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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

OR

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

For the transition period from to

Commission file number: 001-37372

Collegium Pharmaceutical, Inc.

(Exact name of registrant as specified in its charter)

Virginia	**03-0416362**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
100 Technology Center Drive Stoughton, MA	**02072**
(Address of principal executive offices)	(Zip Code)

(781) 713-3699

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	COLL	The NASDAQ Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See 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 October 31, 2019, there were 33,527,077 shares of Common Stock, $0.001 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report on Form 10-Q that are not statements of historical or current facts, such as those under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our current expectations and projections relating to our financial condition, results of operations, plans, objectives, future performance and business. These statements may be preceded by, followed by or include the words "aim," "anticipate," "believe," "estimate," "expect," "forecast," "intend," "outlook," "plan," "potential," "project," "projection," "seek," "may," "could," "would," "should," "can," "can have," "likely," the negatives thereof and other words and terms of similar meaning.

Forward-looking statements are inherently subject to risks, uncertainties and assumptions; they are not guarantees of performance. You should not place undue reliance on these statements. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that our assumptions made in connection with the forward-looking statements are reasonable, we cannot assure you that the assumptions and expectations will prove to be correct.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- our ability to commercialize and grow sales of our products;
- our ability to effectively commercialize in-licensed products and manage our relationships with licensors.
- our ability to obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products and any product candidates, and our ability to service those markets;
- the success of competing products that are or become available;
- our ability to obtain and maintain reimbursement and third-party payor contracts for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- the rate and degree of market acceptance of our products;
- changing market conditions for our products;
- the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P. and Teva Pharmaceuticals USA, Inc.;
- the outcome of any governmental investigation related to the manufacture, marketing and sale of opioid medications;
- the performance of our third-party suppliers and manufacturers;
- our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and to manufacture adequate quantities of commercially salable inventory;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain funding for our operations and business development;
- regulatory developments in the United States;
- our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products and any product candidates;
- our ability to comply with stringent government regulations relating to the manufacturing and marketing of pharmaceutical products, including U.S. Drug Enforcement Agency ("DEA") compliance;
- the loss of key commercial, scientific or management personnel;
- our customer concentration, which may adversely affect our financial condition and results of operations;
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing; and
- the other risks, uncertainties and factors discussed under the heading "Risk Factors" in this Quarterly Report on Form 10-Q.

In light of these risks and uncertainties, expected results or other anticipated events or circumstances discussed in this Quarterly Report on Form 10-Q (including the exhibits hereto) might not occur. We undertake no obligation, and specifically decline any obligation, to publicly update or revise any forward-looking statements, even if experience or future developments make it clear that projected results expressed or implied in such statements will not be realized, except as may be required by law.

These and other risks are described under the heading "Risk Factors" in this Quarterly Report on Form 10-Q. Those factors and the other risk factors described therein are not necessarily all of the important factors that could cause actual results or developments to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. Consequently, there can be no assurance that actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	September 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 153,838	$ 146,633
Accounts receivable	84,380	77,946
Inventory	8,760	7,817
Prepaid expenses and other current assets	2,807	5,116
Total current assets	249,785	237,512
Property and equipment, net	11,579	9,274
Operating lease assets	9,219	—
Intangible assets, net	33,191	44,255
Other noncurrent assets	204	204
Total assets	$ 303,978	$ 291,245
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 11,981	$ 12,150
Accrued expenses	20,614	30,551
Accrued rebates, returns and discounts	165,263	144,783
Current portion of term loan payable	2,875	1,642
Current portion of operating lease liabilities	750	—
Total current liabilities	201,483	189,126
Term loan payable, net of current portion	8,625	9,858
Operating lease liabilities, net of current portion	9,612	—
Other noncurrent liabilities	—	676
Total liabilities	219,720	199,660
Commitments and contingencies (see Note 14)		
Shareholders’ equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at September 30, 2019 and December 31, 2018; issued and outstanding shares - none at September 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at September 30, 2019 and December 31, 2018; issued and outstanding shares - 33,523,858 at September 30, 2019 and 33,265,629 at December 31, 2018	34	33
Additional paid-in capital	441,922	428,729
Accumulated deficit	(357,698)	(337,177)
Total shareholders’ equity	84,258	91,585
Total liabilities and shareholders’ equity	$ 303,978	$ 291,245

