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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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**

COMMISSION FILE NUMBER: 001-37590

CERECOR INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-0705648**
(State of incorporation)	(I.R.S. Employer Identification No.)
540 Gaither Road, Suite 400 **Rockville, Maryland 20850**	**(410) 522-8707**
(Address of principal executive offices)	(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	CERC	Nasdaq Capital 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, a 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 ☑	Smaller 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 ☑

As of November 12, 2019, the registrant had 44,106,794 shares of common stock outstanding.

CERECOR INC.

FORM 10-Q

For the Quarter Ended September 30, 2019

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

CERECOR INC. and SUBSIDIARIES

Condensed Consolidated Balance Sheets

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 5,250,651	$ 10,646,301
Accounts receivable, net	4,955,771	3,157,555
Other receivables	208,204	5,469,011
Inventory, net	402,267	1,110,780
Prepaid expenses and other current assets	1,670,019	1,529,516
Restricted cash, current portion	102,214	18,730
Total current assets	12,589,126	21,931,893
Property and equipment, net	1,496,431	586,512
Intangible assets, net	26,595,239	31,239,468
Goodwill	16,411,123	16,411,123
Restricted cash, net of current portion	101,945	81,725
Total assets	$ 57,193,864	$ 70,250,721
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 826,472	$ 1,446,141
Accrued expenses and other current liabilities	13,133,895	19,731,373
Income taxes payable	1,014,454	2,032,258
Long-term debt, current portion	1,050,000	1,050,000
Contingent consideration, current portion	1,237,401	1,956,807
Total current liabilities	17,262,222	26,216,579
Long-term debt, net of current portion	14,254,856	14,327,882
Contingent consideration, net of current portion	6,236,084	7,093,757
Deferred tax liability, net	98,061	69,238
License obligations	—	1,250,000
Other long-term liabilities	1,121,367	385,517
Total liabilities	38,972,590	49,342,973
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 44,106,794 and 40,804,189 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	44,107	40,804
Preferred stock—$0.001 par value; 5,000,000 shares authorized at September 30, 2019 and December 31, 2018; 2,857,143 shares issued and outstanding at September 30, 2019 and December 31, 2018	2,857	2,857
Additional paid-in capital	134,085,981	119,082,157
Accumulated deficit	(115,911,671)	(98,218,070)
Total stockholders' equity	18,221,274	20,907,748
Total liabilities and stockholders' equity	$ 57,193,864	$ 70,250,721

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Condensed Consolidated Statements of Operations (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 5,513,276	$ 4,074,786	$ 15,374,123	$ 13,045,824
License and other revenue	100,000	—	100,000	—
Sales force revenue	—	—	—	296,875
Total revenues, net	5,613,276	4,074,786	15,474,123	13,342,699
Operating expenses:				
Cost of product sales	1,435,061	3,111,290	3,241,131	5,397,872
Research and development	1,743,435	1,047,877	8,857,220	3,780,352
Acquired in-process research and development	—	18,723,952	—	18,723,952
General and administrative	2,679,396	1,884,293	7,778,386	7,833,612
Sales and marketing	2,630,545	2,310,760	8,676,298	5,889,137
Amortization expense	1,037,414	1,065,398	3,195,108	3,315,843
Impairment of intangible assets	—	159,687	1,449,121	1,861,562
Change in fair value of contingent consideration	(197,219)	84,844	(1,009,168)	360,850
Total operating expenses	9,328,632	28,388,101	32,188,096	47,163,180
Loss from operations	(3,715,356)	(24,313,315)	(16,713,973)	(33,820,481)
Other (expense) income:				
Change in fair value of warrant liability and unit purchase option liability	35,491	(2,994)	6,823	(22,329)
Other (expense) income, net	(15,000)	—	(24,400)	18,655
Interest expense, net	(205,938)	(234,854)	(613,624)	(577,664)
Total other expense, net	(185,447)	(237,848)	(631,201)	(581,338)
Net loss before taxes	(3,900,803)	(24,551,163)	(17,345,174)	(34,401,819)
Income tax expense	115,651	52,412	348,427	92,076
Net loss	$ (4,016,454)	$ (24,603,575)	$ (17,693,601)	$ (34,493,895)
Net loss per share of common stock, basic and diluted	$ (0.07)	$ (0.71)	$ (0.31)	$ (1.05)
Net loss per share of preferred stock, basic and diluted	$ (0.35)	$ —	$ (1.56)	$ —

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows (Unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (17,693,601)	$ (34,493,895)
Adjustments to reconcile net loss provided by (used in) operating activities:		
Depreciation and amortization	3,266,313	3,333,416
Impairment of intangible assets	1,449,121	1,861,562
Stock-based compensation	1,942,196	1,796,387
Acquired in-process research and development, including transaction costs	—	18,723,952
Deferred taxes	28,823	(47,994)
Amortization of inventory fair value associated with acquisition of TRx and Avadel's pediatric products	107,272	262,419
Non-cash interest expense	—	327,224
Change in fair value of warrant liability and unit purchase option liability	(6,823)	22,328
Change in fair value of contingent consideration	(1,009,168)	360,850
Changes in assets and liabilities:		
Accounts receivable, net	(1,798,216)	(73,513)
Other receivables	5,260,807	(3,072,729)
Inventory, net	601,241	(226,735)
Prepaid expenses and other assets	(140,503)	27,571
Escrowed cash receivable	—	3,752,390
Accounts payable	(619,669)	172,243
Income taxes payable	(1,017,804)	(64,100)
Accrued expenses and other liabilities	(6,573,918)	6,186,178
License obligations	(1,250,000)	—
Net cash used in operating activities	(17,453,929)	(1,152,446)
Investing activities		
Acquisition of Avadel's pediatric products	—	(1)
Cash acquired from the acquisition of Ichorion Therapeutics, Inc.	—	1,429,876
Purchase of property and equipment	(262,011)	(65,057)
Net cash (used in) provided by investing activities	(262,011)	1,364,818
Financing activities		
Proceeds from exercise of stock options and warrants	257,993	508,746
Proceeds from sales of common stock under employee stock purchase plan	127,537	8,400
Restricted stock units withheld for taxes	(33,959)	—
Proceeds from sale of shares pursuant to private placement, net	3,737,400	3,857,106
Proceeds from underwritten public offering, net	8,975,960	—
Payment of contingent consideration	(567,911)	(137,008)
Payment of long-term debt	(73,026)	—
Net cash provided by financing activities	12,423,994	4,237,244
(Decrease) increase in cash, cash equivalents and restricted cash	(5,291,946)	4,449,616
Cash, cash equivalents, and restricted cash at beginning of period	10,746,756	2,605,499
Cash, cash equivalents, and restricted cash at end of period	$ 5,454,810	$ 7,055,115
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 787,500	$ 262,500
Cash paid for taxes	$ 1,326,025	$ —
Supplemental disclosures of non-cash activities		
Leased asset obtained in exchange for new operating lease liability	$ 743,025	$ —
Debt assumed in Avadel Pediatric Products acquisition	$ —	$ (15,075,000)

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows:

	September 30,	
	2019	2018
Cash and cash equivalents	$ 5,250,651	$ 6,838,353
Restricted cash, current	102,214	37,027
Restricted cash, non-current	101,945	179,735
Total cash, cash equivalents and restricted cash	$ 5,454,810	$ 7,055,115

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited)

	Common stock		Preferred Stock		Additional paid-in	Contingently issuable stock	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	Amount	deficit	equity
Three Months Ended September 30, 2018:								
Balance, June 30, 2018	33,790,686	$ 33,792	—	$ —	$ 87,241,204	$ —	$ (68,055,580)	$ 19,219,416
Issuance of shares pursuant to common stock private placement, net of offering costs	1,000,000	1,000	—	—	3,856,106	—	—	3,857,106
Issuance of shares in acquisition of Ichorion assets	5,798,735	5,774	—	—	19,965,780	—	—	19,971,554
Exercise of stock options and warrants	90,213	90	—	—	118,182	—	—	118,272
Stock-based compensation	—	—	—	—	945,132	—	—	945,132
Net loss	—	—	—	—	—	—	(24,603,575)	(24,603,575)
Balance, September 30, 2018	40,679,634	$ 40,656	—	$ —	$112,126,404	$ —	$ (92,659,155)	$ 19,507,905
Nine Months Ended September 30, 2018:								
Balance, December 31, 2017	31,266,989	$ 31,268	—	$ —	$ 83,338,136	$ 2,655,464	$ (58,165,260)	$ 27,859,608
Issuance of contingently issuable shares in acquisition of TRx	2,349,968	2,350			2,653,114	(2,655,464)	—	—
Issuance of shares pursuant to common stock private placement, net of offering costs	1,000,000	1,000	—	—	3,856,106	—	—	3,857,106
Issuance of shares in acquisition of Ichorion assets	5,798,735	5,774	—	—	19,965,780	—	—	19,971,554
Exercise of stock options and warrants	243,942	244	—	—	508,501	—	—	508,745
Shares purchased through employee stock purchase plan	20,000	20	—	—	8,380	—	—	8,400
Stock-based compensation	—	—	—	—	1,796,387	—	—	1,796,387
Net loss	—	—	—	—	—	—	(34,493,895)	(34,493,895)
Balance, September 30, 2018	40,679,634	$ 40,656	—	$ —	$112,126,404	$ —	$ (92,659,155)	$ 19,507,905

Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited)

	Common stock		Preferred Stock		Additional paid-in	Contingently issuable stock	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	Amount	deficit	equity
Three Months Ended September 30, 2019								
Balance, June 30, 2019	42,898,251	$ 42,898	2,857,143	$ 2,857	$129,545,721	$ —	$(111,895,217)	$ 17,696,259
Issuance of shares pursuant to common stock private placement, net of offering costs	1,200,000	1,200	—	—	3,736,200	—	—	3,737,400
Exercise of stock options and warrants	539	1	—	—	1,175	—	—	1,176
Restricted Stock Units vested during period	11,250	11	—	—	(11)	—	—	—
Restricted Stock Units withheld for taxes	(3,246)	(3)	—	—	(15,898)	—	—	(15,901)
Stock-based compensation	—	—	—	—	818,794	—	—	818,794
Net loss	—	—	—	—	—	—	(4,016,454)	(4,016,454)
Balance, September 30, 2019	44,106,794	$ 44,107	2,857,143	$ 2,857	$134,085,981	$ —	$(115,911,671)	$ 18,221,274
Nine Months Ended September 30, 2019								
Balance, December 31, 2018	40,804,189	$ 40,804	2,857,143	$ 2,857	$119,082,157	$ —	$ (98,218,070)	$ 20,907,748
Issuance of shares of common stock in underwritten public offering, net of offering costs	1,818,182	1,818	—	—	8,974,142	—	—	8,975,960
Issuance of shares pursuant to common stock private placement, net of offering costs	1,200,000	1,200			3,736,200			3,737,400
Exercise of stock options and warrants	74,952	75	—	—	257,918	—	—	257,993
Restricted Stock Units vested during period	172,500	173	—	—	(173)	—	—	—
Restricted Stock Units withheld for taxes	(6,969)	(7)	—	—	(33,952)	—	—	(33,959)
Shares purchased through employee stock purchase plan	43,940	44	—	—	127,493	—	—	127,537
Stock-based compensation	—	—	—	—	1,942,196	—	—	1,942,196
Net loss	—	—	—	—	—	—	(17,693,601)	(17,693,601)
Balance, September 30, 2019	44,106,794	$ 44,107	2,857,143	$ 2,857	$134,085,981	$ —	$(115,911,671)	$ 18,221,274

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Notes to Unaudited Condensed Consolidated Financial Statements

1. Business

Cerecor Inc. (the “Company” or “Cerecor”) is a biopharmaceutical company focused on becoming a leader in the development and commercialization of treatments for orphan diseases and neurological disorders. The Company's orphan disease pipeline is led by CERC-801, CERC-802 and CERC-803. All three compounds are therapies for inborn errors of metabolism, specifically disorders known as Congenital Disorders of Glycosylation ("CDGs") by means of substrate replacement therapy. The U.S. Food and Drug Administration ("FDA") has granted Rare Pediatric Disease Designation ("RPDD") and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of a new drug application ("NDA"). The PRV may be sold or transferred an unlimited number of times. The Company plans to leverage the 505(b)(2) NDA pathway for all three compounds to accelerate their development and approval. Additionally, CERC-801 and CERC-802 were granted Fast Track Designation ("FTD") from the FDA which helps facilitate and expedite development of each compound. The Company is also in the process of developing one other preclinical orphan disease compound, CERC-913, for the treatment of mitochondrial DNA Depletion Syndrome. The Company's neurology pipeline is led by CERC-301, a Glutamate NR2B selective, NMDA Receptor antagonist, which Cerecor is currently developing as a novel treatment for orthostatic hypotension ("OH"). The Company is also developing CERC-406, a CNS-targeted COMT inhibitor for Parkinson's Disease. The Company also currently has one marketed product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions and indications.

Cerecor was incorporated in 2011, commenced operations in 2011 and completed an initial public offering in October 2015.

On November 17, 2017, the Company acquired TRx Pharmaceuticals, LLC (“TRx”) and its wholly-owned subsidiaries (see "TRx Acquisition" inNote 5 below for a description of this transaction).

On February 16, 2018, Cerecor acquired all rights to Avadel Pharmaceuticals PLC’s (“Avadel”) marketed pediatric products (the “Acquired Products”) in exchange for Cerecor assuming certain financial obligations of Avadel (see "Avadel Pediatric Products Acquisition" in Note 5 below for a description of this transaction).

On September 25, 2018, the Company acquired Ichorion Therapeutics, Inc., a privately-held biopharmaceutical company focused on developing treatments and increasing awareness of inherited metabolic disorders known as CDGs (see "Ichorion Asset Acquisition" in Note 5 below for a description of this transaction).

On October 10, 2019, the Company entered into, and subsequently closed on, an asset purchase agreement (the "Aytu Purchase Agreement") with Aytu BioScience, Inc. (“Aytu”) to sell the Company’s rights, title and interest in, assets relating to its Pediatric Portfolio, namely Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal™ ER, Flexichamber™, Poly-Vi-Flor® and Tri-Vi-Flor™ (the "Divested Assets" or "Pediatric Portfolio"), as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor’s sales force and the assignment of supporting commercial contracts (the “Aytu transaction”). Aytu provided consideration of cash and preferred stock totaling $17 million ($4.5 million in cash and $12.5 million in Aytu preferred stock) and assumed certain of the Company’s liabilities, including the Company’s payment obligations payable to Deerfield CSF, LLC ("Deerfield") of approximately $15 million and certain other liabilities in excess of approximately $11 million. In addition, Aytu assumed future contractual obligations under existing license agreements associated with the Divested Assets. The Aytu transaction closed on November 1, 2019. Upon closing of the transaction, Cerecor terminated all sales force personnel, which included both those that Aytu offered employment, as well as any remaining sales force personnel. Cerecor expects to incur severance charges and legal costs in the fourth quarter as a result of the transaction (see Note 14 for description of this transaction).

Liquidity

In order to meet its cash flow needs, the Company applies a disciplined decision-making methodology as it evaluates the optimal allocation of the Company's resources between investing in the Company's development portfolio and acquisitions or in-licensing of new assets. For the nine months ended September 30, 2019, Cerecor generated a net loss of $17.7 million and negative cash flow from operations of $17.5 million. As of September 30, 2019, Cerecor had an accumulated deficit of $115.9 million and a balance of $5.3 million in cash and cash equivalents.

During the first quarter of 2019, the Company closed an underwritten public offering of common stock for1,818,182 shares of common stock of the Company, at a price to the public of $5.50 per share ("public price"). Armistice Capital Master Fund Ltd. ("Armistice"), our largest stockholder, participated in the offering by purchasing 363,637 shares of common stock of the Company from the underwriter at the public price. Cerecor director Steven J. Boyd is Armistice's Chief Investment Officer. The net proceeds of the offering were approximately $9.0 million (see "Common Stock Offering" in Note 9 below for description of the transaction). During the third quarter of 2019, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold 1,200,000 shares of the Company's common stock for a purchase price of $3.132 per share. Net proceeds of the private placement were approximately $3.7 million. During the fourth quarter of 2019, the Company entered into, and subsequently closed on, the Aytu Purchase Agreement to sell the Company's rights, title and interest in, assets relating to its Pediatric Portfolio and related commercial infrastructure for a combination of cash and preferred stock totaling $17 million ($4.5 million in cash and $12.5 million in Aytu preferred stock) and assumption of certain of the Company's liabilities including the Company's payment obligations payable to Deerfield and certain other liabilities in excess of $15 million.

The Company plans to use its current cash on hand inclusive of the$4.5 million cash collected in the fourth quarter of 2019 from the sale of the Pediatric Portfolio and related commercial infrastructure and the anticipated cash flows from the Company's sales of Millipred to offset costs related to its neurology programs, orphan disease programs, business development, and costs associated with its organizational infrastructure. Cerecor expects to continue to incur significant expenses and operating losses for the immediate future as it continues to invest in the Company's pipeline assets. Our ability to achieve and maintain profitability in the future is dependent on, among other things, the development, regulatory approval, and commercialization of our pipeline assets, the potential sale of any PRVs we receive and revenue from Millipred product sales, all being adequate to support our cost structure and pipeline asset development.

The Company believes it will require additional financing to continue to execute its clinical development strategy and fund future operations. The Company plans to meet its capital requirements through operating cash flows from product sales of Millipred and some combination of PRV sales, equity or debt financings, collaborations, out-licensing arrangements, strategic alliances, federal and private grants, marketing, distribution or licensing arrangements or the sale of current or future assets. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates.

Our plan to aggressively develop our pipeline will require substantial cash in excess of what the Company expects our cash from the current commercial operations to generate. However, the Company expects that our existing cash and cash equivalents, together with anticipated revenue, will enable us to fund our operating expenses, capital expenditure requirements, and other non-operating cash payments through at least November 2020.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The Company's unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows. The condensed consolidated balance sheet at December 31, 2018 has been derived from audited financial statements at that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission ("SEC"). Certain prior period amounts have been reclassified to conform to the current year presentation, as described below.

The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed consolidated financial statements are read in conjunction with the December 31, 2018 audited consolidated financial statements.

Reclassification

During the fourth quarter of 2018, the Company concluded that going forward it would include change in fair value of contingent consideration within its own stand-alone line in operating expenses in the Company's statements of operations. The Company has reclassified $0.1 million and $0.4 million from other expenses to operating expenses in the three and nine months ended September, 30, 2018, respectively, on the statement of operations to conform with current period presentation.

Significant Accounting Policies

During the nine months ended September 30, 2019, there were no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 18, 2019 and amended on April 23, 2019, except for the recently adopted accounting standards described below.

The following significant accounting policy was updated in 2019 to reflect changes upon our adoption of ASU No. 2016-02*Leases* (Topic 842) ("ASU 2016-02").

Leases

The Company determines if an arrangement is a lease at inception. If an arrangement contains a lease, the Company performs a lease classification test to determine if the lease is an operating lease or a finance lease. The Company has identified one operating lease, which is for its corporate headquarters. Right-of-use ("ROU") assets represent the right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease liabilities are recognized on the commencement date of the lease based on the present value of the future lease payments over the lease term and are included in other long-term liabilities and other current liabilities on our condensed consolidated balance sheet. ROU assets are valued at the initial measurement of the lease liability, plus any indirect costs or rent prepayments, and reduced by any lease incentives and any deferred lease payments. Operating ROU assets are recorded in property and equipment, net on the condensed consolidated balance sheet and are amortized over the lease term. To determine the present value of lease payments on lease commencement, we use the implicit rate when readily determinable, however, as most leases do not provide an implicit rate, we use our incremental borrowing rate based on information available at commencement date. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Furthermore, the Company has elected the practical expedient to account for the lease and non-lease components as a single lease component for the leased property asset class. Lease expense is recognized on a straight-line basis over the life of the lease and is included within general and administrative expenses.

Recently Adopted Accounting Pronouncements

Adoption of ASC 842

In February 2016, FASB issued ASU 2016-02, which revises existing practice related to accounting for leases under ASC No. 840,*Leases* ("ASC 840") for both lessees and lessors. The new guidance in ASU 2016-02 requires lessees to recognize a ROU asset and a lease liability for nearly all leases (other than leases that meet the definition of a short-term lease). The lease liability will be equal to the present value of lease payments and the ROU asset will be based on the lease liability, subject to adjustment such as for initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating leases or finance leases. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while finance leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840).

The Company adopted the standard using the modified retrospective transition method on its effective date of January 1, 2019 and therefore did not adjust prior comparative periods as permitted by the codification improvements issued by FASB in July 2018. Additionally, the Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows the Company to carryforward the historical lease classification. As a result of the standard, the Company recorded a lease liability of $1.2 million and a ROU asset of $0.7 million, which is equal to the initial measurement of the lease liability reduced by the unamortized balance of lease incentive received and deferred rent. There was no material impact to our condensed consolidated income statement (see Note 12 below for more information).

Other Adopted Accounting Pronouncements

SEC Simplification

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532 Disclosure Update and Simplification, to eliminate or modify certain disclosure rules that are redundant, outdated, or duplicative of GAAP or other regulatory requirements.

