments from Eisai as a result of positive CVOT study results reported by Eisai and a $2.3 million decrease in revenue from our licensing agreement with Outpost. In connection with the United Therapeutics transaction, during the first quarter of 2019,

we incurred transaction expenses of $14.6 million, which are presented as transaction costs in our condensed consolidated statement of operations.

Research and development expenses. Research and development expenses increased by $79.8 million to $156.9 million for the nine months ended September 30, 2019, from $77.1 million for the nine months ended September 30, 2018. This increase was primarily due to increases of $47.7 million in external clinical and preclinical study fees, $14.6 million in non-cash share-based compensation expense and $14.0 million in salary and other personnel costs. The increases in compensation costs are primarily due to an increase in the number of research and development employees, and an incremental expense associated with performance-based restricted stock units granted in 2019, which is reflected in the non-cash share-based compensation expense.

Included in the $93.8 million of total external clinical and preclinical study fees noted in the table above for the nine months ended September 30, 2019, were the following:

- $72.4 million related to etrasimod, and
- $12.4 million related to olorinab.

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.

General and administrative expenses. General and administrative expenses increased by $23.1 million to $55.4 million for the nine months ended September 30, 2019, from $32.3 million for the nine months ended September 30, 2018. This increase was primarily due to an increase of $11.5 million in non-cash share-based compensation expenses, an increase of $5.0 million in salary and other personnel costs, and an increase of $4.5 million in professional fees. The increases in compensation costs are primarily due to an increase in the number of general and administrative employees, and an incremental expense associated with performance-based restricted stock units granted in 2019, which is reflected in the non-cash share-based compensation expense.

Interest and other income (expense), net. Interest and other income, net increased by $16.7 million to $19.6 million for the nine months ended September 30, 2019, from $2.9 million for the nine months ended September 30, 2018. This increase was primarily due to an increase of $15.2 million in interest income primarily from our available-for-sale investments activity.

Income tax provision. Income tax provision was $110.3 million for the nine months ended September 30, 2019, as a result of the treatment of the United Therapeutics Agreement income as a discrete item during the first quarter of 2019 and the utilization of the deferred tax assets that were recorded in the fourth quarter of 2018.

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 incurred 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 the sale of common stock, the issuance of debt and related financial instruments, payments from collaborators and customers, and sale leaseback transactions.

We believe our cash resources are sufficient to allow us to continue operations for at least the next 12 months from the date this Quarterly Report is filed with the SEC. There is no guarantee that adequate funds will be available when needed from additional debt or equity financing, development and commercialization partnerships or from other sources, or on terms acceptable to us. If our efforts to obtain sufficient additional funds are not successful, we would be required to delay, scale back, or eliminate some or all of our research or development, manufacturing operations, administrative operations, and clinical or regulatory activities, which could negatively affect our ability to achieve certain corporate goals.

Short term liquidity.

At September 30, 2019, we had $1.2 billion in cash, cash equivalents and available-for-sale investments. Our potential sources of liquidity in the short term include (i) milestone and other payments from collaborators or licensees, (ii) entering into new

collaboration, licensing or commercial agreements for one or more of our drug candidates or programs, (iii) the sale or lease of our facilities or other assets and (iv) sale of equity, issuance of debt or other transactions.

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 licensing or collaboration agreements, 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 any drugs 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 provided by operating activities was $630.1 million in the nine months ended September 30, 2019, compared to net cash used in operating activities of $98.5 million in the nine months ended September 30, 2018. This increase was primarily the result of an $800.0 million upfront payment from United Therapeutics received in the nine months ended September 30, 2019, partially offset by an increase of $41.2 million in payments made for external clinical study fees, an increase in cash expenditures of approximately $18.3 million for personnel costs resulting primarily from an increase in the number of employees, a payment of $14.5 million for the expenses related to the United Therapeutics transaction in the first quarter of 2019, reduced by a class action litigation settlement payment of $12.0 million in the second quarter of 2018.

Net cash used in investing activities was $631.1 million in the nine months ended September 30, 2019, compared to net cash provided by investing activities of $62.3 million in the nine months ended September 30, 2018. This change was primarily due to a net increase of $688.7 million in purchases and proceeds from sales and maturities of available-for-sale investments, and an increase of $2.4 million in purchases of property and equipment, partially offset by $1.0 million and $3.4 million in proceeds from the sale of the Manufacturing Operations received during the nine months ended September 30, 2019, and 2018, respectively.