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Product revenues, net	$ 72,942	$ 70,176	$ 222,498	$ 206,986
Costs and expenses				
Cost of product revenues	46,754	46,007	144,572	135,951
Research and development	2,491	1,907	7,942	6,412
Selling, general and administrative	30,072	33,448	91,359	96,309
Total costs and expenses	79,317	81,362	243,873	238,672
Loss from operations	(6,375)	(11,186)	(21,375)	(31,686)
Interest expense	(228)	(5,868)	(698)	(17,726)
Interest income	494	552	1,552	1,198
Net loss	$ (6,109)	$ (16,502)	$ (20,521)	$ (48,214)
Loss per share - basic and diluted	$ (0.18)	$ (0.50)	$ (0.62)	$ (1.46)
Weighted-average shares - basic and diluted	33,481,923	33,012,174	33,360,272	32,950,584

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine months ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (20,521)	$ (48,214)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Amortization expense for Nucynta asset acquisition	11,064	94,340
Depreciation and amortization, excluding Nucynta asset acquisition	535	732
Stock-based compensation expense	12,562	10,180
Non-cash lease expense	409	—
Non-cash interest expense for Nucynta asset acquisition	—	17,112
Changes in operating assets and liabilities:		
Accounts receivable	(6,434)	(56,564)
Inventory	(943)	(1,193)
Prepaid expenses and other assets	2,314	1,523
Accounts payable	(169)	5,995
Accrued expenses	(7,228)	11,181
Accrued rebates, returns and discounts	20,480	92,010
Operating lease assets and liabilities	734	—
Other long-term liabilities	(676)	—
Net cash provided by operating activities	12,127	127,102
Investing activities		
Upfront cash paid for Nucynta asset acquisition	—	(18,877)
Purchases of property and equipment	(5,549)	(3,704)
Net cash used in investing activities	(5,549)	(22,581)
Financing activities		
Cash paid for common stock offerings costs	—	(30)
Proceeds from issuances of common stock from employee stock purchase plans	817	1,117
Proceeds from term loan amendment, net of repayment of amended term loan	—	10,021
Repayment of asset acquisition obligations	—	(98,250)
Proceeds from the exercise of stock options	531	4,087
Payments made for employee restricted stock tax withholdings	(721)	(470)
Net cash provided by (used in) financing activities	627	(83,525)
Net increase in cash, cash equivalents and restricted cash	7,205	20,996
Cash, cash equivalents and restricted cash at beginning of period	146,633	118,794
Cash, cash equivalents and restricted cash at end of period	$ 153,838	$ 139,790
Supplemental disclosure of cash flow information		
Cash paid for offering costs	$ —	$ 30
Cash paid for interest	$ 543	$ 409
Supplemental disclosure of non-cash activities		
Receivable from stock option exercises in other current assets	$ 5	$ —
Acquisition of property and equipment in accounts payable and accrued expenses	$ 552	$ 1,456
Operating lease assets assumed	$ 9,957	$ —
Operating lease liabilities assumed	$ 10,691	$ —
Liabilities assumed from Nucynta asset acquisition included in accrued rebates, returns and discounts	$ —	$ 22,406
Liabilities assumed from Nucynta asset acquisition included as a reduction to accounts receivable	$ —	$ 254

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, in thousands, except share and per share amounts)

1. Nature of Business

Collegium Pharmaceutical, Inc. (the "Company") was incorporated in Delaware in April 2002 and then reincorporated in Virginia in July 2014. The Company has its principal operations in Stoughton, Massachusetts. The Company is a specialty pharmaceutical company committed to being the leader in responsible pain management. The Company's first product, Xtampza® ER ("Xtampza ER") is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the U.S. Food and Drug Administration ("FDA") approved the Company's new drug application ("NDA") for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, the Company announced the commercial launch of Xtampza ER.