Among other changes, the amendments provide that disclosure requirements related to the analysis of stockholders' equity are expanded for interim financial statements. An analysis of the changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The Company began providing this disclosure in the first quarter of 2019 within a separate statement.

New Accounting Pronouncements

Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.” (ASU 2016-13) This guidance applies to all entities and impacts how entities account for credit losses for most financial assets and other instruments. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction to the carrying value of the asset. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate lifetime expected credit losses. This guidance is effective for fiscal years beginning after December 15, 2019 and interim periods therein. The Company is currently evaluating the potential impact of the adoption of this standard, however, does not expect that the adoption of this new standard will have a material impact on the Company's results of operations or disclosures.

Fair Value Measurements

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. This new standard modifies certain disclosure requirements on fair value measurements. This new standard will be effective for the Company on January 1, 2020. The Company is currently evaluating the potential impact of the adoption of this standard on its financial statements.

3. Revenue from Contracts with Customers

The Company generates substantially all of its revenue from sales of prescription pharmaceutical products to its customers. The following table presents net revenues disaggregated by type (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Prescribed dietary supplements	$ 2,318	$ 2,097	$ 5,909	$ 5,767
Prescription drugs	3,195	1,978	9,465	7,279
License and other revenue	100	—	100	—
Sales force revenue	—	—	—	297
Total revenue	$ 5,613	$ 4,075	$ 15,474	$ 13,343

As is typical in the pharmaceutical industry, the Company sells its prescription pharmaceutical products (which include prescribed dietary supplements and prescription drugs) in the United States primarily through wholesale distributors and a specialty contracted pharmacy. Wholesale distributors account for substantially all of the Company’s net product revenues and trade receivables. In addition, the Company earns revenue from sales of its prescription pharmaceutical products directly to retail pharmacies. For the three months ended September 30, 2019, the Company’s three largest customers accounted for approximately 32%, 31%, and 27% of the Company's total net product revenues from sale of prescription pharmaceutical products. For the nine months ended September 30, 2019, the Company's three largest customers accounted for approximately 35%, 31%, and 26% of the Company's total net product revenues from sale of prescription pharmaceutical products.

4. Net Loss Per Share

The Company computes earnings per share ("EPS") using the two-class method. The two-class method of computing EPS is an earnings allocation formula that determines EPS for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings. The Company has two classes of stock outstanding, common stock and preferred stock. The preferred stock was issued in the fourth quarter of 2018 upon Armistice exercising preferred stock warrants to acquire an aggregate of 2,857,143 shares of the Series B Convertible Preferred Stock ("convertible preferred stock"). The convertible preferred

stock has the same rights and preferences as common stock, other than being non-voting and convertible to shares of common stock on a 1-to-5 ratio.

Under the two-class method, the convertible preferred stock is considered a separate class of stock for EPS purposes and therefore basic and diluted EPS is provided below for both common stock and preferred stock. EPS for common stock and EPS for preferred stock is computed by dividing the sum of distributed earnings and undistributed earnings for each class of stock by the weighted average number of shares outstanding for each class of stock for the period. In applying the two-class method, undistributed earnings are allocated to common stock and preferred stock based on the weighted average shares outstanding during the period, which assumes the convertible preferred stock has been converted to common stock.

Diluted net (loss) income per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units, which are included under the "treasury stock method" when dilutive, (ii) common stock to be issued upon the assumed conversion of the Company's unit purchase option (the "UPO") shares, which are included under the "if-converted method" when dilutive; (iii) prior to issuance, the contingently issuable shares in the TRx acquisition, if contingencies would have been satisfied if the end of the contingency period were as of the balance sheet date under the "if-converted method" when dilutive; and (iv) common stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive. Because the impact of these items is generally anti-dilutive during periods of net loss, there is no difference between basic and diluted loss per common share for periods with net losses. In periods of net loss, losses are allocated to the participating security only if the security has not only the right to participate in earnings, but also a contractual obligation to share in the Company's losses.

The following table sets forth the computation of basic and diluted net loss per share of common stock and preferred stock for the three and nine months ended September 30, 2019 and 2018, which includes both classes of participating securities:

	Three Months Ended September 30,			
	2019		2018	
	Common stock	Preferred stock	Common stock	Preferred stock
Numerator:				
Allocation of undistributed net loss	$ (3,019,101)	$ (997,353)	$ (24,603,575)	$ —
Denominator:				
Weighted average shares	43,244,481	2,857,143	34,648,641	—
Basic and diluted net loss per share	$ (0.07)	$ (0.35)	$ (0.71)	$ —

	Nine Months Ended September 30,			
	2019		2018	
	Common stock	Preferred stock	Common stock	Preferred stock
Numerator:				
Allocation of undistributed net loss	$ (13,238,766)	$ (4,454,835)	$ (34,493,895)	$ —
Denominator:				
Weighted average shares	42,453,928	2,857,143	32,749,291	—
Basic and diluted net loss per share	$ (0.31)	$ (1.56)	$ (1.05)	$ —

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the three and nine months ended September 30, 2019 and 2018, as they could have been anti-dilutive:

	Three and Nine Months Ended September 30,	
	2019	2018
Stock options	5,297,124	4,119,187
Warrants on common stock	4,024,708	18,905,064
Restricted Stock Units	267,500	445,000
Underwriters' unit purchase option	40,000	40,000

5. Acquisitions

Asset Acquisitions

Ichorion Asset Acquisition

On September 24, 2018, the Company entered into, and subsequently consummated the transactions contemplated by, an agreement and plan of merger (the "Merger Agreement") by and among the Company and Ichorion Therapeutics, Inc., a Delaware corporation (the “Ichorion Asset Acquisition”), with Ichorion surviving as a wholly owned subsidiary of the Company. The consideration for the Ichorion Asset Acquisition consisted of approximately 5.8 million shares of the Company’s common stock, par value $0.001 per share, as adjusted for Estimated Working Capital, as defined in the Merger Agreement. The shares of common stock issued as part of the acquisition may not be resold until January 2020. Consideration for the Ichorion Asset Acquisition includes certain development milestones worth up to an additional $15.0 million, payable either in shares of the Company's common stock or in cash, at the election of the Company.

The fair value of the common stock shares transferred at closing was approximately $20.0 million based on the Company's stock price close on September 24, 2018 and offset by an estimated discount for lack of marketability calculated using guideline public company volatility for comparable companies. The assets acquired consisted primarily of $18.7 million of acquired in-process research and development ("IPR&D"), $1.6 million of cash and $0.2 million assembled workforce. The Company recorded this transaction as an asset purchase as opposed to a business combination as management concluded that substantially all of the value received was related to one group of similar identifiable assets which was the IPR&D for the three preclinical therapies for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803). The Company considered these assets similar due to similarities in the risks for development, compound type, stage of development, regulatory pathway, patient population and economics of commercialization. The fair value of the IPR&D was immediately recognized as Acquired In-Process Research and Development expense as the IPR&D asset has no other alternate use due to the stage of development. The $0.2 million of transaction costs incurred were recorded to acquired IPR&D expense. The assembled workforce asset recorded to intangible assets will be amortized over an estimated useful life of two years.

The contingent consideration of up to an additional $15.0 million relates to three future development milestones. The first milestone is the first product being approved for marketing by the FDA on or prior to December 31, 2021. If this milestone is met, the Company is required to make a milestone payment of $6.0 million. The second milestone is the second product being approved for marketing by the FDA on or prior to December 31, 2021. If this milestone is met, the Company is required to make a milestone payment of $5.0 million. The third milestone is a protide molecule being approved by the FDA on or prior to December 31, 2023. If this milestone is met, the Company is required to make a milestone payment of $4.0 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of the Company.

The contingent consideration related to the development milestones will be recognized if and when such milestones are probable and can be reasonably estimated. As of September 30, 2019, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

Avadel Pediatric Products Acquisition

On February 16, 2018, the Company entered into an asset purchase agreement with Avadel US Holdings, Inc., Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., Avadel Therapeutics, LLC and Avadel Pharmaceuticals PLC (collectively, the “Sellers”) to purchase and acquire all rights to the Sellers’ pediatric products. Total consideration transferred to the Sellers consisted of: (1) a cash payment of one dollar, (2) the Company's assumption of existing seller debt due in January 2021 with a fair value of $15.1 million, and (3) contingent consideration relating to royalty obligations through February 2026 with a fair value at acquisition date of approximately $7.9 million. As a result of the Avadel pediatric products acquisition, the Company recorded goodwill of $3.8 million, which is deductible over 15 years for income tax purposes.

The transaction was accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible and identifiable intangible assets acquired and liabilities assumed were recorded at fair value as of the date of acquisition, with the remaining purchase price recorded as goodwill. The goodwill recognized was attributable primarily to strategic opportunities related to an expanded commercial footprint and diversified pediatric product portfolio that is expected to provide revenue and cost synergies.

During the second quarter of 2018, the Company identified and recorded measurement period adjustments to the preliminary purchase price allocation. These adjustments are reflected in the tables below. The measurement period adjustments were the result of additional analysis performed and information identified during the second quarter of 2018 based on facts and circumstances that existed as of the purchase date. There were no additional measurement adjustments recorded in 2018.

The following table summarizes the preliminary fair values of the assets acquired and liabilities assumed at the date of acquisition and as adjusted for measurement period adjustments identified during the second quarter of 2018:

	At February 16, 2018 (preliminary)	Measurement Period Adjustments	At February 16, 2018 (as adjusted)
Inventory	$ 2,549,000	$ (1,831,000)	$ 718,000
Prepaid assets	—	570,000	570,000
Intangible assets	16,453,000	1,838,000	18,291,000
Accrued expenses	—	(362,000)	(362,000)
Fair value of debt assumed	(15,272,303)	197,303	(15,075,000)
Fair value of contingent consideration	(7,875,165)	(44,835)	(7,920,000)
Total net liabilities assumed	(4,145,468)	367,468	(3,778,000)
Consideration exchanged	241,000	(240,999)	1
Goodwill	$ 4,386,468	$ (608,467)	$ 3,778,001

The purchase price allocation related to the acquisition of Avadel's pediatric products was finalized in 2018. The fair values of intangible assets, including marketing rights, licenses and developed technology, were determined using variations of the income approach. Varying discount rates were also applied to the projected net cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value. The fair value of intangible assets both as of the date of acquisition and as adjusted by measurement period adjustments identified during the second quarter of 2018 includes the following:

	At February 16, 2018 (preliminary)	Measurement Period Adjustments	At February 16, 2018 (as adjusted)
Acquired Product Marketing Rights - Karbinal	$ 6,221,000	$ (21,000)	$ 6,200,000
Acquired Product Marketing Rights - AcipHex	2,520,000	283,000	2,803,000
Acquired Product Marketing Rights - Cefaclor	6,291,000	1,320,000	7,611,000
Acquired Developed Technology - Flexichamber	1,131,000	546,000	1,677,000
Acquired IPR&D - LiquiTime formulations	290,000	(290,000)	—
Total	**$ 16,453,000**	**$ 1,838,000**	**$ 18,291,000**

Subsequent to the finalization of the purchase price allocation related to the acquisition of Avadel's pediatric products, during thesecond quarter of 2019, the Company made a strategic decision to eliminate sales force efforts related to selling Flexichamber (other than the limited inventory currently on hand). As a result of this decision, paired with significant deviations from forecasted sales, management identified an impairment indicator for Flexichamber during the second quarter of 2019. Accordingly, during the second quarter of 2019, the Company performed a test for recoverability and concluded that the sum of its estimated future undiscounted cash flows was less than its carrying value of $1.4 million. Management then measured the impairment loss by calculating the excess of Flexichamber's carrying amount over its fair value. Management determined that due to the absence of future material cash flows that

the fair value of Flexichamber as of June 30, 2019, which is considered a Level 3 nonrecurring fair value measurement, was $0. Accordingly, a full impairment was recognized in the impairment of intangible asset line for Flexichamber in the amount of $1.4 million for the nine months ended September 30, 2019. In addition, because the Company expects the sale of remaining inventory on hand will not generate material cash flows, the Company wrote down the existing inventory on hand as of June 30, 2019 to $0, which resulted in $0.2 million charge to cost of product sales during the nine months ended September 30, 2019.

TRx Acquisition

On November 17, 2017, the Company entered into, and consummated the transactions contemplated by, an equity interest purchase agreement (the "TRx Purchase Agreement") by and among the Company, TRx, Fremantle Corporation and LRS International LLC, the selling members of TRx (collectively, the "TRx Sellers"), which provided for the purchase of all of the equity and ownership interests of TRx by the Company (the "TRx Acquisition"). The consideration for the TRx Acquisition consisted of $18.9 million in cash, as adjusted for estimated working capital, estimated cash on hand, estimated indebtedness and estimated transaction expenses, as well as 7,534,884 shares of the Company's common stock having an aggregate value on the closing date of $8.5 million and certain potential contingent payments. Upon closing, the Company issued 5,184,920 shares of its common stock to the TRx Sellers. Pursuant to the TRx Purchase Agreement, the issuance of the remaining 2,349,968 shares was subject to the Company's stockholder approval. In May 2018, stockholder approval was obtained and the remaining shares were issued to the TRx Sellers. The contingent shares were initially recorded to contingently issuable shares, which is recorded within stockholder's equity and were reclassed to common stock and additional paid in capital upon issuance, on the consolidating balance sheet date. As a result of the TRx Acquisition, the Company has currently recorded goodwill of $12.6 million, of which $8.7 million was deductible for income taxes.

During the third quarter of 2018, the Company identified and recorded measurement period adjustments to our preliminary purchase price allocation that was disclosed in prior periods. These adjustments are reflected in the tables below. The measurement period adjustments were the result of an arbitration ruling discussed in further detail in Note 13, the facts and circumstances of which existed as of the acquisition date.

The following table summarizes the preliminary acquisition-date fair value of the consideration transferred at the date of acquisition both as disclosed in periods prior to the third quarter of 2018 and as adjusted for measurement period adjustments identified during the third quarter of 2018:

	At November 17, 2017 (preliminary)	Measurement Period Adjustments	At November 17, 2017 (as adjusted)
Cash	$ 18,900,000	$ —	$ 18,900,000
Common stock (including contingently issuable shares)	8,514,419	—	8,514,419
Contingent payments	2,576,633	(1,210,000)	1,366,633
Total consideration transferred	$ 29,991,052	(1,210,000)	28,781,052

The TRx Acquisition was accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible and identifiable intangible assets acquired, and liabilities assumed, were recorded at fair value as of the date of acquisition, with the remaining purchase price recorded as goodwill. The goodwill recognized is attributable primarily to strategic opportunities related to leveraging TRx's research and development, intellectual property, and processes.

The following table summarizes the preliminary fair values of the assets acquired and liabilities assumed at the date of acquisition both as disclosed in periods prior to the third quarter of 2018 and as adjusted for measurement period adjustments identified during the third quarter of 2018:

	At November 17, 2017 (preliminary)	Measurement Period Adjustments	At November 17, 2017 (as adjusted)
Fair value of assets acquired:			
Cash and cash equivalents	$ 11,068	$ —	$ 11,068
Accounts receivable, net	2,872,545	—	2,872,545
Inventory	495,777	—	495,777
Prepaid expenses and other current assets	134,281	—	134,281
Other receivables	—	2,764,515	2,764,515
Identifiable Intangible Assets:			—
Acquired product marketing rights - Metafolin	10,465,000	1,522,000	11,987,000
PAI sales and marketing agreement	2,334,000	219,000	2,553,000
Acquired product marketing rights - Millipred	4,714,000	342,000	5,056,000
Acquired product marketing rights - Ulesfia	555,000	(555,000)	—
Total assets acquired	21,581,671	4,292,515	25,874,186
Fair value of liabilities assumed:			
Accounts payable	192,706	—	192,706
Accrued expenses and other current liabilities	4,850,422	3,764,515	8,614,937
Deferred tax liability	839,773	78,840	918,613
Total liabilities assumed	5,882,901	3,843,355	9,726,256
Total identifiable net assets	15,698,770	449,160	16,147,930
Fair value of consideration transferred	29,991,052	(1,210,000)	28,781,052
Goodwill	$ 14,292,282	$ (1,659,160)	$ 12,633,122

The purchase price allocation related to the acquisition of TRx was finalized in 2018. The fair values of intangible assets, including marketing rights, licenses and developed technology, were determined using variations of the income approach, specifically the multi-period excess earnings method. Varying discount rates were also applied to the projected net cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value. The final fair value of intangible assets both as disclosed in prior periods and as adjusted by measurement period adjustments identified during the third quarter of 2018 includes the following:

	At November 17, 2017 (preliminary)	Measurement Period Adjustments	At November 17, 2017 (as adjusted)
Acquired product marketing rights - Metafolin	$ 10,465,000	$ 1,522,000	$ 11,987,000
PAI sales and marketing agreement	2,334,000	219,000	2,553,000
Acquired product marketing rights - Millipred	4,714,000	342,000	5,056,000
Acquired product marketing rights - Ulesfia	555,000	(555,000)	—
Total	**$ 18,068,000**	**$ 1,528,000**	**$ 19,596,000**

The Company received written notice to terminate the Pharmaceutical Associates, Inc. ("PAI") sales and marketing agreement in the second quarter of 2018. As a result, the Company reassessed the fair value of the PAI sales and marketing agreement on that date (a level III non-recurring fair value measurement) and concluded due to the absence of future cash flows beyond the date of termination

that the fair value was $0. An impairment charge was recognized in the second quarter of 2018 in the amount of $1.9 million, representing the remaining net book value of the PAI sales and marketing agreement intangible asset.

Pro Forma Impact of Business Combinations

The following supplemental unaudited pro forma information presents Cerecor's financial results as if the acquisition of Avadel pediatric products, which was completed on February 16, 2018, had occurred on January 1, 2018:

	Nine Months Ended September 30, 2018
Total revenues, net	$ 15,047,699
Net loss	$ (35,539,494)
Basic and diluted net loss per share of common stock	$ (1.09)
Basic and diluted net loss per share of preferred stock	$ —

The above unaudited pro forma information was determined based on the historical GAAP results of Cerecor and Avadel's pediatric products. The unaudited pro forma consolidated results are provided for informational purposes only and are not necessarily indicative of what Cerecor's condensed consolidated results of operations would have been had the acquisition of Avadel's pediatric products been completed on the date indicated or what the consolidated results of operations will be in the future.

6. Fair Value Measurements

ASC No. 820, *Fair Value Measurements and Disclosures* ("ASC 820"), defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities that are measured at fair value on a recurring basis:

	September 30, 2019 Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 3,221,364	$ —	$ —
Liabilities			
Contingent consideration	$ —	$ —	$ 7,473,485
Warrant liability**	$ —	$ —	$ 850
Unit purchase option liability**	$ —	$ —	$ 2,493

	December 31, 2018 Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 7,324,932	$ —	$ —
Liabilities			
Contingent consideration	$ —	$ —	$ 9,050,564
Warrant liability**	$ —	$ —	$ 2,950
Unit purchase option liability**	$ —	$ —	$ 7,216

*Investments in money market funds are reflected in cash and cash equivalents on the accompanying condensed consolidated balance sheets.

**Warrant liability and UPO liability are reflected in accrued expenses and other current liabilities on the accompanying condensed consolidated balance sheets.

As of September 30, 2019 and December 31, 2018, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses and other current liabilities, short term and long-term debt, warrant liability, the underwriters' UPO liability, and contingent consideration. The carrying amounts reported in the accompanying condensed consolidated financial statements for cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses, and other current liabilities approximate their respective fair values because of the short-term nature of these accounts. The estimated fair value of the Company's long-term debt of $15.0 million as of September 30, 2019 was based on current interest rates for similar types of borrowings and is in Level 2 of the fair value hierarchy.

Level 3 Valuation

The tables presented below are a summary of changes in the fair value of the Company's Level 3 valuations for the warrant liability, UPO liability and contingent consideration for the nine months ended September 30, 2019 and 2018:

	Warrant liability	Unit purchase option liability	Contingent consideration	Total
Balance at December 31, 2018	$ 2,950	$ 7,216	$ 9,050,564	$ 9,060,730
Payment of contingent consideration	—	—	(567,911)	(567,911)
Change in fair value due to Lachlan Settlement	—	—	(1,277,150)	(1,277,150)
Other changes in fair value	(2,100)	(4,723)	267,982	261,159
Balance at September 30, 2019	$ 850	$ 2,493	$ 7,473,485	$ 7,476,828

	Warrant liability	Unit purchase option liability	Contingent consideration	Total
Balance at December 31, 2017	$ 8,185	$ 26,991	$ 2,576,633	$ 2,611,809
Issuance of contingent consideration	—	—	7,920,000	7,920,000
Payment of contingent consideration	—	—	(137,008)	(137,008)
Purchase price allocation measurement period adjustment of contingent consideration	—	—	(1,210,000)	(1,210,000)
Change in fair value	6,145	16,183	360,850	383,178
Balance at September 30, 2018	$ 14,330	$ 43,174	$ 9,510,475	$ 9,567,979

In 2014, the Company issued warrants to purchase 625,208 shares of convertible preferred stock. Upon the closing of our initial public offering ("IPO") in October 2015 these warrants became warrants to purchase 22,328 shares of common stock, in accordance with their terms. The warrants expire in October 2020. The warrants represent a freestanding financial instrument that is indexed to an obligation, which the Company refers to as the warrant liability. The warrant liability is marked-to-market each reporting period with the change in fair value recorded to other income, net in the accompanying statements of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified to stockholders' equity. The fair value of the warrant liability is estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the option pricing model for valuing the warrant liability as of September 30, 2019, include (i) volatility of 50%, (ii) risk free interest rate of 1.74%, (iii) strike price of $8.40, (iv) fair value of common stock of $3.29, and (v) expected life of 1.0 years.