Net cash of $10.3 million was provided by financing activities in the nine months ended September 30, 2019, as a result of $12.7 million in proceeds from stock option exercises, partially offset by $2.4 million on our lease financing obligations. 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, partially offset by payments of $3.0 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, 2018, and there have been no material changes during the nine months ended September 30, 2019.

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, 2018.

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.

We are not currently subject to any material legal proceedings.

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, 2018, as filed with the Securities and Exchange Commission, or SEC.

Risks Relating to Our Business

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 ongoing and 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:

- side effects experienced by study participants or other safety issues;
- lack of effectiveness of any drug candidate during clinical trials;
- 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 or planned 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, enrolling patients in, or completing our studies or trials or advancing our programs on our projected timetable, if at all. Any failure to initiate or delays in our studies, trials or development programs, or unfavorable results or decisions or negative perceptions regarding any of our programs, could cause our stock price to decline significantly. This is particularly the case with respect to our clinical programs.

We 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 internal programs are in the development stage, and we may not have adequate funds to develop all of 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.

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 the drug candidates that we or our collaborators and licensees are developing (including etrasimod, ralinepag and olorinab) 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.

It is generally our strategy to develop drug candidates that we believe will be first-in-class, best-in-class, or similar descriptions, or otherwise have broad clinical utility, optimized pharmacology or optimized pharmacokinetics. Some or all of our drug candidates may not achieve these goals. For example, failure to complete enrollment in clinical trials on schedule or at all could prevent a drug candidate from being first-in-class. Similarly, comparing data from different trials, or making predictions based on preclinical data,

may not allow us to correctly determine whether our drug candidates are superior to competitive drugs or drug candidates in the same way that comparisons can be made from conducting trials in which our and a competitive drug is tested “head to head” in the same trial. The failure of our drugs or drug candidates to be first-in-class, best-in-class, or similar descriptions, or have broad clinical utility, optimized pharmacology, or optimized pharmacokinetics, could adversely affect development, regulatory approval, third-party payor support, or market adoption, which would have a material adverse impact on our business.

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 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 that entered Phase 3 clinical development before etrasimod for the same indications that we are pursuing, such as ulcerative colitis.

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’ and licensees’ 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 and licensees 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. Lorcaserin is the only approved and marketed drug in which we have a financial interest. Our future revenue for the near-term is substantially dependent on our license and partnership agreements.

We cannot guarantee future product sales or achievement of milestones under our collaborations and license agreements. For example, our license agreement with United Therapeutics for ralinepag does not contain a covenant obligating United Therapeutics to use any particular efforts to develop or commercialize any product, and we may never receive any milestone or royalty payments under this license agreement. In addition, our Transaction Agreement with Eisai for lorcaserin, and 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' and licensee's 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, or 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, executive, and judicial activity around, attempts to repeal, replace, or modify the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or TCJA, 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 ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, the United States Department of Health and Human Services' Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the TCJA. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business and operations.

Further, there has been heightened governmental scrutiny in the United States and other countries of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in 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 drugs. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. 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 or licensee is willing to pay to license our programs or drug candidates in the future, which may prevent us from being able to establish and maintain collaborations and license agreements, 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, 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 attract and retain 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 are expanding 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, including in and outside of headquarters in San Diego, California. For example, in addition to our headquarters in San Diego, we currently have operations in Zug, Switzerland, and Boston, Massachusetts. 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 develop and then 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.

Any new data generated, 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 the drug from the market, or result in litigation. In addition, analyses of previous data can have similar risks. 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 any approved drug could have an adverse effect on our or our collaborator's or licensee's 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.

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. The safety issues that have affected other weight loss drugs 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 or results under such agreements could negatively impact our business.**

Our collaborators and licensees may have primary responsibility for the regulatory approval, marketing and distribution, and, in certain circumstances, development, of our drug candidate in the territory or territories under the applicable collaboration. We may have limited or no control over our collaborator's decisions, including the amount and timing of resources that any of these collaborators will dedicate to such activities. This is the case for our ralinepag exclusive license agreement with United Therapeutics and our lorcaserin Transaction Agreement with Eisai.

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

- our collaborators and licensees may not comply with applicable laws or regulatory guidelines, which could adversely impact the commercialization or development of the drug candidate;
- 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 and licensees may not effectively allocate adequate resources, may have limited experience in a particular territory, or may generate unfavorable data or result; and
- our collaborators and licensees 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 or licensees 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 all our drugs and drug candidates, 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.

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.