The underwriters' UPO was issued to the underwriters of the Company's IPO in 2015 and provides the underwriters the option to purchase up to a total of 40,000 units. The units underlying the UPO will be, immediately upon exercise, separated into shares of common stock, underwriters' Class A warrants and underwriters' Class B warrants (such warrants together referred to as the Underwriters' Warrants). The Underwriters' Warrants were warrants to purchase shares of common stock. The Class B warrants expired in April 2017 and the Class A warrants expired in October 2018, while the UPO expires in October 2020. The Company classifies the UPO as a liability, as it is a freestanding marked-to-market derivative instrument that is precluded from being classified in stockholders' equity. The UPO liability is marked-to-market each reporting period with the change in fair value recorded to other income, net in the accompanying statements of operations until the UPO is exercised, expires or other facts and circumstances lead the UPO to be reclassified to stockholders' equity. The fair value of the UPO liability is estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the simulation model for valuing the UPO as of September 30, 2019, include (i) volatility of 50%, (ii) risk free interest rate of 1.74% , (iii) unit strike price of $7.47, (iv) fair value of underlying equity of $3.29, and (v) expected life of 1.0 years.

The Company's business acquisitions of Avadel's pediatric products and TRx (see Note 5) involve the potential for future payment of consideration that is contingent upon the achievement of operation and commercial milestones and royalty payments on future product sales. The fair value of contingent consideration was determined at the acquisition date utilizing unobservable inputs such as the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event), and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liabilities are remeasured at the current fair value with changes recorded in the condensed consolidated statement of operations.

As part of the acquisition of Avadel's pediatric products, the Company became obligated to pay a 15% annual royalty on net sales of the acquired Avadel pediatric products through February 2026, up to an aggregate amount of $12.5 million. The fair value of the future royalty was the expected future value of the contingent payments discounted to a present value. The estimated fair value of the royalty payments as of September 30, 2019 was $7.5 million. The significant assumptions used in estimating the fair value of the royalty payment as of September 30, 2019 include (i) the expected net sales of the acquired Avadel pediatric products for that are subject to the 15% royalty based on the Company's net sales forecast and, (ii) the risk-adjusted discount rate of 7.86%, which is comprised of the risk-free interest rate of 1.60% and a counterparty risk of 6.26% utilized to discount the expected royalty payments. The liability is reduced by periodic payments. As detailed in Note 14, in connection with the Company entering into the Aytu transaction in October 2019, the contingent consideration related to Avadel's pediatric products was transferred to Aytu upon closing of the transaction on November 1, 2019. However, the liability as of September 30, 2019 does not factor in the transfer of the liability because the transaction occurred subsequent to quarter end.

The consideration for the TRx acquisition included certain potential contingent payments. First, pursuant to the TRx Purchase Agreement, the Company would have been required to pay $3.0 million to the Sellers if the gross profit related to TRx products equaled or exceeded $12.6 million in 2018. The Company did not achieve this contingent event in 2018 and therefore no value was assigned to the contingent payout as of December 31, 2018. Additionally, the Company may have been required to pay the following: (1) $2.0 million upon the transfer of the Ulesfia NDA to the Company ("NDA Transfer Milestone"), and (2) $2.0 million upon FDA approval of a new dosage of Ulesfia ("FDA Approval Milestone"). However, as part of the settlement the Company entered into during the second quarter of 2019 with Lachlan Pharmaceuticals, an Irish company controlled by the previous owners of TRx, among additional terms discussed in Note 13, the Company gave up its right to sell Ulesfia, except for a limited amount of inventory on hand until that inventory is sold or expired. As a result, the Settlement released the Company from the potential contingent payments related to the NDA Transfer Milestone and FDA Approval Milestone and therefore no value was assigned to the two milestones as of September 30, 2019 resulting in the Company recognizing a gain on the change of fair value of contingent consideration of $1.3 million for the nine months ended September 30, 2019.

No other changes in valuation techniques or inputs occurred during the nine months ended September 30, 2019 and 2018. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2019 and 2018.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of September 30, 2019 and December 31, 2018 consisted of the following:

	As of	
	September 30, 2019	December 31, 2018
Sales returns and allowances	$ 5,143,150	$ 3,972,510
Medicaid rebates	2,603,632	2,237,269
Minimum sales commitments, royalties payable, and purchase obligations	957,243	9,662,901
Compensation and benefits	1,993,211	1,953,065
Research and development expenses	1,409,738	278,132
Sales and marketing	125,494	1,112,378
General and administrative	775,163	235,721
Other	126,264	279,397
Total accrued expenses and other current liabilities	$ 13,133,895	$ 19,731,373

As detailed in Note 14, in connection with the Company entering into the Aytu transaction in October 2019, Aytu assumed certain of the Company's liabilities including certain accrued expenses and other current liabilities primarily related to sales returns and Medicaid rebates, upon closing of the transaction on November 1, 2019. However, accrued expenses and other current liabilities as of September 30, 2019 do not factor in Aytu's assumption of such liabilities because the transaction occurred subsequent to quarter end.

8. Deerfield Obligation

In relation to the Company's acquisition of Avadel's pediatric products on February 16, 2018, the Company assumed an obligation that Avadel had to Deerfield CSF, (the "Deerfield Obligation"). Beginning in July 2018 through October 2020, the Company is required to pay a quarterly payment of $262,500 to Deerfield. In January 2021, a balloon payment of $15,250,000 is due. As payments were made, the difference between the gross value and fair value of these payments was recorded as interest expense in the Company's condensed consolidated statements of operations using the effective interest method. Interest expense for the three and nine months ended September 30, 2019 was $0.2 million and $0.7 million, respectively, and is included in interest expense, net on the accompanying consolidated statement of operations. The amounts due within the next year are included in current portion of long-term debt on the Company's condensed consolidated balance sheets. The amounts due in greater than one year are included in long-term debt, net of current portion, on the Company's condensed consolidated balance sheets. The Deerfield Obligation was $15.3 million as of September 30, 2019, of which $1.1 million is recorded as a current liability.

As detailed in Note 14, in connection with the Company entering into the Aytu transaction in October 2019, Aytu assumed the Deerfield Obligation upon closing of the transaction on November 1, 2019. However, the balance as of September 30, 2019 does not factor in Aytu's assumption of the liability because the transaction occurred subsequent to quarter-end.

On November 1, 2019, in conjunction with the closing of the Aytu transaction, the Company entered into a guarantee (the “Guarantee”) in favor of Deerfield CSF. The Guarantee guarantees the payment by Aytu of the assumed liabilities to Deerfield, which includes the debt obligation and the contingent consideration related to future potential royalties on Avadel's pediatric products. Additionally, on November 1, 2019, the Company entered into a contribution agreement (the “Contribution Agreement”) with Armistice and Avadel, which governs contribution rights and obligations of the Company, Armistice and Avadel with respect to amounts that are paid by Armistice and Avadel to Deerfield CSF under certain guarantees made by Armistice and Avadel to Deerfield CSF. The liabilities to Deerfield, which include the debt obligation (consisting of the balloon payment and the remaining interest payments) and the undiscounted contingent consideration related to future potential royalties on Avadel's pediatric products, were $25.7 million as of the closing date on November 1, 2019.

9. Capital Structure

According to the Company's amended and restated certificate of incorporation, the Company is authorized to issuetwo classes of stock, common stock and preferred stock. At September 30, 2019, the total number of shares of capital stock the Company was authorized to issue was 205,000,000 of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of $0.001 per share.

On December 26, 2018, the Company filed a Certificate of Designation of Preferences of Series B Non-Voting Convertible Preferred Stock ("Series B Convertible Preferred Stock" or "convertible preferred stock") of Cerecor Inc. (the "Certificate of Designation of the Series B Preferred Stock") classifying and designating the rights, preferences and privileges of the Series B Convertible Preferred Stock. The Certificate of Designation of the Series B Convertible Preferred Stock authorized 2,857,143 shares of convertible preferred stock. The Series B Convertible Preferred Stock converts to shares of common stock on a 1-for-5 ratio and has the same rights, preferences, and privileges as common stock other than it holds no voting rights.

Convertible Preferred Stock

December 2018 Armistice Private Placement

On December 27, 2018, the Company entered into a series of transactions as part of a private placement with Armistice in order to generate cash to continue to develop our pipeline assets and for general corporate purposes. The transactions are considered one transaction for accounting purposes. As part of the transaction, the Company exchanged common stock warrants issued on April 27, 2017 to Armistice for the purchase up to 14,285,714 shares of the Company's common stock at an exercise price of $0.40 per share (the "original warrants") for like-kind warrants to purchase up to2,857,143 shares of the Company's newly designated Series B Convertible Preferred Stock with an exercise price of $2.00 per share (the "exchanged warrants"). Armistice immediately exercised the exchanged warrants and acquired an aggregate of 2,857,143 shares of the convertible preferred stock. Net proceeds of the transaction were approximately $5.7 million for the year ended December 31, 2018.

In order to provide Armistice an incentive to exercise the exchanged warrants, the Company also entered into a securities purchase agreement with Armistice pursuant to which the Company issued warrants for 4,000,000 shares of common stock of the Company with a term of5.5 years and an exercise price of $12.50 per share (the "incentive warrants"). For accounting purposes, the Company calculated the fair value of the incentive warrants of $1.7 million, which was considered a deemed distribution to Armistice for the year ended December 31, 2018.

Voting

Holders of the Company's convertible preferred stock are not entitled to vote.

Dividends

The holders of convertible preferred stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of the Company's convertible preferred stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all debts and other liabilities.

Rights and Preferences

Each share of convertible preferred stock converts to shares of common stock on a 1-for5 ratio. There are no other preemptive or subscription rights and there are no redemption or sinking fund provisions applicable to the Company's common stock.

Common Stock

September 2019 Armistice Private Placement

On September 4, 2019, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold1,200,000 shares of the Company's common stock for a purchase price of $3.132 per share, which represents the average closing price of the Common Stock on Nasdaq for thefive trading days immediately preceding September 4, 2019. Net proceeds of the private placement were approximately $3.7 million.

Common Stock Offering

On March 8, 2019, the Company closed on an underwritten public offering of common stock for 1,818,182 shares of common stock of the Company, at a price to the public of $5.50 per share. Armistice participated in the offering by purchasing 363,637 shares of common stock of the Company from the underwriter at the public price. The gross proceeds to the Company, before deducting underwriting discounts and commissions and offering expenses, were approximately $10.0 million. The net proceeds were approximately $9.0 million.

December 2018 Armistice Private Placement

As discussed in detail above, on December 27, 2018 the Company exchanged previously outstanding warrants for like-kind warrants for 2,857,143 shares of the Company's convertible preferred stock with an exercise price of $2.00 per share. Armistice immediately exercised these warrants for 2,857,143 shares of convertible preferred stock for net proceeds to the Company of $5.7 million. The convertible preferred stock converts to common stock on a 1-for-5 ratio (or to 14,285,714 shares of common stock in total). Additionally, on December 27, 2018, in order to provide Armistice an incentive to exercise the exchanged warrants, the Company entered into a securities purchase agreement with Armistice pursuant to which the Company issued warrants for 4,000,000 shares of common stock of the Company with a term of 5.5 years and an exercise price of $12.50 per share.

August 2018 Armistice Private Placement

On August 17, 2018, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold 1,000,000 shares of the Company’s common stock for a purchase price of $3.91 per share, which was the closing price of shares of the Common Stock on August 16, 2018. Net proceeds of this securities purchase agreement were approximately $3.9 million.

Ichorion Asset Acquisition

On September 25, 2018, under the terms of the Ichorion Asset Acquisition noted above in Note 5, the Company issued approximately 5,800,000 shares of common stock of the Company upon closing.

Contingently Issuable Shares

Under the terms of TRx acquisition noted above in Note 5, the Company was required to issue common stock having an aggregate value as calculated in the TRx Purchase Agreement on the Closing Date of $8.1 million (the “Equity Consideration”). Upon closing, the Company issued 5,184,920 shares of its common stock. Pursuant to the TRx Purchase Agreement, the issuance of the remaining 2,349,968 shares as a part of the Equity Consideration was subject to stockholder approval at the Company's 2018 Annual Stockholder's Meeting. This approval was obtained in May 2018 and the remaining shares were issued to the TRx Sellers.

Voting

Common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

The holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of the Company’s liquidation, dissolution or winding up, holders of the Company’s common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all debts and other liabilities.

Rights and Preferences

Holders of the Company’s common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the Company’s common stock.

Common Stock Warrants

At September 30, 2019, the following common stock warrants were outstanding:

Number of shares underlying warrants	Exercise price per share	Expiration date
22,328*	$ 8.40	October 2020
2,380*	$ 8.68	May 2022
4,000,000	$ 12.50	June 2024
4,024,708		

*Accounted for as a liability instrument (see Note 6)

10. Stock-Based Compensation

2016 Equity Incentive Plan

On April 5, 2016, the Company's board of directors adopted the 2016 Equity Incentive Plan (the "2016 Plan") as the successor to the 2015 Omnibus Plan (the "2015 Plan"). The 2016 Plan was approved by the Company's stockholders and became effective on May 18, 2016 (the "2016 Plan Effective Date").

Upon the 2016 Plan Effective Date, the 2016 Plan reserved and authorized up to 600,000 additional shares of common stock for issuance, as well as 464,476 unallocated shares remaining available for grant of new awards under the 2015 Plan. An Amended and Restated 2016 Equity Incentive Plan (the "2016 Amended Plan") was approved by the Company's stockholders in May 2018, which increased the share reserve by an additional 1.4 million shares. A Second Amended and Restated 2016 Equity Incentive Plan (the "2016 Second Amended Plan") was approved by the Company's stockholders in August 2019 which increased the share reserve by an additional 850,000 shares. During the term of the 2016 Second Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year by an amount equal to 4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. As of September 30, 2019, there were 1,963,869 shares available for future issuance under the 2016 Amended Plan.

Option grants expire after ten years. Employee options typically vest over three or four years. Options granted to directors typically vest over one or three years. Directors may elect to receive stock options in lieu of board compensation, which vest immediately. For stock options granted to employees and non-employee directors, the estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the individuals' service periods, which is the period in which the awards vest. Stock-based compensation expense includes expense related to stock options, restricted stock units and ESPP shares. The amount of stock-based compensation expense recognized for the three and nine months ended September 30, 2019 and 2018 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 176,261	$ 32,202	$ 354,347	$ 64,077
General and administrative	473,905	843,122	1,139,241	1,599,703
Sales and marketing	168,627	69,809	448,608	132,607
Total stock-based compensation	$ 818,793	$ 945,133	$ 1,942,196	$ 1,796,387

In April 2019, the former CEO resigned, however he remains on the Company's board of directors. Subsequent to his resignation, during the second quarter of 2019, the former CEO agreed to forfeit the unvested portion of his equity awards granted to him during his service as CEO. As a result, he forfeited a total of 1,489,583 equity awards, which included 689,583 unvested service-based vesting options, 500,000 unvested market-based options and 300,000 unvested restricted stock units. The Company accounts for forfeitures as they occur. Because the requisite service period of 2.8 years was not rendered for the market-based options, the forfeiture of the market-based options resulted in the reversal in the second quarter of 2019 of the full expense recognized to date of $0.5 million, which was recorded as a reduction to general and administrative expense. Stock-based compensation during the three and nine months ended September 30, 2018 includes $0.3 million of expense related to modifications of awards related to a separated executive.

Stock options with service-based vesting conditions

The Company has granted awards that contain service-based vesting conditions. The compensation cost for these options is recognized on a straight-line basis over the vesting periods. A summary of option activity for the nine months ended September 30, 2019 is as follows:

	Options Outstanding			
	Number of shares	Weighted average exercise price per share	Weighted average grant date fair value of options	Weighted average remaining contractual term (in years)
Balance at December 31, 2018	3,746,597	$ 4.16		7.8
Granted	2,618,264	$ 5.71	$ 8,076,475	
Exercised	(75,178)	$ 3.44		
Forfeited	(902,767)	$ 5.16	$ 2,640,665	
Expired	(389,792)	$ 5.03	$ 992,343	
Balance at September 30, 2019	4,997,124	$ 4.74		8.2
Exercisable at September 30, 2019	2,155,081	$ 4.36		6.9

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2019, the aggregate intrinsic value of options outstanding and currently exercisable was $1.3 million and $0.9 million, respectively. The total grant date fair value of shares which vested during the nine months ended September 30, 2019 was $1.3 million. The per-share weighted-average grant date fair value of the options granted during the nine months ended September 30, 2019 was estimated at $3.08. There were 622,583 options that vested during the nine months ended September 30, 2019 with a weighted average exercise price of $3.54 per share.

The Company recognized stock-based compensation expense of $0.6 million and $1.6 million related to stock options with service-based vesting conditions for the three and nine months ended September 30, 2019, respectively. At September 30, 2019, there was $7.0 million of total unrecognized compensation cost related to unvested service-based vesting condition awards. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 3.0 years.

Stock options with market-based vesting conditions

The Company has granted awards that contain market-based vesting conditions. The following table summarizes the Company's market-based option activity for the nine months ended September 30, 2019:

	Options Outstanding			
	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (1)
Balance at December 31, 2018	500,000	$ 4.24	9.2	
Granted	300,000	$ 4.98		
Exercised	—			
Forfeited	(500,000)	$ 4.24		
Balance at September 30, 2019	300,000	$ 4.98	9.65	$ —
Exercisable at September 30, 2019	—			

(1) The aggregate intrinsic value in the above table represents the total pre-tax amount that a participant would receive if the option had been exercised on the last day of the respective fiscal period. Options with a market value less than its exercise value are not included in the intrinsic value amount.

During the second quarter of 2019, the Company granted the Executive Chairman of the Board an option to purchase300,000 shares of Company common stock with market-based vesting conditions at an exercise price of $4.98 per share. One-third of the shares vest upon the Company's common stock closing at or above $8.00 per share for three consecutive days, one-third of the shares vest upon the Company's stock closing at or above $10.50 per share for three consecutive days, and one-third of the shares vest upon the Company's stock closing at or above $13.00 per share for three consecutive days. Each vesting tranche represents a unique requisite service period and therefore the compensation cost for each vesting tranche is recognized on a straight-line basis over its respective vesting period.

The Company recognized stock-based compensation expense of $0.1 million and $(0.2) million related to stock options with market-based based vesting conditions for the three and nine months ended September 30, 2019, respectively. The expense recognized for the nine months ended September 30, 2019 includes the reversal of expense for the former CEO's forfeited options and the expense related to the market-based options granted during the second quarter of 2019. At September 30, 2019, there was $0.9 million of total unrecognized compensation cost related to unvested market-based vesting conditions awards. This compensation cost is expected to be recognized over a weighted-average period of 2.2 years.

Stock-based compensation assumptions

The following table shows the assumptions used to compute stock-based compensation expense for stock options granted to employees and members of the board of directors under the Black-Scholes valuation model and the assumptions used to compute stock-based compensation expense for market-based stock options grants under a Monte Carlo simulation for the nine months ended September 30, 2019:

Service-based options	
Expected dividend yield	—%
Expected volatility	55%
Expected life (in years)	5.0 - 6.25
Risk-free interest rate	1.47 - 2.59%
Market-based options	
Expected dividend yield	—%
Expected volatility	60%
Expected life (in years)	10
Risk-free interest rate	2.32%

Restricted Stock Units

The Company has granted restricted stock units ("RSU") to certain employees. The Company measures the fair value of the restricted awards using the stock price on the date of the grant. The restricted shares typically vest annually over a four-year period beginning on the first anniversary of the award. The following table summarizes the Company's RSU activity for nine months ended September 30, 2019:

	RSUs Outstanding	
	Number of shares	Weighted average grant date fair value
Unvested RSUs at December 31, 2018	445,000	$ 4.27
Granted	295,000	$ 4.98
Vested	(172,500)	$ 4.52
Forfeited	(300,000)	$ 4.24
Unvested RSUs at September 30, 2019	267,500	

During the second quarter of 2019, the Company granted its newly appointed Executive Chairman of the Board250,000 RSUs, of which 50,000 shares vested immediately on the grant date and the remainder are to vest in three equal annual increments based on continued service.

The Company recognized stock-based compensation expense of $0.1 million and $0.4 million related to RSUs for the three and nine months ended September 30, 2019, respectively. At September 30, 2019, there was $1.3 million of total unrecognized compensation cost related to the RSU grants. This compensation cost is expected to be recognized over a weighted-average period of 2.6 years.

Employee Stock Purchase Plan

On April 5, 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan (the "ESPP"). The ESPP was approved by the Company's stockholders and became effective on May 18, 2016 (the "ESPP Effective Date").

Under the ESPP, eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the administrator. The ESPP is administered by the compensation committee of the Company's board of directors. Under the ESPP, eligible employees may purchase stock at 85% of the lower of the fair market value of a share of the Company's common stock (i) on the first day of an offering period or (ii) on the purchase date. Eligible employees may contribute up to 15% of their earnings during the offering period. The Company's board of directors may establish a maximum number of shares of the Company's common stock that may be purchased by any participant, or all participants in the aggregate, during each offering or offering period. Under the ESPP, a participant may not accrue rights to purchase more than $25,000 of the fair market value of the Company's common stock for each calendar year in which such right is outstanding.

Upon the ESPP Effective Date, the Company reserved and authorized up to 500,000 shares of common stock for issuance under the ESPP. On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP shall automatically increase by a number equal to the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, and (ii) 500,000 shares of the Company's common stock, or (iii) a number of shares of the Company's common stock as determined by the Company's board of directors or compensation committee. The number of shares increased by 408,042 on January 1, 2019. As of September 30, 2019, 1,148,085 shares remained available for issuance.

In accordance with the guidance in ASC 718-50, *Employee Stock Purchase Plans*, the ability to purchase shares of the Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized stock-based compensation expense of $42,278 and $129,963 for the three and nine months ended September 30, 2019, respectively.

11. Income Taxes

The provision for income taxes was $115,651 and $348,427 for the three and nine months ended September 30, 2019, respectively, and is comprised of current year state income taxes and amortization of tax-deductible goodwill. Additionally, discrete to the three and nine months ended September 30, 2019, the Company recorded interest and penalties on the outstanding taxes payable to the IRS and various state authorities.

12. Leases

Corporate Headquarters' Lease

The Company identified one operating lease, which is for its corporate headquarters located in Rockville, Maryland. The annual base rent for the office space is $161,671, subject to annual 2.5% increases over the term of the lease. The lease provides for a rent abatement for a period of 12 months following the Company's date of occupancy. The lease has an initial term of 10 years from the date the Company makes its first annual fixed rent payment, which is expected to occur in January 2020. The Company has the option to extend the lease two times, each for a period of five years, and may terminate the lease as of the sixth anniversary of the first annual fixed rent payment, upon the payment of a termination fee. As of the lease commencement date, it is not reasonably certain that the Company will exercise the renewal periods or early terminate the lease and therefore the end date of the lease for accounting purposes is January 31, 2030. The remaining term of the lease at September 30, 2019 was 10.3 years.

Supplemental balance sheet information related to the lease is as follows:

	As of	
	September 30, 2019	December 31, 2018
Property and equipment, net	$ 719,113	$ —
Other current liabilities	$ 114,387	$ —
Other long-term liabilities	$ 1,121,367	$ —

The operating lease ROU asset is included in property and equipment and the lease liability is included in accrued expenses and other current liabilities and other long-term liabilities in our condensed consolidated balance sheets. In order to determine the present value of lease payments, the Company utilized a discount rate of 7.7%. This rate was determined based on available information of the rate of interest the Company would pay to borrow on a collateralized basis at an amount equal to the lease payments in a similar economic environment over a similar term on the transition date.

The components of lease expense for the three and nine months ended September 30, 2019 and 2018 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating lease cost*	$ 32,326	$ 47,371	$ 126,467	$ 144,172

*Includes short-term leases, which are immaterial.

Because the corporate headquarter lease provides for a 12-month lease abatement, the cash paid for amounts included in the measurement of lease liabilities was $0 as of September 30, 2019.

The following table shows a maturity analysis of the operating lease liability as of September 30, 2019:

	Undiscounted Cash Flows
October 1, 2019 through December 31, 2019	$ —
2020	155,815
2021	169,510
2022	173,748
2023	178,092
Thereafter	1,183,290
Total lease payments	$ 1,860,455
Less implied interest	$ (624,701)
Total	$ 1,235,754

13. Commitments and Contingencies

Litigation

The Company is or may become party in various contractual disputes, litigation, and potential claims arising in the ordinary course of business. The Company currently does not believe that the resolution of such matters will have a material adverse effect on our financial position or results of operations except as otherwise disclosed in this document.

TRx 2018 Target Gross Profit Dispute

As part of the TRx acquisition, pursuant to the TRx Purchase Agreement, the Company was required to pay $3.0 million to the Sellers (or "former TRx owners") if the gross profit, as defined in the TRx Purchase Agreement, related to TRx products equaled or exceeded $12.6 million in 2018. The Company believes it did not achieve this contingent event in 2018 and therefore no amount is due to the former TRx owners. However, during the second quarter of 2019 the former TRx owners disputed the Company's calculation of gross profit, arguing the Company met the $12.6 million target in 2018. Pursuant to the TRx Purchase Agreement, the dispute was submitted to an independent accounting firm for resolution during the third quarter of 2019. The dispute was resolved on October 8, 2019, with the independent accounting firm ruling in favor of the Company, therefore resulting in no financial statement impact.

Lachlan Pharmaceuticals Settlement

As discussed in Note 5, in November 2017, the Company acquired TRx and its wholly-owned subsidiaries, including Zylera. The previous owners of TRx beneficially own more than 10% of our outstanding common stock. Zylera, which is now our wholly owned subsidiary, entered into an agreement with Lachlan Pharmaceuticals, an Irish company controlled by the previous owners of TRx (“Lachlan”), effective December 18, 2015 (the "Lachlan Agreement"). Pursuant to the Lachlan Agreement, Lachlan named Zylera as its exclusive distributor of Ulesfia in the United States and agreed to supply Ulesfia to Zylera exclusively for marketing and sale in the United States. On May 22, 2019, the Company, Lachlan, the owners of Lachlan and Concordia Pharmaceuticals Inc., Sarl (“Concordia”), which is the unrelated third party from which Lachlan obtained rights to distribute Ulesfia, entered into a Settlement Agreement and related side letter and terminated the Lachlan Agreement, as discussed in more detail below (the Settlement Agreement and related side letter collectively the “Settlement”).

The Lachlan Agreement required Zylera to purchase a minimum of 20,000 units per year, or approximately $1.2 million worth of product, from Lachlan, unless and until there was a “Market Change” involving a new successful competitive product. Zylera was required to pay Lachlan $58.84 per unit and handling fees equal to $4.03 per unit of fully packaged Ulesfia in 2019, escalating 10% annually. The Lachlan Agreement also required that Zylera make certain cumulative net sales milestone payments and royalty payments to Lachlan with a $3.0 million annual minimum payment unless and until there was a Market Change. Lachlan was obligated to pay identical amounts to the unrelated third party from which it obtained rights to Ulesfia, with the payments ultimately flowing through Shionogi, Inc. to Summers Laboratories, Inc. ("Summers Labs"). Because of the dispute described below, the Company had not made any payments to Lachlan under the Lachlan Agreement subsequent to the acquisition date.

On December 10, 2016, Zylera informed Lachlan that a Market Change had occurred due to the introduction of Arbor Pharmaceuticals' lice product, Sklice®. On June 5, 2017, Lachlan and Zylera entered into joint legal representation along with other unrelated third parties in negotiation and arbitration of a dispute with Summers Labs regarding the existence of a Market Change and the concomitant obligations of the parties. The arbitration panel issued an interim ruling on October 23, 2018 that no Market Change had occurred up to and including the date of the hearing. The arbitration panel issued a second interim ruling on December 26, 2018, rejecting Summers Labs' request to accelerate future minimum royalties, but ruling in favor of Summers Labs that it is owed reimbursement for all reasonable costs and expenses, including legal fees, by Shionogi, as well as interest, as stipulated in the contract. The arbitration panel issued a final award on March 1, 2019 that dictated the final amount of reimbursable costs and interest. The rulings and final award had no direct bearing on the Company because the Company was not a named defendant to the original claim by Summers Labs and a federal court denied Zylera's ability to be a counterclaimant in the matter. Furthermore, the Company was not subject to the guarantee or interest provisions identified in the second ruling as these elements of the contractual relationship were not passed down to or through Lachlan. However, the Company interpreted the rulings’ impact on the Lachlan Agreement to mean that the minimum purchase obligation and minimum royalty provisions of the contract were active and due for any prior periods as well as future periods.

Prior to the Settlement, the Company had recognized an $8.7 million liability for these minimum obligations and $0.4 million for the royalty payable in accrued liabilities as of March 31, 2019. Additionally, prior to settlement, under the terms of the TRx Purchase Agreement, the former TRx owners were required to indemnify the Company for 100% of all “Pre-Acquisition Ulesfia Losses,” as defined in the TRx Purchase Agreement, related to this arbitration, including legal costs, in excess of $1.0 million. Furthermore, the former TRx owners were required to indemnify the Company for 50% of “Post-Acquisition Ulesfia Losses,” as defined in the TRx Purchase Agreement, which would include losses resulting from having to fund these minimum obligations post-acquisition. The Company had recorded an indemnity receivable of $5.2 million in other receivables as of March 31, 2019, which the Company believed was fully collectible.

Pursuant to the Settlement, during the second quarter of 2019, the Company made a $2.3 million cash payment to Concordia for a full release of all current and future liabilities related to the Lachlan Agreement as of June 30, 2019. As a result, the Company reversed the $8.7 million liability for the minimum obligations and $0.4 million royalty payable in accrued liabilities during the second quarter of 2019. The Settlement also released the former TRx owners of their requirement to indemnify the Company for the losses discussed above. Thus, the Company reversed the $5.2 million indemnity receivable in other receivables during the second quarter of 2019. The Settlement resulted in a net reversal of $1.6 million in previously recognized expense to cost of product sales for the nine months ended September 30, 2019.

Additionally, with the termination of the Lachlan Agreement, the Company gave up its right to sell Ulesfia, except for a limited amount of inventory on hand until that inventory is all sold or expired. Finally, as discussed in detail in Note 6, the Settlement released the Company from having to make any acquisition milestone payout for the NDA transfer of Ulesfia and the FDA approval of

an alternate dosing. Therefore, no value is assigned to the two milestones as of September 30, 2019, which resulted in the recognition of a gain on the change in fair value of contingent consideration of $1.3 million for the nine months ended September 30, 2019.

Karbinal Royalty Make-Whole Provision

As discussed in Note 5, on February 16, 2018, in connection with the acquisition of Avadel's pediatric products, the Company entered into a supply and distribution agreement with TRIS Pharma (the "Karbinal Agreement"). As part of this agreement, the Company had an annual minimum sales commitment, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2033. The Company was required to pay TRIS a royalty make whole payment (“Make-Whole Payments”) of $30 for each unit under the 70,000 units annual minimum sales commitment through 2033.

As a part of the sale of the Pediatric Portfolio to Aytu, which closed on November 1, 2019, the Company assigned all payment obligations, including the Make-Whole Payments, under the Karbinal Agreement (collectively, the “TRIS Obligations”) to Aytu. However, the Company remains liable for TRIS Obligations to the extent Aytu fails to make the required payments. The future Make-Whole Payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

Possible future milestone proceeds for out-licensed compounds

On August 8, 2019, the Company entered into an assignment of license agreement (the “Assignment Agreement”) with ES Therapeutics, LLC (“ES Therapeutics”), a wholly-owned subsidiary of Armistice, a significant stockholder of the Company. Pursuant to the Assignment Agreement, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics. The Company initially licensed the compound from Eli Lilly Company ("Lilly") in September 2016. Under the Assignment Agreement, Armistice paid the Company an upfront payment of $0.1 million. The Company recognized the payment as license and other revenue for the three and nine months ended September 30, 2019. The Assignment Agreement also provides for: (a) a $7.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $750.0 million; and (b) a $12.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $1.3 billion. The Assignment Agreement also releases the Company of obligations related to CERC-611, including the $1.3 million contingent payment to Lilly upon the first subject dosage of CERC-611 in a multiple ascending dose study, which was recorded as a license obligation on the balance sheet as of June 30, 2019. The decrease of this license obligation to $0 as of September 30, 2019 resulted in an offset of research and development expense of$1.3 million for the three and nine months ended September 30, 2019. The Assignment Agreement also releases the Company from additional potential future payments due to Lilly upon achievement of certain development and commercialization milestones, including the first commercial sale, and milestone payments and royalty on net sales upon commercialization of the compound.

In August 2017, the Company sold its worldwide rights to CERC-501 to Janssen Pharmaceuticals, Inc. (“Janssen”) in exchange for initial gross proceeds of$25.0 million. There is a potential future $20.0 million regulatory milestone payment to the Company upon acceptance of an NDA for any indication. The terms of the agreement provide that Janssen will assume ongoing clinical trials and be responsible for any new development and commercialization of CERC-501.

Possible future milestone payments

As detailed in Note 5, on September 24, 2018, the Company acquired Ichorion Therapeutics, Inc., thus acquiringthree compounds for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803) and one other preclinical orphan disease compound, CERC-913, for the treatment of mitochondrial DNA Depletion Syndrome. Consideration for the transaction included approximately 5.8 million shares of the Company’s common stock (adjusted for estimated working capital) and certain contingent development milestones worth up to an additional $15.0 million.

The contingent consideration of up to an additional$15.0 million relates to three future development milestones for the acquired compounds. The first milestone is the first product being approved for marketing by the FDA on or prior to December 31, 2021. If this milestone is met, the Company is required to make a milestone payment of $6.0 million. The second milestone is the second product being approved for marketing by the FDA on or prior to December 31, 2021. If this milestone is met, the Company is required to make a milestone payment of $5.0 million. The third milestone is a protide molecule being approved by the FDA on or prior to December 31, 2023. If this milestone is met, the Company is required to make a milestone payment of $4.0 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of the Company.

The contingent consideration related to the development milestones will be recognized if and when such milestones are probable and can be reasonably estimated. As of September 30, 2019, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

14. Subsequent Events

On October 10, 2019, the Company entered into the Aytu Purchase Agreement to sell the Company's rights, title and interest in, assets relating to its Pediatric Portfolio, namely Aciphex® Sprinkle™ , Cefaclor for Oral Suspension, Karbinal™ ER, Flexichamber™ , Poly-Vi-Flor® and Tri-Vi-Flor™ as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts. Aytu provided consideration of cash and preferred stock totaling $17 million ($4.5 million in cash and $12.5 million in Aytu preferred stock) and assumed certain of the Company's liabilities, including the Company's payment obligations payable to Deerfield CSF, LLC of approximately $15 million and certain other liabilities in excess of approximately $11 million primarily related to contingent consideration, Medicaid rebates and sales returns. In addition, Aytu assumed future contractual obligations under existing license agreements associated with the Divested Assets. The transaction closed on November 1, 2019. Armistice, a significant stockholder of the Company, is also a significant stockholder of Aytu.

Upon closing of the transaction, Cerecor terminated all sales force personnel, which included both those that Aytu offered employment, as well as any remaining sales force personnel. Cerecor expects to incur severance charges and legal costs in the fourth quarter as a result of the transaction. Additionally, Cerecor retained all rights to Millipred®. As part of a transition services agreement the Company entered into with Aytu, Aytu will manage the commercial operations of Millipred ® until the Company establishes an independent commercial infrastructure for the product.

On November 1, 2019, in conjunction with the closing of the Aytu transaction, the Company entered into a Guarantee in favor of Deerfield CSF. The Guarantee guarantees the payment by Aytu of the assumed liabilities to Deerfield, which includes the debt obligation and the contingent consideration related to future potential royalties on Avadel's pediatric products. Additionally, on November 1, 2019, the Company entered into a Contribution Agreement with Armistice and Avadel, which governs contribution rights and obligations of the Company, Armistice and Avadel with respect to amounts that are paid by Armistice and Avadel to Deerfield CSF under certain guarantees made by Armistice and Avadel to Deerfield CSF. The liabilities to Deerfield, which include the debt obligation (consisting of the balloon payment and the remaining interest payments) and the undiscounted contingent consideration related to future potential royalties on Avadel's pediatric products, were $25.7 million as of the closing date on November 1, 2019.

The Company is in-process of determining the financial effect of the Aytu transaction, however, the Company preliminarily estimates it will recognize a gain related to the sale upon closing the transaction during the fourth quarter of 2019.

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

This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "may," "will," "plans," "intends," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential" or other similar words (including their use in the negative), or by discussions of future matters such as the development of product candidates or products, technology enhancements, possible changes in legislation, and other statements that are not historical. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II – Item 1A, "Risk Factors," as well as in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 18, 2019, as amended on April 23, 2019 and in our other filings with the SEC. Statements made herein are as of the date of the filing of this Quarterly Report on Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2018 appearing in our Annual Report on Form 10-K filed with the SEC on March 18, 2019, as amended on April 23, 2019.

Overview

Cerecor Inc. (the "Company" or "Cerecor") is a biopharmaceutical company focused on becoming a leader in the

development and commercialization of treatments for orphan diseases and neurological disorders. The Company's orphan disease pipeline is led by CERC-801, CERC-802 and CERC-803. All three compounds are therapies for inborn errors of metabolism, specifically disorders known as Congenital Disorders of Glycosylation ("CDGs") by means of substrate replacement therapy. The U.S. Food and Drug Administration ("FDA") has granted Rare Pediatric Disease Designation ("RPDD") and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of a new drug application ("NDA"). The PRV may be sold or transferred an unlimited number of times. The Company plans to leverage the 505(b)(2) NDA pathway for all three compounds to accelerate their development and approval. Additionally, CERC-801 and CERC-802 were granted Fast Track Designation ("FTD") from the FDA which helps facilitate and expedite development of each compound. The Company is also in the process of developing one other preclinical orphan disease compound, CERC-913, for the treatment of mitochondrial DNA Depletion Syndrome. The Company's neurology pipeline is led by CERC-301, a Glutamate NR2B selective, NMDA Receptor antagonist, which Cerecor is currently developing as a novel treatment for orthostatic hypotension ("OH"). The Company is also developing CERC-406, a CNS-targeted COMT inhibitor for Parkinson's Disease. The Company also currently has one marketed product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions and indications.

Recent Developments

Sale of Pediatric Portfolio and Related Commercial Infrastructure to Aytu BioScience

On October 10, 2019, the Company entered into, and subsequently closed on, an asset purchase agreement (the "Aytu Purchase Agreement") with Aytu BioScience, Inc. (“Aytu”) to sell the Company’s rights, title and interest in, assets relating to its Pediatric Portfolio, namely Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal™ ER, Flexichamber™, Poly-Vi-Flor® and Tri-Vi-Flor™ (the "Divested Assets" or "Pediatric Portfolio"), as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor’s sales force and the assignment of supporting commercial contracts (the “Aytu transaction”). Aytu provided consideration of cash and preferred stock totaling $17 million ($4.5 million in cash and $12.5 million in Aytu preferred stock) and assumed certain of the Company’s liabilities, including the Company’s payment obligations payable to Deerfield CSF, LLC ("Deerfield") of approximately $15 million and certain other liabilities in excess of approximately $11 million. In addition, Aytu assumed future contractual obligations under existing license agreements associated with the Divested Assets. The transaction closed on November 1, 2019.

Upon closing of the transaction, Cerecor terminated all sales force personnel, which included both those that Aytu offered employment, as well as any remaining sales force personnel. Cerecor expects to incur severance charges and legal costs in the fourth quarter as a result of the transaction. James Harrell, Cerecor’s former Executive Vice President of Marketing and Investor Relations, was promoted to Chief Commercial Officer upon close of the Aytu transaction. Additionally, Cerecor retained all rights to Millipred®. As part of a transition services agreement the Company entered into with Aytu, Aytu will manage the commercial operations of Millipred ® until the Company establishes an independent commercial infrastructure for the product.

The Company believes the consideration received as part of the Aytu transaction, paired with the extinguishment of the debt obligation and future obligations under the license agreements associated with the Pediatric Portfolio, will help the Company fund its portfolio of pipeline assets focusing on long-term value drivers, which include the near-term development of our CERC-800 series of assets and the advancement and expansion of the CERC-301 program.

Recent Financing

During the third quarter of 2019, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold 1,200,000 shares of the Company’s common stock for a purchase price of $3.132 per share. Net proceeds of this securities purchase agreement were approximately $3.7 million.

Research and Development Update

Orphan Pipeline Update

In July 2019, the Company announced that the FDA granted FTD for CERC-802, an ultra-pure, oral formulation of D-mannose currently in development for the treatment of Mannose-Phosphate Isomerase Deficiency, also known as MPI-CDG or CDG-1b. FTD is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the FTD provision is to help facilitate and expedite development of drugs to treat serious and life-threatening conditions where an unmet medical need exists. Sponsors of drugs that receive FTD have the opportunity for more frequent interactions with the FDA review team throughout the development program. These can include meetings to discuss study design, data required to support approval, or other aspects of the clinical program. Additionally, products

that have been granted FTD may be eligible for priority review of a NDA and the FDA may consider reviewing portions of an NDA before the sponsor submits the complete application (known as a rolling review).

In October 2019, the Company completed dosing healthy volunteers in a Phase 1 Safety Study of CERC-802. The single-center, US-based safety, tolerability and pharmacokinetic study was an open-label, randomized, single-dose, 4-way crossover study in 16 healthy adult volunteers. Pharmacokinetic ("PK") data is expected in early 2020

All three CERC-800 programs have been granted RPDD and ODD by the FDA and CERC-801 and CERC-802 have received FTD by the FDA. There are numerous benefits associated with receipt of ODD, which include seven-year marketing exclusivity (upon approval) in the United States, tax credits (up to 25% of clinical development costs) and waiver of Prescription Drug User Fee Act application fees (filing fees). RPDD provides eligibility for receipt of a PRV upon approval of an NDA. The PRV, which may be sold and ownership may be transferred an unlimited amount of times, can be used to obtain priority review for a subsequent new drug application or biologics license application. Cerecor has previously held pre-IND meetings with the FDA and plans to leverage data from the CDG FIRST Trial, existing clinical and nonclinical data from published literature and sponsor-initiated studies to accelerate development and time to approval of all three compounds under the 505(b)(2) pathway.