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. 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 and others we contract with 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, and we were provided with observations of objectionable conditions or practices with respect to our business. 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. Unfavorable trial results from postmarketing studies could negatively impact market acceptance of the drug; limit the revenues we generate from sales; result in the drug's withdrawal from the market; negatively impact the potential approval of the drug in other territories; 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 and license agreement 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 or licensees, 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 or licensees 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 or licensees 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 or licensees, 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 or licensee 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 or license agreement activities, which could prevent us from entering into additional collaborations;
- unwillingness on the part of a collaborator or licensee 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 or licensee's research, development, regulatory or commercialization efforts with respect to our drug candidates or drugs; or
- litigation or arbitration.

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 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 rely on third parties, including investigators, clinical research organizations, manufacturers and laboratories, 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 developer.

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, and limited revenues. If we are unable to generate cash from operations in the future sufficient to meet our financial obligations, we will need to obtain additional funds from other sources, at all or on terms favorable to our stockholders or us.

Also, if we do not have sufficient cash in the future and are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet 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.

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 provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We conduct clinical trials in the EU, and in the future we may expand our business operations to include additional operations in the EU. 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.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to

California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA will likely impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

We and third parties we contract with use hazardous materials in our operations.

Our activities involve the use of materials that could be hazardous to human health and safety or the environment. We cannot completely eliminate the risks associated with their use, storage or disposal, 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 primarily located in a business park in San Diego. We also have certain operations in Boston, Massachusetts, and Zug, Switzerland. We depend on our facilities and on collaborators, licensees, 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 and our licensees 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 companies in the pharmaceuticals industry often experience significant stock price volatility. For example, beginning in 2010, a number of lawsuits were filed against us and certain of our employees and directors alleging we and the other defendants 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. These lawsuits were settled in 2018.

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 any drugs we and our collaborators and licensees 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, including relating to public companies, may be costly and impact our ability to attract and retain directors and executive officers.

Laws and regulations affecting public companies, including rules adopted by the SEC and by Nasdaq, as well as other laws and regulations, including, for example, of foreign governments and relating to privacy, may result in increased costs to us, particularly as we continue to develop the required capabilities in the United States and abroad to develop and 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.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including from December 22, 2018, to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our disclosure controls and procedures and our internal control over financial reporting may not prevent potential errors and fraud

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.

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

As of December 31, 2018, we had federal and state net operating loss carryforwards of $1,274.2 million. Our federal net operating loss carryforwards ($869.4 million) will begin to expire, if not utilized, beginning in 2023, and our state net operating loss carryforwards ($404.8 million) begin expiring in 2028. Our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. In January 2019, a taxable income-generating event, the transaction pursuant to the United Therapeutics Agreement, resulted in it being more likely than not that a portion of our net operating loss carryforwards would be used to offset our estimates of taxable income in 2019. If the estimates we have made, or the assumptions on which we relied, in estimating our taxable income in 2019 prove inaccurate, our net operating loss carryforwards to be used to offset our taxable income in 2019 may vary from our estimates. 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.

Current and future tax laws and regulation could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, or TCJA, which significantly revised the Internal Revenue Code of 1986, as amended. The TCJA among other things, contained 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 TCJA 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 this federal tax law.

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 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 we 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 third-party patents, as well as a third-party patent application, with broad claims to administering an S1P modulator 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.

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. 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 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 our drugs.

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, 2018, to November 1, 2019, the market price of our stock was as low as $30.00 per share and as high as $64.48 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, expenses and other operating results) 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.

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 we will evaluate various funding alternatives from time to time. 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.

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 1, 2019, there were (i) options to purchase 8,504,679 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of $34.21 per share, (ii) 23,564 restricted stock unit awards outstanding under our equity incentive plans, (iii) 212,085 performance restricted stock units outstanding under our equity incentive plans, (iv) 3,113,587 additional shares of common stock remaining issuable under our Amended and Restated 2017 Long-Term Incentive Plan, and (v) 1,000,000 shares issuable under our 2019 Employee Stock Purchase 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 1, 2019, there were 50,107,145 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 they may 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 transaction 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	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101. INS

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, 2019

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)

Exhibit 31.1

CERTIFICATION

I, Amit D. Munshi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Arena Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2019

/s/ Amit D. Munshi

Amit D. Munshi, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Kevin R. Lind, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Arena Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 8, 2019

/s/ Kevin R. Lind

Kevin R. Lind, Executive Vice President
and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Arena Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Amit D. Munshi, as President and Chief Executive Officer of the Company, and Kevin R. Lind, as Executive Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Amit D. Munshi
Amit D. Munshi
President and Chief Executive Officer

Date: November 8, 2019

/s/ Kevin R. Lind
Kevin R. Lind
Executive Vice President and Chief Financial Officer

Date: November 8, 2019