Neurological Pipeline Update

In July 2019, the Company announced final positive results from its completed Phase 1 study of CERC-301 for the treatment of Neurogenic Orthostatic Hypotension ("nOH") in Parkinson's disease patients. The results demonstrated that CERC-301 produces a rapid, robust and sustained improvement in systolic blood pressure ("SBP") upon standing in Parkinson's patients suffering from nOH in all doses studied. As part of the study, a single 20 mg dose of CERC-301, which was the highest dose tested, achieved clinically meaningful improvements over baseline and placebo with a maximum improvement of 29.1 mmHg upon standing throughout the 6-hour study period. The Company believes this data may support a single daily dose and has the potential to be used in a broader OH patient population.

In October 2019, the Company enrolled its first patient in a Phase 1 Proof-of-Concept Trial investigating the safety, tolerability and effects on blood pressure in patients with orthostatic hypotension associated with diabetes ("DOH"). This study is a randomized, double-blind, placebo-controlled, two-way cross-over trial over two 24-hour in-clinic visits. At each visit, subjects will receive a single 20 mg dose of CERC-301 or placebo then undergo a series of orthostatic challenge tests over the 24 hour in-clinic period. Patients will also complete an OH symptomatic assessment following each orthostatic challenge. Safety, tolerability and pharmacokinetic (“PK”) data will also be collected. As part of the routine laboratory tests, particular interest will be paid to the patient’s plasma glucose levels over the course of the study.

The following chart summarizes upcoming research & development milestones over the next 12 to 18 months:

	Program	Target Indication	Upcoming Milestone
Metabolic Disorders	CERC-801*	PGM1-CDG	FDA Meeting Request YE19 Targeted NDA Submission 2021
	CERC-802*	MPI-CDG	FDA Meeting Request 1H20 Targeted NDA Submission 2021
	CERC-803*	SLC35C1-CDG	IND Filing 2020 Targeted NDA Submission 2022
Neurology Disorders	CERC-301	Orthostatic Hypotension	Initiate Proof-of-Concept in Additional Indication(s) YE19 Initiate Phase II 2020
	CERC-406	Parkinson's Disease	Targeting IND Filing 2020

*505(b)(2) Pathway

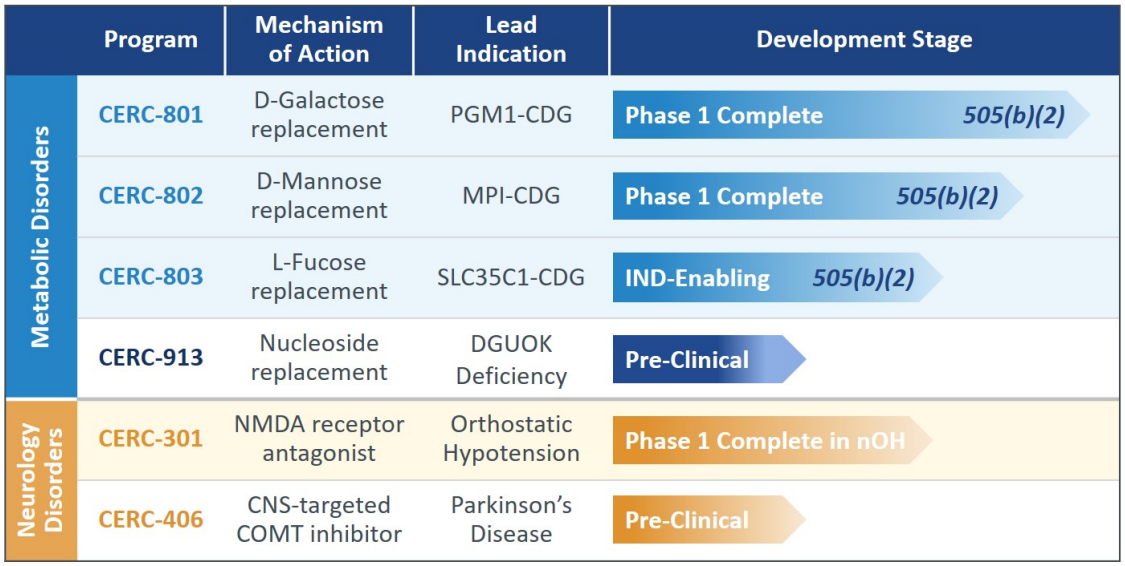
Our Strategy

Our strategy for increasing shareholder value includes:

- Advancing our pipeline of compounds through development and to regulatory approval;
- Acquiring or licensing rights to targeted, complimentary differentiated preclinical and clinical stage pipeline assets;
- Developing go-to-market strategy in preparation to quickly and effectively market, launch, and distribute each of our assets that receive marketing approval; and
- Opportunistically out-licensing rights to indications or geographies.

Product Pipeline Assets

The following table summarizes key information about our product candidates and further detail regarding each product candidate follows:



On August 8, 2019, the Company entered into an assignment of license agreement (the "Assignment Agreement") with ES Therapeutics, LLC ("ES Therapeutics"), a wholly-owned subsidiary of Armistice, a significant stockholder of the Company. Pursuant to the Assignment Agreement, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics. The Company initially licensed the compound from Eli Lilly Company ("Lilly") in September 2016. Under the Assignment Agreement, Armistice paid the Company an upfront payment of $0.1 million. The Company recognized the payment as license and other revenue for the three and nine months ended September 30, 2019. The Assignment Agreement also provides for: (a) a $7.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $750.0 million; and (b) a $12.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $1.3 billion. The Assignment Agreement also releases the Company of obligations related to CERC-611, including the $1.3 million contingent payment to Lilly upon the first subject dosage of CERC-611 in a multiple ascending dose study, which was recorded as a license obligation on the balance sheet as of June 30, 2019. The decrease of this license obligation to $0 as of September 30, 2019 resulted in an offset of research and development expense of $1.3 million for the three and nine months ended September 30, 2019. The Assignment Agreement also releases the Company from additional potential future payments due to Lilly upon achievement of certain development and commercialization milestones, including the first commercial sale, and milestone payments and royalty on net sales upon commercialization of the compound.

Results of Operations

Expectations of Results of Operations related to Aytu Transaction

In connection with the Aytu transaction, which was entered into and subsequently closed in the fourth quarter of 2019, the Company expects significant reductions in subsequent periods to the following: net product revenue, cost of product sales, sales and marketing expense, amortization expense and interest expense. However, the results of operations for the three and nine months ended September 30, 2019, as discussed below, do not factor in such expectations because the transaction was entered into and subsequently closed in the fourth quarter of 2019.

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table summarizes our revenue for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Product revenue, net	$ 5,513	$ 4,075
License and other revenue	100	—
	$ 5,613	$ 4,075

Product Revenue, net

Net product revenue increased $1.4 million for the three months ended September 30, 2019 as compared to the same period in 2018. The increase was due to a more favorable product mix and unit growth during the current period.

License and Other Revenue

In August 2019, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics in exchange for initial gross proceeds of $0.1 million, which was recognized as license and other revenue for the three months ended September 30, 2019. Under the Assigned Agreement, the Company is also eligible for the following potential milestone payments: (a) a $7.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $750.0 million; and (b) a $12.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $1.3 billion. There was no license and other revenue for the three months ended September 30, 2018.

Cost of Product Sales

Cost of product sales was $1.4 million for the three months ended September 30, 2019, as compared to $3.1 million for the three months ended September 30, 2018, which represents a $1.7 million decrease. For the three months ended September 30, 2018, the Company recognized $1.7 million in cost of product sales related to the post-acquisition minimum obligations pursuant to the Lachlan Agreement, net of indemnity receivable. Prior to the third quarter of 2018, the Company had not recognized any post-acquisition minimum obligations related to the Lachlan Agreement because the Company previously believed a market change had occurred thus not contractually requiring the Company to pay such minimum obligations. In October 2018, the Company received an interim ruling related to the market change dispute in which it interpreted to mean that a market change had not occurred and therefore the minimum purchase obligation and minimum royalty provisions of the contract were active and due for any prior periods as well as going forward for any future periods. Accordingly, during the three months ended September 30, 2018, the Company recognized $1.7 million in cost of product sales related to the post-acquisition minimum obligations. During the second quarter of 2019, the Company entered into a settlement agreement that fully released all current and future liabilities related to the Lachlan Agreement. Accordingly, no cost of products sales was recognized for the three months ended September 30, 2019 related to the minimum obligations pursuant to the Lachlan Agreement, thus driving the $1.7 million decrease from the same period in 2018.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Preclinical expenses	$ 140	$ 120
Clinical expenses	718	473
CMC expenses	1,360	18
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	581	324
Stock-based compensation expense	176	31
Other	(1,232)	82
	$ 1,743	$ 1,048

Research and development expenses increased $0.7 million for the three months ended September 30, 2019 compared to the same period in 2018. The overall increase is driven by an increase in research and development activities during the current year as the Company continues to develop its pipeline assets. Chemistry, Manufacturing, and Controls ("CMC") expenses increased $1.3 million for the three months ended September 30, 2019 compared to the same period in 2018 due to additional spending on manufacturing to support clinical development. Clinical expenses increased $0.2 million primarily due to increased activities related to CERC-801, CERC-802, and CERC-803, which were acquired as part of the Ichorion Acquisition in September 2018. Salaries, benefits and related costs increased by $0.3 million compared to the same period in 2018 due to an increase in headcount and salary-related costs needed to maintain and grow our research and development activities as we continue to invest in our pipeline. Additionally, stock-based compensation increased by $0.1 million due to an increase in stock option grants in 2019 driven by an increased headcount, as well as the additional expense related to the annual stock option award that was granted on April 1, 2019.

These increases were partially offset by a $1.3 million reversal of research and development expense previously recorded in the prior year related to the Company's assignment of its license agreement with respect to CERC-611 to ES Therapeutics in the third quarter of 2019. Pursuant to the Assignment Agreement, the Company assigned and transferred its rights, interest and obligations related to the compound, thus releasing the Company's contingent payment of $1.3 million to Lilly upon the first subject dosage of CERC-611 in a multiple ascending dose study, which was previously recorded as a license obligation on the balance sheet as of June 30, 2019. The decrease of the license obligation to $0 as of September 30, 2019 resulted in an offset of research and development expense for the three months ended September 30, 2019.

Acquired In-Process Research and Development Expenses

As part of the asset acquisition of Ichorion in the third quarter of 2018, the Company acquired $18.7 million of in-process research and development ("IPR&D") for three preclinical therapies for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803). The fair value of the IPR&D was immediately recognized as acquired in-process research and development expense as the IPR&D asset has no other alternate use due to the stage of development. There was no acquired in-process research and development expense for the three months ended September 30, 2018.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for thethree months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Salaries, benefits and related costs	$ 852	$ 1,139
Legal, consulting and other professional expenses	1,197	(203)
Stock-based compensation expense	474	843
Other	156	105
	$ 2,679	$ 1,884

General and administrative expenses were $2.7 million for the three months ended September 30, 2019, which is an increase of $0.8 million compared to the three months ended September 30, 2018. The overall increase was driven by a $1.4 million increase in legal, consulting, and other professional expenses, partially offset by a $0.7 million decrease in stock-based compensation and salaries, benefits and related costs.

For the three months ended September 30, 2018, the Company recognized a $1.0 million reversal of legal expenses due to a purchase price allocation measurement period adjustment identified for TRx acquisition during the third quarter of 2018. As this was specific to purchase price allocation, no such reversal was recognized for the three months ended September 30, 2019, thus driving $1.0 million of the increase in legal, consulting and other professional expense as compared to the same period in 2018. Additionally, for the three months ended September 30, 2019, there was a $0.4 million increase in legal costs related to business development activities during the quarter. Stock-based compensation for the three months ended September 30, 2019 decreased $0.4 million as compared to the same period in 2018 mainly due to $0.3 million of expense recognized for three months ended September 30, 2018 attributable to modifications of awards related to a separated executive during the third quarter of 2018. Finally, salaries, benefits and related costs decreased $0.3 million mainly due to severance benefits paid to a separated executive in the third quarter of 2018, which was not repeated in the third quarter of 2019.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Salaries, benefits and related costs	$ 1,629	$ 1,456
Logistics, insurance and other commercial operations expenses	370	338
Stock-based compensation expense	169	70
Advertising and marketing expense	423	415
Other	39	32
	$ 2,630	$ 2,311

Sales and marketing expenses increased $0.3 million for the three months ended September 30, 2019 as compared to the same period in 2018. Salaries, benefits and related costs increased $0.2 million as a result of increasing sales and sales support personnel needed to maintain and grow our commercial sales activities in connection with the acquisition of TRx and Avadel's pediatric products. Specifically, during the third quarter of 2018, the Company initiated an expansion of the sales force, which was largely completed in the first quarter of 2019. Stock-based compensation expense increased $0.1 million due to an increase in stock option grants during second half of 2018 driven by the sales force expansion as well as the additional expense related to the annual stock option award that was granted on April 1, 2019.

Amortization Expense

The following table summarizes our amortization expense for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Amortization of intangible assets	$ 1,037	$ 1,065

Amortization expense relates to the acquisition of intangible assets as part of the acquisition of TRx in November 2017 and Avadel's pediatric products in February 2018.

Change in Fair Value of Contingent Consideration

The following table summarizes our change in fair value of contingent consideration for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Change in fair value of contingent consideration	$ (197)	$ 85

The Company recognized a gain on the change in fair value of contingent consideration of $0.2 million for the three months ended September 30, 2019 as compared to a loss of $0.1 million for the same period in 2018. The contingent consideration is related to the potential for future payment of consideration that is contingent upon the achievement of operation and commercial milestones and royalty payments on future product sales as part of the Company's acquisition of Avadel's pediatric products. The fair value of contingent consideration was determined at the acquisition date. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at the current fair value with changes recorded in operating expenses in the condensed consolidated statement of operations. The $0.2 million gain recognized for the three months ended September 30, 2019 was related to the decrease in the fair value of contingent consideration related to the future potential royalties on Avadel's pediatric products.

Other Expense, Net

The following table summarizes our other expense, net for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Change in fair value of warrant liability and unit purchase option liability	$ 35	$ (3)
Other expense, net	(15)	—
Interest expense, net	(206)	(235)
	$ (186)	$ (238)

Income Tax Expense

The following table summarizes our income tax expense for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Income tax expense	$ 116	$ 52

The provision for income taxes was $0.1 million for three months ended September 30, 2019 and includes estimated cash taxes and deferred taxes related to the amortization of tax deductible goodwill. Additionally, discrete to the three months ended September 30, 2019, the income tax expense includes interest and penalties on the outstanding taxes payable to the IRS and various state authorities. The provision for income taxes was $0.1 million for the three months ended September 30, 2018 and was composed of state income tax for one of the Company's wholly owned subsidiaries.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes our revenue for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Product revenue, net	$ 15,374	$ 13,046
License and other revenue	100	—
Sales force revenue	—	297
	$ 15,474	$ 13,343

Product Revenue, Net

Net product revenue increased $2.3 million for the nine months ended September 30, 2019 as compared to the same period in 2018. The increase was due to favorable product mix and unit growth driven by the sales force expansion as well as due to a full year of sales of products that were acquired during the first quarter of 2018.

License and Other Revenue

In August 2019, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics in exchange for initial gross proceeds of $0.1 million, which was recognized as license and other revenue for the three months ended September 30, 2019. Under the Assignment Agreement, we are also eligible for the following potential milestone payments: (a) a $7.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $750.0 million; and (b) a $12.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $1.3 billion. There was no license and other revenue for the nine months ended September 30, 2018.

Sales Force Revenue

As part of the acquisition of TRx in November 2017, the Company acquired a sales and marketing agreement with PAI under which the Company received a monthly marketing fee to promote, market and sell certain products on behalf of PAI. The Company was also entitled to a share of PAI's profits. For the nine months ended September 30, 2018, sales force revenue was $0.3 million. The PAI contract was canceled during the second quarter of 2018 and therefore there is no sales force revenue for the nine months ended September 30, 2019.

Cost of Product Sales

Cost of product sales was $3.2 million for the nine months ended September 30, 2019, as compared to $5.4 million for the nine months ended September 30, 2018. For the nine months ended September 30, 2018, the Company recognized $1.7 million in cost of product sales related to post-acquisition minimum obligations pursuant to the Lachlan Agreement net of indemnity receivable. Prior to the third quarter of 2018, the Company had not recognized any post-acquisition minimum obligations related to the Lachlan Agreement because the Company previously believed a market change had occurred thus not contractually requiring the Company to pay such minimum obligations. In October 2018, the Company received an interim ruling related to the market change dispute in which it interpreted to mean that a market change had not occurred and therefore the minimum purchase obligation and minimum royalty provisions of the contract are active and due for any prior periods as well as going forward for any future periods. Accordingly, for the nine months ended September 30, 2018, the Company recognized $1.7 million in cost of product sales related to the post-acquisition minimum obligations. During the second quarter of 2019, the Company entered into a Settlement Agreement which fully released all current and future liabilities related to the Lachlan Agreement, resulting in a net reversal of $1.6 million to cost of products sales for the nine months ended September 30, 2019.

The decrease is partially offset by increased cost of product sales recognized for sales of our pediatric products driven by increased sales for the nine months ended September 30, 2019. The decrease was further partially offset by the write down of Flexichamber inventory as of June 30, 2019 to $0 (related to the impairment of the Flexichamber intangible asset recognized during the second quarter of 2019), which resulted in a $0.2 million charge to cost of product sales for the nine months ended September 30, 2019.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Preclinical expenses	$ 1,686	$ 1,403
Clinical expenses	3,999	1,122
CMC expenses	2,551	157
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,489	809
Stock-based compensation expense	354	64
Other	(1,222)	225
	$ 8,857	$ 3,780

Research and development expenses increased $5.1 million for the nine months ended September 30, 2019 compared to the same period in 2018. The overall increase is driven by an increase in research and development activities during the current year as the Company continues to develop its pipeline assets. Clinical expenses increased $2.9 million primarily due to increased activities related to the CERC-301 clinical study in nOH during the first half of 2019 and activities related to CERC-801, CERC-802, and CERC-803, which were acquired as part of the Ichorion Acquisition in September 2018. CMC expenses increased $2.4 million for the nine months ended September 30, 2019 compared to the same period in 2018 due to additional spending on manufacturing to support clinical development. Salaries, benefits and related costs increased by $0.7 million compared to the same period in 2018 due to an increase in headcount and salary-related costs needed to maintain and grow our research and development activities as we continue to invest in our pipeline. Additionally, stock-based compensation increased by $0.3 million due to an increase in stock option grants in 2019 driven by an increased headcount, as well as the additional expense related to the annual stock option award that was granted on April 1, 2019.

These increases were partially offset by a $1.3 million reversal of research and development expense related to the Company's assignment of its license agreement with respect to CERC-611 to ES Therapeutics in the third quarter of 2019. Pursuant to the Assignment Agreement, the Company assigned and transferred its rights, interest and obligations related to the compound, thus releasing the Company's contingent payment of $1.3 million to Lilly upon the first subject dosage of CERC-611 in a multiple ascending dose study, which was previously recorded as a license obligation on the balance sheet as of June 30, 2019. The decrease of the license obligation to $0 as of September 30, 2019 resulted in an offset of research and development expense for the nine months ended September 30, 2019.

Acquired In-Process Research and Development Expenses

As part of the asset acquisition of Ichorion in the third quarter of 2018, the Company acquired $18.7 million of IPR&D for three preclinical therapies for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803). The fair value of the IPR&D was immediately recognized as acquired IPR&D expense as the IPR&D asset has no other alternate use due to the stage of development. There was no acquired IPR&D expense for the nine months ended September 30, 2019.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for thenine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Salaries, benefits and related costs	$ 3,308	$ 2,614
Legal, consulting and other professional expenses	2,858	3,324
Stock-based compensation expense	1,139	1,600
Other	473	296
	$ 7,778	$ 7,834

General and administrative expenses decreased $0.1 million for the nine months ended September 30, 2019 compared to the same period in 2018. The overall minimal decrease compared to the prior year was driven by a $0.5 million decrease in legal, consulting and other professional fees and a $0.5 million decrease in stock-based compensation, largely offset by a $0.7 million increase in salaries, benefits and related costs and a $0.2 million increase in other general and administrative expenses.

Legal, consulting and other professional expenses decreased $0.5 million, which was driven by a substantial decrease in consulting fees in the current year. The consulting fees incurred in the prior year were related to the integration of the acquisitions of TRx and Avadel's pediatric products. The Company has since increased corporate headcount and therefore utilizes less consulting services to meet accounting and reporting requirements. Further, stock-based compensation expense decreased $0.5 million for the nine months ended September 30, 2019 as compared to the same period in 2018 mainly due to the recognition of $0.3 million of stock-based compensation expense related to the modification of a separated executive's awards for the nine months ended September 30, 2018, and due to the current year reversal of the full expense recognized of $0.5 million related to the former CEO's unvested market-based options that were forfeited during the second quarter of 2019, partially offset by expense recognized for stock options granted to executives in the period and the Company's annual stock option award. The decreases to general and administrative expenses were largely offset by a $0.7 million increase in salaries, benefits and related costs due to an increase in headcount and salary-related costs. Additionally, other expenses increased $0.2 million primarily due to increased licenses and fees in the current year and an increase in expenses related to the Company's new corporate headquarters.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for thenine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Salaries, benefits and related costs	$ 5,269	$ 4,086
Logistics, insurance and other commercial operations expenses	1,053	847
Stock-based compensation expense	449	133
Advertising and marketing expense	1,726	728
Other	179	95
	$ 8,676	$ 5,889

Sales and marketing expenses increased $2.8 million for the nine months ended September 30, 2019 as compared to the same period in 2018. Salaries, benefits and related costs increased $1.2 million as a result of increasing sales and sales support personnel needed to maintain and grow our commercial sales activities in connection with the acquisition of TRx and Avadel's pediatric products. Specifically, during the third quarter of 2018, the Company initiated an expansion of the sales force, which was largely completed in the first quarter of 2019. Stock-based compensation expense increased $0.3 million due to an increase in stock option grants during the second half of 2018 driven by the sales force expansion as well as the additional expense related to the annual stock option award that was granted on April 1, 2019. Advertising and marketing expenses increased $1.0 million due to an increased focus on advertising and marketing initiatives during the current year to support the portfolio of pediatric drugs and to support the go-to-market strategy of the CERC-800s.

Amortization Expense

The following table summarizes our amortization expense for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Amortization of intangible assets	$ 3,195	$ 3,316

Amortization expense relates to the acquisition of intangible assets as part of the acquisition of TRx in November 2017 and Avadel's pediatric products in February 2018.

Impairment of Intangible Assets

The following table summarizes our expense related to impairment of intangible assets for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Impairment of intangible assets	$ 1,449	$ 1,862

The Company recorded expense related to impairment of intangible assets of $1.4 million for the nine months ended September 30, 2019 due to the impairment of the Flexichamber intangible asset. During the second quarter of 2019, the Company made a strategic decision to cease sales force promotion of Flexichamber. As a result of this decision paired with significant deviations from forecasted sales, management identified an impairment indicator for Flexichamber during the second quarter of 2019. Accordingly, the Company performed a test for recoverability and concluded that the sum of its estimated future undiscounted cash flows was less than its carrying value. Management then measured the impairment loss by calculating the excess of the carrying amount of Flexichamber over its fair value. Management determined that due to the absence of future material cash flows that the fair value was $0 and therefore the impairment loss equated Flexichamber's carrying amount on June 30, 2019 of $1.4 million.

The Company recorded impairment of intangible asset expense of $1.9 million for the nine months ended September 30, 2018 due to the impairment of the PAI sales and marketing agreement intangible asset upon termination of the corresponding agreement.

Change in Fair Value of Contingent Consideration

The following table summarizes our change in fair value of contingent consideration for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Change in fair value of contingent consideration	$ (1,009)	$ 361

The Company recognized a gain on the change in fair value of contingent consideration of $1.0 million for the nine months ended September 30, 2019 as compared to a loss of $0.4 million for the same period in 2018. The contingent consideration is related to the potential for future payment of consideration that is contingent upon the achievement of operation and commercial milestones and royalty payments on future product sales as part of the Company's acquisitions of Avadel's pediatric products and TRx. The fair value of contingent consideration was determined at the acquisition date. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at the current fair value with changes recorded in operating expenses in the condensed consolidated statement of operations.

The gain recognized in the current period is largely related to the Company entering into the Lachlan Settlement Agreement during the second quarter of 2019 which released the Company from the potential contingent payments related to the TRx acquisition, thus reducing the fair value down to $0 as of June 30, 2019. This represented a gain on the change of fair value of contingent consideration of $1.3 million for the nine months ended September 30, 2019.

Other Expense, Net

The following table summarizes our other income (expense) for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Change in fair value of warrant liability and unit purchase option liability	$ 7	$ (22)
Other (expense) income, net	(24)	19
Interest expense, net	(614)	(578)
	$ (631)	$ (581)

Income Tax Expense

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Income tax expense	$ 348	$ 92

The provision for income taxes was $0.3 million for the nine months ended September 30, 2019 and includes estimated cash taxes and deferred taxes related to the amortization of tax deductible goodwill. Additionally, discrete to the nine months ended September 30, 2019, the income tax expense includes interest and penalties on the outstanding taxes payable to the IRS and various state authorities. The provision for income taxes was $0.1 million for the nine months ended September 30, 2018 and was composed of state income tax for one of the Company's wholly owned subsidiaries.

Liquidity and Capital Resources

In order to meet its cash flow needs, the Company applies a disciplined decision-making methodology as it evaluates the optimal allocation of the Company's resources between investing in the Company's development portfolio and acquisitions or in-licensing of new assets. For the nine months ended September 30, 2019, Cerecor generated a net loss of $17.7 million and negative cash flow from operations of $17.5 million. As of September 30, 2019, Cerecor had an accumulated deficit of $115.9 million and a balance of $5.3 million in cash and cash equivalents.

During the first quarter of 2019, the Company closed an underwritten public offering of common stock for 1,818,182 shares of common stock of the Company, at a price to the public of $5.50 per share ("public price"). Armistice Capital Master Fund Ltd. ("Armistice"), our largest stockholder, participated in the offering by purchasing 363,637 shares of common stock of the Company from the underwriter at the public price. Cerecor director Steven J. Boyd is Armistice's Chief Investment Officer. The net proceeds of the offering were approximately $9.0 million. During the third quarter of 2019, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold 1,200,000 shares of the Company's common stock for a purchase price of $3.132 per share. Net proceeds of the private placement were approximately $3.7 million. During the fourth quarter of 2019, the Company entered into, and subsequently closed on, the Aytu Purchase Agreement to sell the Company's rights, title and interest in, assets relating to its Pediatric Portfolio and related commercial infrastructure for a combination of cash and preferred stock totaling $17 million ($4.5 million in cash and $12.5 million in Aytu preferred stock) and assumption of certain of the Company's liabilities including the Company's payment obligations payable to Deerfield and certain other liabilities in excess of $15 million.

The Company plans to use its current cash on hand inclusive of the the $4.5 million cash collected in the fourth quarter of 2019 from the sale of the Pediatric Portfolio and related commercial infrastructure and the anticipated cash flows from the Company's product sales of Millipred to offset costs related to its neurology programs, orphan disease programs, business development, and costs associated with its organizational infrastructure. Cerecor expects to continue to incur significant expenses and operating losses for the immediate future as it continues to invest in the Company's pipeline assets. Our ability to achieve and maintain profitability in the future is dependent on, among other things, the development, regulatory approval, and commercialization of our pipeline assets, the potential sale of any PRVs we receive and revenue from from Millipred product sales, all being adequate to support our cost structure and pipeline asset development.

The Company believes it will require additional financing to continue to execute its clinical development strategy and fund future operations. The Company plans to meet its capital requirements through operating cash flows from product sales of Millipred and some combination of PRV sales, equity or debt financings, collaborations, out-licensing arrangements, strategic alliances, federal and private grants, marketing, distribution or licensing arrangements or the sale of current or future assets. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates.

Our plan to aggressively develop our pipeline will require substantial cash in excess of what the Company expects our cash from the current commercial operations to generate. However, the Company expects that our existing cash and cash equivalents, together with anticipated revenue, will enable us to fund our operating expenses, capital expenditure requirements, and other non-operating cash payments through at least November 2020.

Uses of Liquidity

The Company uses cash and the anticipated positive net cash flows from the Company's product sales of Millipred to fund research and development expenses related to its neurology and pediatric rare disease pipelines, business development and costs associated with its organizational infrastructure.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (17,454)	$ (1,152)
Investing activities	(262)	1,365
Financing activities	12,424	4,237
Net (decrease) increase in cash and cash equivalents	$ (5,292)	$ 4,450

Net cash used in operating activities

Net cash used in operating activities was $17.5 million for the nine months ended September 30, 2019 and consisted primarily of a net loss of $17.7 million, which was driven by increased research and development activities as the Company continues to fund its pipeline of development assets and also by increased sales and marketing expenses incurred to support commercial sales activities. The net loss was partially offset by non-cash depreciation and amortization of $3.3 million, non-cash impairment of intangible assets of $1.4 million related to the impairment of Flexichamber and non-cash stock-based compensation expense of $1.9 million. Changes in working capital included a decrease in other receivables of $5.3 million, an increase in accounts receivable of $1.8 million, a decrease in accrued expenses and other liabilities of $6.6 million, a decrease in license obligations of $1.3 million and a decrease in income taxes payable of $1.0 million. The $5.3 million decrease in other receivables was driven by the Lachlan Settlement that was entered into during the period that, among other terms, released the former TRx owners of their requirement to indemnify the Company for pre-acquisition Ulesfia losses. The decrease in accrued expenses and other liabilities was also driven by the Lachlan Settlement that also released the Company of all current and future liabilities including minimum purchase obligations and royalties related to the Lachlan Agreement.

Net cash used in operating activities was $1.2 million for the nine months ended September 30, 2018 and consisted primarily of a net loss of $34.5 million, offset by non-cash acquired IPR&D of $18.7 million, non-cash depreciation and amortization of $3.3 million, non-cash impairment of intangible assets of $1.9 million, non-cash stock-based compensation expense of $1.8 million and changes in working capital, primarily, an increase in accrued expenses of $6.2 million and a decrease in escrowed cash receivable of $3.8 million offset by an increase in other receivable of $3.1 million.

Net cash (used in) provided by investing activities

Net cash used in investing activities was $0.3 million for the nine months ended September 30, 2019 and consisted primarily of the purchase of property and equipment in connection with the Company's new corporate headquarters.

Net cash provided by investing activities was $1.4 million for the nine months ended September 30, 2018 and consisted primarily of cash received as part of the Ichorion Asset Acquisition.

Net cash provided by financing activities

Net cash provided by financing activities was $12.4 million for the nine months ended September 30, 2019 and consisted primarily of net proceeds of approximately $9.0 million from the underwritten public offering of common stock for 1,818,182 shares of common stock of the Company, at a price to the public of $5.50 per share, which the Company closed on during the first quarter of 2019. The Company also received $3.7 million from a private placement of equity securities with Armistice during the third quarter of 2019. Additionally, for the nine months ended September 30, 2019, the Company received $0.3 million of proceeds from exercise of stock options and warrants and $0.1 million of proceeds from sales of common stock under the employee stock purchase plan. The increase was partially offset by $0.6 million of payments of contingent consideration related to the Avadel acquisition.

Net cash provided by financing activities was $4.2 million for the nine months ended September 30, 2018 and consisted primarily of net proceeds of $3.9 million from a private placement of equity securities with Armistice and $0.5 million of proceeds from option and warrant exercises, partially offset by $0.1 million payment of contingent consideration.

Critical Accounting Policies, Estimates, and Assumptions

This Management’s Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. In preparing the financial statements in conformity with GAAP, the Company makes estimates and assumptions that have an impact on assets, liabilities,

revenue and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk, and financial condition. In our unaudited condensed consolidated financial statements, estimates are used for, but not limited to, revenue recognition, cost of product sales, stock-based compensation, fair value measurements (including those relating to contingent consideration), cash flows used in management's going concern assessment, income taxes, goodwill, and other intangible assets and clinical trial accruals. The Company believes, given current facts and circumstances, our estimates and assumptions are reasonable, adhere to GAAP and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from estimates, and estimates may vary as new facts and circumstances arise. Our most critical accounting estimates and assumptions are included in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 18, 2019 and amended on April 23, 2019.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable SEC rules and regulations.

Recently Adopted Accounting Pronouncements

See Item 1 of Part I, “Notes to Unaudited Financial Statements,” Note 2, of this Quarterly Report on Form 10-Q.

JOBS Act

The JOBS Act contains provisions that, among other things, reduce reporting requirements for an “emerging growth company.” As an emerging growth company, we have elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10-Q that 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 party to any material legal proceedings and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 1A. Risk Factors.

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our warrants and common stock would likely decline.

Risks Related to Our Business and Industry

Our product candidates that we intend to commercialize are in early stages of development. If we do not successfully complete preclinical testing and clinical development of our product candidates or experience significant delays in doing so, our business may be materially harmed.

We have invested a significant portion of our efforts and financial resources in the identification and preclinical and clinical development of product candidates. Our ability to increase product revenues will depend on our ability to advance our one clinical product candidate and our preclinical product candidates into clinical development and successfully complete preclinical testing of our clinical stage product candidates. The outcome of preclinical studies and Phase 1 clinical trials might not predict the success of future clinical trials. Preclinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed in clinical development. Our inability to successfully complete development of our product candidates could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining required approvals from regulatory authorities for the sale of future product candidates, we alone, or with a partner, must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials might not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Our product candidates will require additional clinical and preclinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply on our own or from a third party, expansion of our commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from sales of any of those product candidates approved for marketing. We do not know whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates would be adversely impacted.

If we experience delays in clinical testing, we will be delayed in obtaining regulatory approvals and commercializing our product candidates, our costs may increase and our business may be harmed.

We do not know whether any clinical trials will begin as planned, whether the design will be revised prior to or during conduct of the study, completed on schedule or conducted at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects.

Events which may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching an agreement with or failure in obtaining authorization from the FDA, other regulatory authorities or institutional review boards, or IRBs, to commence or amend a clinical trial;
- imposition of a Clinical Hold or trial termination following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities, or due to concerns about trial design, or a decision by the FDA, other regulatory authorities, IRBs or the company, or recommendation by a data safety monitoring board, to place the trial on hold or otherwise suspend or terminate clinical trials at any time for safety issues or for any other reason;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
- failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- failure to enter into agreements with third parties to obtain the results of clinical trials;
- delays in the importation and manufacture of clinical supply;
- delays in the testing, validation and delivery of the clinical supply of the product candidates to the clinical sites;
- for clinical trials in selected subject populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected subjects;
- delays in recruiting suitable subjects to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or disease progression;
- delays in adding new investigators and clinical trial sites;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Any inability by us or our partners to timely complete clinical development could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales.

If we are unable to enroll appropriate subjects in clinical trials, we will be unable to complete these trials on a timely basis or at all.

Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit appropriate subjects to participate in testing our product candidates, as well as completion of required follow-up periods. If subjects are unwilling to participate in our trials because of negative publicity from adverse events in the biotechnology industry or for other reasons, including competitive clinical trials for similar subject populations, the timeline for recruiting subjects, conducting trials and obtaining marketing approval of potential products may be delayed.

Difficulty or delays in patient recruitment into our trials could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. Many factors affect subject enrollment, including:

- the size and nature of the subject population;
- the number and location of clinical sites we enroll;
- the proximity of subjects to clinical sites;
- perceived risks and benefits of the product candidate under trial;
- competition with other companies for clinical sites or subjects;
- competing clinical trials;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- effectiveness of publicity for the clinical trials;
- inability to obtain and maintain subject consents;
- ability to monitor subjects adequately during and after the administration of the product candidate and the ability of subjects to comply with the clinical trial requirements;
- risk that enrolled subjects will drop out or be withdrawn before completion; and
- clinicians' and subjects' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

There is significant competition for recruiting subjects in clinical trials for product candidates for the treatment of neurological disorders and we or our partners may be unable to enroll the subjects we need to complete clinical trials on a timely basis or at all. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. If we are unable to enroll sufficient subjects in our clinical trials, if enrollment is slower than we anticipate, or if our clinical trials require more subjects than we anticipate, our clinical trials may be delayed or might not be completed. If we experience delays in our clinical trials, the commercial prospects of our product candidates will be harmed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our lead product candidates or our other product candidates.

We may face significant delays in our clinical studies and trials due to an inability to recruit patients for our clinical studies and trials or to retain patients in the clinical studies and trials we may perform.

We may not be able to locate and enroll enough eligible patients to participate in these trials as required by the FDA, the EMA or similar regulatory authorities outside the United States and the European Union. This may result in our failure to initiate or continue clinical trials for our product candidates or may cause us to abandon one or more clinical trials altogether. In particular, because several of our programs are focused on the treatment of patients with rare, orphan or ultra-orphan diseases, our ability to enroll eligible patients in these trials may be limited or slower than we anticipate in light of the small patient populations involved and the specific age range required for treatment eligibility in some indications. In addition, our potential competitors, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, may seek to develop competing therapies, which would further limit the small patient pool available for our studies.

Completion of orphan clinical trials may take considerably more time than other trials, sometimes years, depending on factors such as type, complexity, novelty and intended use of a product candidate. As a result of the uncertainties described above, there can be no assurance that we will meet timelines that we establish for any of our clinical trials.

Even if we were to obtain approval for our product candidates with the Rare Pediatric Disease Designation, the Rare Pediatric Disease Priority Review Voucher Program may no longer be in effect at the time of such approval or we might not be able to capture the value of the Rare Pediatric Disease Priority Review Voucher Program.

Rare pediatric disease designation by the FDA is granted in the case of serious or life-threatening diseases affecting fewer than 200,000 people in the United States in which the serious or life-threatening manifestations are primarily in individuals 18 years of age and younger. The designation provides regulatory incentives for companies to develop and market therapies that treat these conditions. The sponsor of a drug for a rare pediatric disease may be eligible for a priority review voucher upon approval of the drug that can be used to obtain a priority review of a subsequent marketing application. The priority review voucher may be sold or transferred an unlimited number of times. Congress has extended the priority review voucher program until September 30, 2020 with new drug approvals that meet the voucher criteria grandfathered through 2022. This program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for some of our product candidates and qualify for such a priority review voucher, the program may no longer be in effect at the time of approval. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a Priority Review Voucher.

We may in the future conduct clinical trials for certain of our product candidates at sites outside the United States, and the FDA might not accept data from trials conducted in such locations.

We may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical principles and current Good Clinical Practice, or GCPs. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any of our clinical trials that we determine to conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the product candidate.

We may fail to successfully identify, in-license, acquire, develop or commercialize potential product candidates.

The success of our business depends in part upon our ability to identify and validate new therapeutic targets and identify, develop and commercialize therapeutics, which we may develop ourselves, in-license or acquire from others. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research efforts may initially show promise in identifying potential therapeutic targets or candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our methodology, including our screening technology, might not successfully identify medically relevant potential product candidates;
- our competitors may develop alternatives that render our product candidates obsolete;
- we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable;
- our product candidates may cause adverse effects in subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- our product candidates might not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- our product candidates might not demonstrate a meaningful benefit to subjects;
- our potential collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product; and
- our reliance on third party clinical trials may cause us to be denied access to clinical results that may be significant to further clinical development.

Additionally, we may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations.

We might not be successful in our efforts to develop and commercialize our preclinical product candidates.

Our continued development of our preclinical product candidates will be dependent on receiving positive preclinical and clinical data that, in our judgment, merits advancing such programs. Even if we are successful in continuing to build and expand our pipeline, the potential product candidates that we identify might not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Similarly, even if the FDA approves our INDs, there is no guarantee that we will be successful in our efforts to advance our preclinical product candidates into clinical trials. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

The marketing approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, costly and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

The time required to obtain approval to market new drugs by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval. Moreover, the filing of an NDA for products that have not been granted ODD requires a payment of a significant PDUFA NDA application fee upon submission. Any subsequent clinical data submissions to the NDA (i.e. for new indications) are also assessed an NDA application fee. The filing of an NDA for our product candidates may be delayed due to our lack of financial resources to pay such user fee.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree on the design or implementation of our clinical trials, including the methodology used in our trial, our chosen endpoints, our statistical analysis, or our proposed product indication. For instance, the FDA may find that the designs that we are utilizing in our planned clinical trial do not support an adequate and well-controlled study. The FDA also might not agree with the various disease scales and evaluation tools that we may use in our clinical trials to assess the efficacy of our product candidates. Further, the FDA might not agree with our endpoints and/

or indications selected for our development programs;
- the FDA or comparable foreign regulatory authorities may disagree with our development plans for our product candidates;
- our failure to demonstrate to the satisfaction of the FDA or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
- our clinical trials may fail to meet the level of statistical significance required for approval;
- we may fail to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may be insufficient to support the submission and filing of an NDA, other submission or to obtain marketing approval, and FDA may require additional studies to show that our product candidates are safe or effective;
- we may fail to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- there may be changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or comparable foreign regulatory authority may require more information, including additional preclinical or clinical studies to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any or all of our product candidates for fewer or more limited indications than we request, may require that contraindications, warnings or precautions be included in the product labeling, including a black-box warning, may grant approval with a requirement of costly post-marketing clinical trials or other post-market requirements, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

As appropriate, we intend to seek all available periods of regulatory exclusivity for our product candidates. However, there is no guarantee that we will be granted these periods of regulatory exclusivity or that we will be able to maintain these periods of exclusivity.

The FDA grants product sponsors certain periods of regulatory exclusivity, during which the agency might not approve, and in certain instances, might not accept, certain marketing applications for competing drugs. For example, product sponsors may be eligible for five years of exclusivity from the date of approval of a new chemical entity, seven years of exclusivity for drugs that are designated to be orphan drugs, and/or a six-month period of exclusivity added to any existing exclusivity period or patent life for the submission of FDA requested pediatric data. While we intend to apply for all periods of market exclusivity that we may be eligible for, there is no guarantee that we will receive all such periods of market exclusivity. Additionally, under certain circumstances, the FDA may revoke the period of market exclusivity. Thus, there is no guarantee that we will be able to maintain a period of market exclusivity, even if granted. Moreover, we have not sought to obtain ODD for any of our product candidates, which the FDA must first grant to be eligible for orphan drug exclusivity, but may if we determine that we may be eligible. In the case of orphan designation, other benefits, such as tax credits and exemption from user fees may be available. If we are not able to obtain or maintain ODD or any period of market exclusivity to which we may be entitled, we will be materially harmed, as we will potentially be subject to greater market competition and may lose the benefits associated with programs.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials (a "Clinical Hold") and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authority. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

Should our clinical studies of our product candidates reveal undesirable side effects, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities as well as IRBs could order us to suspend or cease clinical trials. The FDA or comparable regulatory authorities could also deny approval of our product candidates for any or all targeted indications or only for a limited indication or patient population or could require label warnings, contraindications or precautions, including black box warnings, post-market studies, testing and surveillance programs or other conditions including distribution restrictions or other risk management mechanisms under a costly risk evaluation and mitigation strategy ("REMS"). Drug-related side effects could affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm

our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others (regulatory agencies, consumers, etc.) later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label or other label modifications;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a REMS or other restrictions on marketing and distribution, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such side effects for distribution to patients or restrict distribution of our products and impose burdensome implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies; and
- we could be sued and held liable for harm caused to subjects or patients.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late-stage clinical trials towards regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval.

Similarly, changes in the location of manufacturing or addition of manufacturing facilities may increase our costs and require additional studies and FDA approval. This may require us to ensure that the new facility meets all applicable regulatory requirements, is adequately validated and qualified, and to conduct additional studies of product candidates manufactured at the new location. Any of the above could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay regulatory approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a narrower indication than we expect.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies might not complete their review processes in a timely manner, or we might not be able to obtain marketing approval from the relevant regulatory agencies. Additional delays may result if the FDA, an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for fewer or more limited indications than requested, may impose significant limitations in the form of narrow indications, warnings, including black-box warnings, precautions or contra-indications with respect to conditions of use or may grant approval subject to the performance of costly post-marketing clinical trials or other post-marketing requirements, including a REMS. In addition, regulatory agencies might not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Our drugs, if approved, may be required to carry warnings comparable to this and other class-wide warnings. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we were able to commercialize our products focused on orphan diseases, product sales of these products might not justify the cost of development.

Because of the small patient population for a orphan disease, if pricing is not approved or accepted in the market at an appropriate level for an approved therapeutic product with ODD, such drug may not generate enough revenue to offset costs of development, manufacturing, marketing, and commercialization despite any benefits received from the ODD, such as market exclusivity, assistance in clinical trial design, or a reduction in user fees or tax credits related to development expense. Furthermore, our estimates regarding potential market size for any rare indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a therapeutic product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Once commercialized, some of our products may face significant competition from non-prescription competition and consumer substitution, and our operating results will suffer if we fail to compete effectively.

We may be subject to non-prescription competition and consumer substitution for certain of our pipeline assets. For example, the three preclinical therapies in our orphan disease pipeline, CERC-801, CERC-802 and CERC-803, are ultra-pure formulations of D-galactose, D-mannose and L-fucose, respectively. These formulations are naturally occurring substances contained in various foods, including dairy products and fruit. Additionally, these formulations, particularly D-mannose, are also marketed by others as non-prescription dietary supplements. Once approved by the FDA and commercially available, we cannot be sure physicians will view the pharmaceutical grade purity and tested safety of CERC-801, CERC-802 or CERC-803 as having a superior therapeutic profile to the naturally occurring formulations and dietary supplements. In addition, to the extent the net price of CERC-801, CERC-802 or CERC-803, after insurance and offered discounts, is significantly higher than the prices of commercially available formulations marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these commercial alternatives instead of writing or filling prescriptions for CERC-801, CERC-802 or CERC-803, or patients may elect on their own to take commercially available supplements. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of CERC-801, CERC-802 and CERC-803 due to reduced market acceptance.

Even if our product candidates receive marketing approval, we will still be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even if we obtain marketing approval for a product candidate, we would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and annual reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. In addition, any marketing approvals that we obtain for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing and other requirements, including Phase 4 clinical trials, imposition of a REMS and surveillance to monitor the safety and efficacy of the product candidate.

In addition, manufacturers of drug products and their facilities, including contracted facilities, are subject to periodic inspections by the FDA and other regulatory authorities for compliance with current GMP regulations and standards. If we or a regulatory agency discover previously unknown problems with the facility where the product is manufactured, we may be subject to reporting obligations and a regulatory agency may impose restrictions on that product, the manufacturing facility, us, or our suppliers, including requesting recalls or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, our contractors, the manufacturing facilities for our product candidates or others working on our behalf fail to comply with applicable regulatory requirements, either before or after marketing approval, a regulatory agency may:

- issue Warning Letters or Untitled Letters;
- mandate modifications to promotional materials or labeling, or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines, restitution or disgorgement, as well as imprisonment;
- suspend or withdraw marketing approval;
- suspend or terminate any ongoing clinical studies;

- refuse to approve pending applications or supplements to applications filed by us;
- debar us from submitting marketing applications, exclude us from participation in federal healthcare programs, require a corporate integrity agreement or deferred prosecution agreements, debar us from government contracts and refuse future orders under existing contracts;
- suspend or impose restrictions on operations, including restrictions on marketing, distribution or manufacturing of the product, or the imposition of costly new manufacturing requirements or use of alternative suppliers; or
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to continue our development programs, commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. While the FDA does not restrict physicians from prescribing approved drugs for uses outside of the drugs' approved labeling, known as off-label use, pharmaceutical manufacturers are strictly prohibited from promoting and marketing their products for such uses. Violations, including promotion of our products for off-label uses, are subject to enforcement letters, inquiries, investigations, civil and criminal sanctions by the government, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and refusal of future orders under existing contracts, and exclusion from participation in federal healthcare programs. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, debarment from government contracts and refusal of future orders under existing contracts, deferred prosecution agreements, and corporate integrity agreements with governmental authorities that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in any fines or settlement funds. If the government does not intervene, the individual may proceed on his or her own. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, such as settlements regarding certain sales practices promoting off-label drug uses involving fines that are as much as $3.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

If we are unable to, or are delayed in obtaining, state regulatory licenses for the distribution of our products, we would not be able to sell our product candidates in such states.

The majority of states require manufacturer and/or wholesaler licenses for the sale and distribution of drugs into that state. The application process is complicated, time consuming, costly and requires dedicated personnel or a third party to oversee and manage. If we are delayed in obtaining these state licenses, or denied the licenses, even with FDA approval, we would not be able to sell or ship product into that state which would adversely affect our sales and revenues.

If any of our product candidates are ultimately regulated as controlled substances, we, our contract manufacturers, as well as distributors, prescribers, and dispensers will be required to comply with additional regulatory requirements which could delay the marketing of our product candidates, and increase the cost and burden of manufacturing, distributing, dispensing, and prescribing our product candidates.

Before we can commercialize our product candidates, the United States Drug Enforcement Administration, or DEA, may need to determine the controlled substance Schedule, taking into account the recommendation of the FDA. This may be a lengthy process that

could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. While we currently do not know whether any of our product candidates will be considered to be controlled substances, certain of our product candidates may be regulated as controlled substances.

If any of our product candidates are regulated as controlled substances, depending on the controlled substance schedule in which the product candidates are placed, we, our contract manufacturers, and any distributers, prescribers, and dispensers of the scheduled product candidates may be subject to significant regulatory requirements, such as registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. Moreover, if any of our product candidates are regulated as controlled substances, we and our contract manufacturers would be subject to initial and periodic DEA inspection. If we or our contract manufacturers are not able to obtain or maintain any necessary DEA registrations, we might not be able to commercialize any product candidates that are deemed to be controlled substances or we may need to find alternative contract manufacturers, which would take time and cause us to incur additional costs, delaying or limit our commercialization efforts.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates, should they be deemed to contain controlled substances. Failure to comply with the applicable controlled substance laws and regulations can also result in administrative, civil or criminal enforcement. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings or consent decrees. Individual states also independently regulate controlled substances.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States, which would limit our market opportunities and adversely affect our business.

In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country might not be accepted by regulatory authorities in other countries. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We might not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Also, regulatory approval for any of our product candidates may be withdrawn. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for approval of drugs in foreign countries;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign taxes;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face substantial competition and rapid technological change and the possibility that others may discover, develop or commercialize products before or more successfully than us.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain marketing approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

There are numerous currently approved therapies for treating the pediatric conditions our products address and, consequently, competition in these markets is intense. Many of these approved drugs are well established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection and non-patent regulatory exclusivity, and others are available on a generic basis.

Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that any or our product candidates, if approved, would be priced at a significant premium over competitive generic, including branded generic, products, but, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. This may make it difficult for us to differentiate our product from currently approved therapies, which may adversely impact our business strategy. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer.

Our products might not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidates have or receive marketing approval, they might not gain adequate market acceptance among physicians, patients and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, generally, which may be difficult or time-consuming to obtain, may be limited in scope or might not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- prevalence and severity of any side effects of our product candidates;
- relative convenience and ease of administration of our product candidates;
- cost effectiveness of our product candidates;
- the claims we may make for our product candidates based on the approved label or any restrictions placed upon our marketing and distribution of our product candidates;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- how quickly and effectively we alone, or with a partner, can market, launch, and distribute any of our product candidates that receive marketing approval;

- the ability to commercialize any of our product candidates that receive marketing approval;
- the price of our products, including in comparison to branded or generic competitors and relative to alternative treatments;
- potential or perceived advantages of disadvantages over alternative treatments;
- the ability to collaborate with others in the development and commercialization of new products;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates;
- the entry of generic versions of our products onto the market;
- the number of products in the same therapeutic class as our product candidates;
- the effect of current and future healthcare laws on our drug candidates;
- the ability to secure favorable managed care formulary positions, including federal healthcare program formularies;
- the ability to manufacture commercial quantities of any of our product candidates that receive marketing approval;
- acceptance of any of our product candidates that receive marketing approval by physicians and other healthcare providers; and
- potential post-marketing commitments imposed on regulatory authorities, such as patient registries.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, third-party payors and patients, we might not generate or derive sufficient revenue from that product candidate and might not become or remain profitable.

Even if we commercialize any of our product candidates, these products may become subject to unfavorable third-party coverage and reimbursement policies, healthcare reform initiatives, or pricing regulations, any of which could negatively impact our business.

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products will be available from government authorities (such as Medicare and Medicaid), private health insurers, health maintenance organizations and other entities. These third-party payors determine which medications they will cover and establish reimbursement levels, and increasingly attempt to control costs by limiting coverage and the amount of reimbursement for particular medications. Several third-party payors are requiring that drug companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for drugs. In addition, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or available only to limited levels, we might not successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates for a drug may vary according to the clinical setting in which it is used and may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors, and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Moreover, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment

in one or more product candidates even if our product candidates obtain marketing approval.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications might not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our current revenue depends on one product; so if we do not successfully commercialize it, our revenue might not grow, which could affect our stock price.

Following the sale of our Pediatric Portfolio, we currently have rights to only one commercial pharmaceutical product, Millipred. We do not expect Millipred to generate significant revenue and profits, but we currently rely on it for all our commercial revenue. Our ability to increase revenue in the future will depend on commercializing it successfully, as well as developing and commercializing our current pipeline of product candidates. Any failure to do so could require us to raise additional financing, and could negatively impact our stock price.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential drug candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- revised the definition of "average manufacturer price," or AMP, for reporting purposes, which can increase the amount of Medicaid drug rebates manufacturers are required to pay to states, and created a separate AMP for certain categories of drugs provided in non-retail outpatient settings;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- enacted substantial new provisions affecting compliance which may affect our business practices with healthcare practitioners.

We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which has not yet fully occurred. For example, in January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Since January 2017, the President of the United States has signed two Executive Orders and other directives designed to delay the implementation of any certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act 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." Congress will likely consider other legislation to replace elements of the Affordable Care Act. The Affordable Care Act is likely to continue the downward pressure on pharmaceutical pricing and may also increase our regulatory burdens and operating costs. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included further reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years.

Further, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs and reform government program reimbursement methodologies for drugs. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to pharmaceutical product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the current administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, the President of the United States laid out his administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. Although some of these and other proposals will require authorization through additional legislation to become effective, Congress and the U.S. presidential administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Moreover, the Drug Supply Chain Security Act, which was enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and related to the commercial sale of our products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. For example, we may be sued if any product we sell allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our stock price.

We currently hold product and clinical trial liability insurance coverage, but it might not adequately cover all liabilities that we incur. We might not be able to maintain clinical trial insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We also maintain insurance coverage for our commercially available products, which might not adequately cover all liabilities that we may incur. We might not be able to maintain insurance coverage for our approved products at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A product liability claim or series of claims brought against us, whether or not successful, but particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our reputation and business.

Our relationships with commercial and government customers, healthcare providers, and third-party payors and others are subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare related laws, regulations and requirements, which could expose us to criminal sanctions, civil penalties, exclusion from participation in federal healthcare programs, contractual damages and consequences, reputational harm, administrative burdens and diminished profits and future earnings.

Pharmaceutical companies participating in federal and/or state healthcare programs such as Medicare and Medicaid are subject to a multitude of federal and state laws and regulations which are intended to address and prevent “fraud and abuse”. These laws also apply to the physicians and third-party payors who play a primary role in the recommendation and prescription of our commercially-available products. Our arrangements with providers, payors, and patients may expose us to broadly-applicable fraud and abuse laws. These laws may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products. There are also laws, regulations, and requirements applicable to the award and performance of federal grants and contracts.

Actions resulting in violations of these laws regulations, and requirements may result in civil and criminal liability, damages and restitution, as well as exclusion from participation in federal healthcare programs, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts or contractual damages, and other consequences. Restrictions under applicable federal and state healthcare related laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the civil federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement

to avoid, decrease or conceal an obligation to pay money to the federal government. Civil False Claims Act liability may be imposed for Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not cause by a false or fraudulent act;

- the criminal federal False Claims Act imposes criminal fines or imprisonment against individuals or entities who willfully make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the Veterans Health Care Act requires manufacturers of covered drugs to offer them for sale on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects us to contractual remedies as well as administrative, civil and criminal sanctions;
- the federal Health Insurance Portability and Accountability Act and its related regulations ("HIPAA") impose criminal liability for, among other actions, knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as directly applicable privacy and security standards and requirements;
- the civil monetary penalties statute imposes penalties against any person or entity who, 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 Sunshine Act, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics 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 Centers for Medicare and Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members;
- the FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations; and
- analogous or similar state, federal, and foreign laws, regulations, and requirements such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws, regulations, and requirements applicable to the award and performance of federal contracts and grants and state, federal and foreign laws that govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. For example, we must ensure that all applicable price concessions are included in prices calculated and reported to federal agencies. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. In addition, recent health care reform legislation has strengthened these laws. For example, recent case law from the U.S. Supreme Court interpreted the federal False Claims Act to include liability for implied false certifications, in certain instances. If our operations are found to be in violation of any of these laws or any other governmental regulations or requirements that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, restitution exclusion from government funded healthcare programs, such as Medicare and Medicaid, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts, contractual damages, the curtailment or restructuring of our operations and other consequences. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including

exclusions from government funded healthcare programs. Moreover, availability of any federal grant funds which we may receive or for which we may apply is subject to federal appropriations law. Grant funding may also be withdrawn or denied for other reasons.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We maintain a large quantity of sensitive information, including confidential business information and information associated with clinical trials. If our security measures are breached or fail and/or are bypassed because of third-party action, inadvertent disclosures through technological or human error (including employee error), malfeasance, hacking, ransomware, social engineering (including phishing schemes), computer viruses, malware, or otherwise, unauthorized acquisition of or access to sensitive information may occur. As a result, our reputation could be damaged, our business might suffer, information might be lost, and we could face damages for breach of contract, penalties for violation of applicable laws or regulations, costly litigation or government investigations, and significant costs for remediation and remediation efforts to prevent future occurrences. The harm associated with these negative results is likely to be exacerbated if the affected information is personally identifiable.

We may be subject to laws and regulations governing the privacy and security of personal information, including regulations pertaining to health information. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues that may affect our business. In the U.S., there are numerous federal and state privacy and data security laws and regulations that govern the collection, use, disclosure, and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions. For example, violations of HIPAA may result in civil fines of up to $57,051 per violation and a maximum civil penalty of $1,711,533in a calendar year for violations of the same requirement, as well as criminal penalties. Recently, the U.S. Department of Health and Human Services Office for Civil Rights, which enforces HIPAA, appears to have increased its enforcement activities. Additionally, state attorneys general may bring civil actions seeking either injunctions or damages in response to violations of HIPAA that threaten the privacy of state residents. Privacy and data security has become an area of emphasis for some state legislatures. For example, California recently enacted and amended the California Consumer Protection Act (“CCPA”), which could present implementation challenges and risk of enforcement. There may be additional amendments to the CCPA, and regulations promulgated pursuant to the CCPA may alter how the law applies; therefore, the extent to and manner in which the CCPA would apply to our operations is unclear. In addition to the risk associated with enforcement, compliance with these evolving laws, rules, and regulations regarding the privacy, security and protection of personal information could result in higher compliance and technology costs for us and present challenges for our business model.

There are numerous federal and state laws that generally require notice to affected individuals, regulators, and sometimes the media or credit reporting agencies in the event of a data breach impacting personal information. For example, at the federal level, HIPAA Breach Notification Rule mandates notification of breaches affecting protected health information to affected individuals and regulators under conditions set forth in the Rule. Covered Entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay, but not to exceed 60 days of discovery of the breach by a Covered Entity or its agents. Notification must also be made to Department of Health and Human Services and, in certain circumstances involving large breaches, to the media. Business Associates must report breaches of unsecured protected health information to Covered Entities within 60 days of discovery of the breach by the Business Associate or its agents. All states, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands have enacted data breach notification laws. These laws may impose notification obligations in addition to, or inconsistent with, the HIPAA Breach Notification Rule when a data breach implicates protected health information. In that event that we fail to detect or timely report a data breach we may be subject to significant penalties under federal and state law. In the event that we report a data breach as required by federal or state law, federal or state regulators may initiate an investigation into, and/or litigation related to, our privacy or data security practices. Private plaintiffs may also initiate costly class-action litigation following a data breach.

Numerous other countries have, or are developing, laws governing the collection, use, and transmission of personal information. These laws often impose significant compliance obligations. For example, since May 25, 2018, the General Data Protection Regulation (“GDPR”), has imposed more stringent obligations and restrictions on the ability to collect, analyze, and transfer personal information, including health data from clinical trials and substantial fines for breaches of the data protection rules in the European Economic Area.

To the extent that our activities are or become subject to the GDPR, we may need to devote significant effort and resources to complying with those legal regimes. Any failure to comply with the rules arising from the GDPR could lead to government enforcement actions and significant penalties against us and adversely impact our operating results. Under GDPR, for example, fines of €20.0 million or 4% of annual global turnover may be imposed for violations.

If we fail to attract and keep management and other key personnel, as well as our board members, we may be unable to develop our

product candidates or otherwise implement our business plan.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

If our employees, independent contractors, principal investigators, CROs, manufacturers, consultants or vendors commit fraud or other misconduct, including noncompliance with regulatory standards and requirements and insider trading, our business may experience serious adverse consequences.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, manufacturers, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, (2) manufacturing standards, (3) federal and state healthcare fraud and abuse laws and regulations or (4) laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. The improper use of information obtained in the course of clinical trials could also result in significant legal sanctions and serious harm to our reputation. In addition, federal procurement laws and regulations impose substantial penalties for misconduct in connection with government contracts and require contractors to maintain a code of business conduct and ethics. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity might not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including regulatory enforcement action, the imposition of significant criminal and civil fines, penalties, or other sanctions, including imprisonment, exclusion from participation in federal healthcare programs, and deferred prosecution and corporate integrity agreements.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. We have adopted an Insider Trading and Window Period Policy, but despite the adoption of such policy, we might not be able to prevent a director, an executive or an employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, administrative, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. The hiring, training and integration of new employees may be more difficult, costly and/or time-consuming for us because we have fewer resources than a larger organization. We

might not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

If, in the future, we are unable to grow our own sales, or establish marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we might not be successful in commercializing our product candidates.

We do not currently have a robust sales or marketing infrastructure. To develop our internal sales, distribution and marketing capabilities for new product candidates, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any new product candidates will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- inability of marketing personnel to develop effective marketing materials;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the clinical benefits of our products to achieve market acceptance;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the costs associated with training sales personnel on legal compliance matters and monitoring their actions;
- liability for sales personnel failing to comply with the applicable legal requirements; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Where and when appropriate, we may elect to utilize contract sales forces or strategic partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we might not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. Such third parties may also not comply with the applicable regulatory requirements, which could potentially expose us to regulatory and legal enforcement actions.

Risks Related to Our Dependence on Third Parties

We might not succeed in establishing and maintaining development collaborations, which could adversely affect our ability to develop and commercialize product candidates.

A part of our strategy is to enter into product development collaborations in the future, including collaborations with major biotechnology or pharmaceutical companies for the development or commercialization of our current and future product candidates. We also face significant competition in seeking appropriate development partners and the negotiation process is time-consuming and complex. We might not succeed in our efforts to establish development collaborations or other alternative arrangements for any of our existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and/or third parties might not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy.

Furthermore, any collaborations that we enter into might not be successful. The success of our development collaborations will depend heavily on the efforts and activities of our collaborators. Furthermore, any collaborations that we enter into might not be successful. The success of our development collaborations will depend heavily on the efforts and activities of our collaborators. Our relationship with any future collaborations may pose several risks, including the following:

- collaborators have significant discretion in determining the amount and timing of the efforts and resources that they will apply to these collaborations;
- collaborators might not perform their obligations as expected;
- the nonclinical studies and clinical trials conducted as part of these collaborations might not be successful;
- collaborators might not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on nonclinical study or clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay nonclinical studies and clinical trials, provide insufficient funding for nonclinical studies and clinical trials, stop a nonclinical study or clinical trial or abandon a product candidate, repeat or conduct new nonclinical studies or

clinical trials or require a new formulation of a product candidate for nonclinical studies or clinical trials;

- we might not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval might not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators might not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership or inventorship of intellectual property developed pursuant to our collaborations;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the terms of our collaboration agreement may restrict us from entering into certain relationships with other third parties, thereby limiting our options; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Even if we are successful in our efforts to establish development collaborations, the terms that we agree upon might not be favorable to us and we might not be able to maintain such development collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into development collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market. Additionally, collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

If we fail to establish and maintain additional development collaborations related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing, which might not be available on favorable terms, or at all;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates;
- we may have to expend unexpected efforts and funds if we are unable to obtain the results of third-party clinical trials; and
- the competitiveness of any product candidate that is commercialized could be reduced.

We rely on third parties to conduct, supervise and monitor our clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we might not obtain marketing approval for or commercialize our product candidates in a timely manner or at all.

We rely upon third-party CROs to monitor and manage data for our clinical programs. We rely on these parties for execution of our clinical trials and, while we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our clinical trial sites, and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we, any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the

FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, if at all. In addition, we are required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by principal investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests, or significant payments of other sorts. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP requirements. In addition, we must conduct our clinical trials with product produced under applicable GMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the marketing approval process.

Our CROs and clinical trial sites are not our employees, and, except for remedies available to us under our agreements with such CROs and clinical trial sites, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. These CROs and clinical trial sites may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If CROs or clinical trial sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we might not be able to obtain marketing approval for or successfully commercialize our product candidates or we may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

We use third parties to manufacture all of our product candidates. This may increase the risk that we will not have sufficient quantities of our product candidates to conduct our clinical trials or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates.

We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale.

We currently outsource all manufacturing of our product candidates to third parties typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our product candidates may delay the development or commercialization of our other product candidates.

In addition, we do not currently have any agreements with third-party manufacturers for the long-term commercial supply of our product candidates. We may be unable to enter agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as GMP requirements, for manufacture of both active drug substances and finished drug products for clinical supply and eventually for commercial supply, if we receive regulatory approval. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. Failure of our contract manufacturers to comply with the applicable regulatory requirements may also subject us to regulatory enforcement actions. In addition, other than through our contractual agreements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would

significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

Reliance on third-party manufacturers subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control;
- the possible misappropriation of our proprietary information, including trade secrets and know-how;
- the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities;
- the disruption and costs associated with changing suppliers, including additional regulatory filings;
- failure to satisfy their contractual duties or obligations;
- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and/or product quality issues related to manufacturing development and scale-up;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations, and standards, including cGMP and similar foreign standards;
- deficient or improper record-keeping;
- contractual restrictions on our ability to engage additional or alternative manufacturers;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- lack of access or licenses to proprietary manufacturing methods used by third-party manufacturers to make our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or regulatory sanctions related to the manufacture of our or other company's products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under GMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control, manufacturing, and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions.

We will continue to depend on Aytu to provide us with certain services to manage the operations of Millipred.

In connection with the sale of our Pediatric Portfolio to Aytu, we retained the rights to Millipred and entered into a Transition Services Agreement with Aytu. Pursuant to the Transition Services Agreement, Aytu is responsible for managing the commercial operations of Millipred, including providing accounting reporting services and managing the third-party logistics provider. We exercise no control over the activities of Aytu, other than the contractual rights we have pursuant to our Transition Services Agreement. If Aytu were to fail to fulfill all of its obligations under the Transition Service Agreement, the Company could suffer operational difficulties or significant losses. If Aytu ceases to provide services pursuant to the Transition Services Agreement, we might not be able to reestablish our commercial infrastructure to replace these services in a timely manner, if at all, which would materially adversely affect our financial position.

The revenue generated by sales of Millipred will be received by Aytu and subsequently transferred to us, and any delay or default in payment by Aytu to us of these revenues could adversely affect our cash flows, financial condition, and results of operations. Pursuant to the Transition Services Agreement, Aytu is responsible for managing the commercial operations of Millipred and is obligated to transfer the revenue generated by sales of Millipred to us on a timely basis. Adverse economic conditions or financial difficulties of Aytu could impair its ability to remit such payment or could cause Aytu to delay such payments. Furthermore, if Aytu were unable to meet its obligations, it could consider restructuring under the bankruptcy laws, which might make it difficult for us to collect all or a significant portion of the revenues generated by Millipred. Our inability to collect our revenues generated by Millipred from Aytu could adversely affect our cash flows, financial condition, and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain or maintain intellectual property rights, or if the scope of patent protection is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and we might not be able to compete effectively in our market.

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties' rights to patent portfolios.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators might not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we might not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaborators. Therefore, these patents and applications might not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications might not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio might not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, might not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

If we breach the license agreements related to our product candidates, we could lose the ability to develop and commercialize our product candidates.

Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to develop, manufacture, market and sell our product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the

proprietary rights of third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates or face other penalties under these agreements. We have entered into exclusive license agreements with Merck & Co., Inc. and its affiliates ("Merck") pursuant to which Merck has granted us rights to the compounds used in CERC-301 and the COMTi platform, including CERC-406. If we fail to comply with the obligations under these agreements, including payment terms, Merck and Lilly may have the right to terminate any of these agreements, in which event we might not be able to develop, market or sell the relevant product candidate. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which might not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs. Any of these occurrences may harm our business, financial condition and prospects significantly.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the United States Patent and Trademark Office, or USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, inter partes reviews or derivation proceedings before the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, timeconsuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe on our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors or collaborators might not prevent third parties

from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws might not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' or collaborators' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Third party preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also 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 material adverse effect on the price of our warrants or shares of our common stock.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In addition, we may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement to each party who in fact develops intellectual property that we regard as our own. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license might not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Though we seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, as well as by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we might not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our

competitive position.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

We might not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or collaborators might not be able to prevent third parties from practicing our and our licensors' or collaborators' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' or collaborators' technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we and our licensors or collaborators have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' patents or other intellectual property rights might not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators might not prevail in any lawsuits that we or our licensors or collaborators initiate and the damages or other remedies awarded, if any, might not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which

could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Risks Related to Our Financial Position and Capital Needs

We might require additional capital to continue to fund our operations and to finance the further advancement of our product candidates, which might not be available to us on acceptable terms, or at all. Failure to obtain any necessary capital will force us to delay, limit or terminate our product development efforts or cease our operations.

At September 30, 2019, we had $5.3 million in cash and cash equivalents and $17.3 million in current liabilities. Accordingly, we might not currently have sufficient funds to finance our continuing operations beyond the short term or to further advance any of our product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into clinical trials or obtain and advance additional product candidates. Circumstances may cause us to consume capital more rapidly than we currently anticipate. We may need to raise additional funds or otherwise obtain funding through collaborations if we choose to initiate additional clinical trials for product candidates.

Additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

- significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or cease operations altogether;
- seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves.

Our future funding requirements, both short and long term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical and clinical studies for our product candidates and future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than we currently expect to perform;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing; and
- the cost of developing our sales, marketing and distribution capabilities to accommodate any of our product candidates for which we receive marketing approval and that we determine to commercialize ourselves or in collaboration with our partners.

Our role as a guarantor of Certain Obligations assigned to Aytu exposes us to risk of loss or illiquidity

In connection with the sale of our pediatric portfolio to Aytu, Aytu assumed our financial obligations to Deerfield CSF, LLC ("Deerfield"), which include a $15 million loan due in January 2021 and royalty payments of 15% of net sales through February 2026 (the "Deerfield Obligation"). We also assigned payment obligations ("TRIS Obligations") to Aytu under a supply and distribution agreement with TRIS Pharma (the "Karbinal Agreement"). As a part of these assignments, we also became a guarantor to the Deerfield Obligation and the TRIS Obligation. If Aytu defaults under the terms of the agreement with Deerfield or TRIS, we could be liable as a

guarantor for unpaid amounts of the Deerfield Obligation and the TRIS Obligation. We currently do not have cash on hand to permit us to pay the entire amount that could become due under the Deerfield Obligation, and any amount we would be required to pay under the Karbinal Agreement would limit the amount of cash available for development of our clinical pipeline. If we were to become required to pay the Deerfield Obligation, such obligation could significantly impair our ability to continue as a going concern and our ability to continue operations. Even if we were to have sufficient liquidity to pay the TRIS Obligation, or obtain funding to meet the Deerfield Obligation, we might not be able to recover the cost of such a payment and may therefore be exposed to significant losses, which would materially and adversely affect our results of operations.

We have incurred significant net losses in most periods since our inception and we might continue to incur net losses in the future.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate an adequate effect or acceptable safety profile, gain marketing approval and become commercially viable. Historically, we financed our operations primarily through private placements of our common and convertible preferred stock and convertible debt. We incurred net loss of $4.0 million for the three months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of $115.9 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development program and from general and administrative costs associated with our operations.

We expect to continue to incur losses in the future and we might never achieve profitability on an annual basis. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our future profitability will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

The Company had a significant amount of gross net operating losses ("NOLs") for federal and state purposes that will begin to expire in 2031.

Unused losses for the current tax year and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused losses generated after December 31, 2017, under new tax legislation signed into law on December 22, 2017, known as the Tax Cuts and Jobs Act of 2017, or the Tax Act, will not expire and may be carried forward indefinitely but will be only deductible to the extent of 80% of current year taxable income in any given year. In addition, both our current and our future unused losses may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"). Sections 382 and 383 of the IRC subject the future utilization of NOLs and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes. In general, an "ownership change" is defined as a greater than 50% change (by value) in equity ownership over a three-year period).

U.S. federal income tax reform could adversely affect our business and financial condition.

The Tax Act significantly revised the IRC. The revised federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reduction of tax credits under the Orphan Drug Act). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and revenues and related disclosure of contingent assets and liabilities. For example, we estimate returns, wholesaler fees, prompt payment

discounts, chargebacks and government rebates. We also estimate clinical trial costs incurred using subject data and information from our CROs. If we underestimate or overestimate these expenses, adjustments to expenses may be necessary in future periods. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

Our operating results fluctuate from quarter to quarter and year-to-year, making future operating results difficult to predict.

Our quarterly and annual operating results historically have fluctuated and are likely to continue to fluctuate depending on several factors, many of which are beyond our control. Accordingly, our quarterly and annual results are difficult to predict prior to the end of the quarter or year, and we may be unable to confirm or adjust expectations with respect to our operating results for a particular period until that period has closed. Any failure to meet our quarterly or annual revenue or earnings targets could adversely impact the market price of our securities. Therefore, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We engage in in-licensing, acquisitions or other strategic transactions that could impact our liquidity, increase our expenses and divert a significant amount of our management's time.

Since inception, we have acquired or in-licensed product candidates, most recently product candidates we acquired from Ichorion. As a part of the Ichorion acquisition, we issued approximately 5,798,735 shares of our common stock, and payment of certain development milestones of up to an additional $15,000,000, payable either in shares of our common stock or in cash. From time to time we may consider additional in-licensing of products and other strategic transactions, such as acquisitions of companies, asset purchases and out-licensing of product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including strategic partnerships, collaborations, joint ventures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions or to fund the operations;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or other counterparties of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Risks Related to our Stock

If we are not able to comply with the applicable continued listing requirements or standards of The NASDAQ Capital Market, NASDAQ could delist our common stock.

Our common stock is currently listed on the NASDAQ Capital Market ("NASDAQ"). In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

In the event that our common stock is delisted from NASDAQ and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

Such a de-listing would also likely have a negative effect on the price of our common stock and would impair your ability to

sell or purchase our common stock when you wish to do so. In the event of a de-listing, we may take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

An active trading market for our securities might not be sustained.

Although our common shares are listed on the NASDAQ we cannot assure you that an active trading market for our common shares will continue to develop or be sustained, particularly because one investor, Armistice, now holds a significant amount of our outstanding stock. If an active market for our common shares is not sustained it may impair your ability to sell your warrants or shares of our common stock at the time you wish to sell them or at a price that you consider reasonable, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common shares and may impair our ability enter into strategic collaborations or acquire companies or products by using our by using our common shares as consideration.

The market price of our stock is volatile, and you could lose all or part of your investment.

The market price of our shares of our common stock has been highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. From our initial public offering in October 2015 through September 30, 2019, the per share trading price of our common stock has been as high as $7.65 and as low as $0.34. As a result of this volatility, you might not be able to sell your shares of our common stock at a favorable price. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors that could negatively affect or result in fluctuations in the market price of shares of our common stock include:

- our ability to generate significant product revenues, cash flows and a profit;
- the development status of our product candidates, and when any of our product candidates receive marketing approval;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our failure to commercialize our product candidates, if approved;
- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- the performance of third parties on whom we rely to manufacture our products and product candidates, supply API and conduct our clinical trials, including their ability to comply with regulatory requirements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- variations in the level of expenses related to our product candidates or preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- warrant or share price and volume fluctuations attributable to inconsistent trading volume levels of our warrants or shares;
- announcement or expectation of additional financing efforts;
- sales of our warrants or shares of our common stock by us, our insiders or our other security holders;
- changes in the structure of healthcare payment systems;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions in the pharmaceutical and biotechnology sectors;
- our execution of collaborative, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- additional state and federal healthcare reform measures that could put downward pricing pressure on our products;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC

and announcements relating to litigation or other disputes, strategic transactions or intellectual property impacting us or our business;
- announcement related to litigation;
- fluctuations in quarterly operating results, as well as differences between our actual financial and operating results and those expected by investors;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our warrants or shares of common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our warrants or shares of common stock;
- ratings downgrades by any securities analysts who follow our warrants or shares of common stock;
- the development and sustainability of an active trading market for our shares of common stock;
- future sales of our shares of common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of shares of common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a material adverse impact on the market price of our shares of common stock. When the market price of a stock is volatile, security holders often institute class action litigation against the company that issued the stock. If we become involved in this type of litigation, regardless of the outcome, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Future sales and issuances of shares of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to our existing stockholders.

We are authorized to grant equity awards, including stock grants and stock options, to our employees, directors and consultants. As of September 30, 2019, there were 1,963,869 shares available for future issuance under the Second Amended and Restated 2016 Equity Incentive Plan ("the 2016 Amended Plan"). During the term of the 2016 Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, by an amount equal to 4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. On January 1, 2019, on the terms of the 2016 Amended Plan an additional 1,632,167 shares were made available for issuance for a total of 2,234,824 shares available for issuance. In addition, as of September 30, 2019, there were 1,148,085 shares available for future issuance under the 2016 Employee Stock Purchase Plan (the "ESPP"). On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP shall automatically increase by a number equal to the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, and (ii) 500,000 shares of the Company's common stock, or (iii) a number of shares of the Company's common stock as determined by the Company's board of directors or compensation committee. Future issuances, as well as the possibility of future issuances, under our 2016 Plan or 2016 ESPP or other equity incentive plans could cause the market price of our common stock to decrease.

Armistice has significant influence over our company, and its interests may be different from or conflict with those of our other stockholders.

Armistice beneficially owns approximately 63% of our outstanding common stock. As a consequence, Armistice continues to be able to exert a significant degree of influence over our management, affairs, and matters requiring stockholder approval, including the election of directors, a merger, consolidation or sale of all or substantially all of our assets, and any other significant transaction. The interests of Armistice might not always coincide with our interests or the interests of our other stockholders. For instance, this concentration of ownership may have the effect of delaying or preventing a change in control of us otherwise favored by our other stockholders and

could depress our stock price.

Armistice makes investments in companies and may, from time to time, acquire and hold interests in businesses that compete directly or indirectly with us. Armistice may also pursue, for its own account, acquisition opportunities that may be complementary to our business, and as a result, those acquisition opportunities might not be available to us. The interests of the Armistice may supersede ours, causing Armistice or their affiliates to compete against us or to pursue opportunities instead of us, for which we have no recourse. Such actions on the part of Armistice and inaction on our part could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Armistice controls a seat on our board of directors. Since Armistice could invest in entities that directly or indirectly compete with us, when conflicts arise between the interests of Armistice and the interests of our stockholders, this director might not be disinterested.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. As additional shares of our common stock become available for resale in the public market pursuant to this offering, and otherwise, the supply of our common stock will increase, which could decrease its price. In addition, some or all of the shares of common stock may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for our shares of common stock. Therefore, we cannot predict the effect that future sales of our common stock would have on the market price of our common stock.

We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Consequently, currently stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our securities less attractive to investors and adversely affect the market price of our securities.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer.
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We may take advantage of these exemptions until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" upon the earliest of: (i) the first fiscal year following the fifth anniversary of our initial public offering; (ii) the first fiscal year after our annual gross revenues are $1.07 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than $1.07 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

We have determined to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company." For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act.

Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC which may make it more difficult for investors and securities analysts to evaluate our company. Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities, and the securities prices may be more volatile and may decline.

We may be subject to future litigation against us, including securities litigation, which could be costly and time-consuming to defend.

The market price of our securities may be volatile, and in the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. Any adverse determination in litigation could also subject us to significant liabilities.

We may also become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business such as claims brought by our clients in connection with commercial disputes, or employment claims made by our current or former associates. Litigation might result in substantial costs and may divert management's attention and resources, which might seriously harm our business, overall financial condition, and operating results. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby reducing our operating results and leading analysts or potential investors to reduce their expectations of our performance, which could reduce the trading price of our stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our securities prices and trading volume could decline.

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited, and might not sustain, research coverage by securities and industry analysts. If we do not sustain coverage of our company, the trading price for securities would be negatively impacted. If the securities and industry analysts are unable to predict accurately the demand and net of sales our products, that could result in our reported revenues and earnings being lower than the so-called "market consensus" of our projected revenues, which could negatively affect our stock price. Additionally, if the securities and industry analysts are unable to predict accurately the cost of advancing our pipeline, that could result in our reported costs being different than expectations, which could negatively affect our stock price. If we do obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, our securities prices would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our securities could decrease, which could cause our securities prices and trading volume to decline.

The requirements of being a public company may strain our resources and divert management's attention, and our minimal public company operating experience may impact our business and stock price.

As a public company, we incur significant legal, accounting and other expenses, and these expenses may increase even more after we are no longer an "emerging growth company." We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC, NASDAQ and other applicable securities rules and regulations imposed on public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Because these rules and regulations are often subject to varying interpretations, it is difficult to accurately estimate or predict

the amount or timing of these additional costs. Further, the lack of specificity of many of the rules and regulations may result in an application in practice that may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Our disclosure controls and procedures might not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act, Sarbanes-Oxley Act and NASDAQ rules and regulations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We cannot assure, in the future, a material weakness or significant deficiency will not exist or otherwise be discovered. If that were to happen, it could harm our operating results and cause stockholders to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our securities.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and second amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders

to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL") which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation might not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or second amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our securities.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
10.1#	Cerecor Inc. Second Amended and Restated 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 8, 2019).
10.2	Securities Purchase Agreement, dated September 4, 2019, between Cerecor Inc. and the investor(s) named therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 9, 2019).
10.3	Registration Rights Agreement, dated September 4, 2019, between Cerecor Inc. and the investor(s) named therein (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on September 9, 2019).
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

Management contract or compensatory agreement.

* This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

Cerecor Inc.

Date: November 14, 2019

/s/ Joseph M. Miller

Joseph M. Miller

Chief Financial Officer

(on behalf of the registrant and as the registrant's principal executive officer, principal financial officer and principal accounting officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph M. Miller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cerecor 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 14, 2019

/s/ Joseph M. Miller

Joseph M. Miller

Chief Financial Officer

(Registrant’s principal executive officer, principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
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 of Cerecor Inc. (the "Registrant") on Form 10-Q for the three and nine months ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph M. Miller, Chief Financial Officer of the Registrant, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 14, 2019

/s/ Joseph M. Miller

Joseph M. Miller

Chief Financial Officer

(Registrant's principal executive officer, principal financial officer and principal accounting officer)

The foregoing certifications are not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and are not to be incorporated by reference into any filing of Cerecor Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.