The Company's product portfolio also includes Nucynta ER and Nucynta IR (the "Nucynta Products"). In December 2017, the Company entered into a Commercialization Agreement (the "Nucynta Commercialization Agreement") with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio"), pursuant to which the Company acquired the right to commercialize the Nucynta Products in the United States. The Company began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and began marketing the Nucynta Products in February 2018. Nucynta ER is an extended-release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

The Company's operations are subject to certain risks and uncertainties. The principal risks include inability to successfully commercialize products, changing market conditions for products and development of competing products, changing regulatory environment and reimbursement landscape, litigation related to opioid marketing and distribution practices, manufacture of adequate commercial inventory, inability to secure adequate supplies of active pharmaceutical ingredients, key personnel retention, protection of intellectual property, patent infringement litigation and the availability of additional capital financing on terms acceptable to the Company.

The Company believes that its cash and cash equivalents at September 30, 2019, together with expected cash inflows from the commercialization of its products, will enable the Company to fund its operating expenses, debt service and capital expenditure requirements under its current business plan for the foreseeable future.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of Collegium Pharmaceutical, Inc. (a Virginia corporation) as well as the accounts of Collegium Securities Corp. (a Massachusetts corporation), incorporated in December 2015, and Collegium NF, LLC (a Delaware limited liability company), organized in December 2017, both wholly owned subsidiaries requiring consolidation. The consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete consolidated financial statements.

In the opinion of the Company's management, the accompanying unaudited Condensed Consolidated Financial Statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to fairly present the financial position of the Company as of September 30, 2019, the results of operations for the three and nine months ended September 30, 2019 and 2018, and cash flows for the nine months ended September 30, 2019 and 2018. The

results of operations for the nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the full year.

When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of its products, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, impairment of intangible assets, and tax valuation reserves. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company's actual results may differ from these estimates under different assumptions or conditions. The consolidated interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the "Annual Report").

Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the Company's Annual Report. There have been no material changes in the Company's significant accounting policies, other than the adoption of accounting pronouncements below, as compared to the significant accounting policies described in the Annual Report.

Recently Adopted Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective dates.

The Company adopted Accounting Standard Updated ("ASU") 2016-02, *Leases (ASC Topic 842*), as amended, on January 1, 2019, using the modified retrospective approach by initially applying the new standard at the adoption date and recognizing a cumulative-effect adjustment. This adoption method did not impact prior period financial statements and related disclosures. In addition, the Company utilized the package of practical expedients permitted within the transition guidance, which, among other things, allowed the Company to carryforward the historical lease classification. Upon adoption, the new standard resulted in the Company recording material operating lease assets and corresponding operating lease liabilities on its balance sheet. As of September 30, 2019, the Company had operating lease assets of $9,219 and operating lease liabilities of $10,362 primarily related to the operating lease agreement for its corporate headquarters. In addition, the Company implemented new accounting policies, processes and controls to identify and account for leases going forward. For additional information related to lease arrangements and accounting policies, please see Note 11.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* which requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The new standard is effective for annual and interim periods beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the standard's effect on the Company's consolidated financial statements.

3. Revenue from Contracts with Customers

The Company's only source of revenue to date has been generated by sales of the Company's products, which are primarily sold to distributors ("customers"), which in turn sell the product to pharmacies for the treatment of patients.

Revenue Recognition

In accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"), the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Performance Obligations

The Company determined that performance obligations are satisfied and revenue is recognized when a customer takes control of the Company's product, which occurs at a point in time. This generally occurs upon delivery of the products to customers, at which point the Company recognizes revenue and records accounts receivable, which represents the Company's only contract asset. Payment is typically received 30 to 60 days after satisfaction of the Company's performance obligations and generally does not have an effect on contract asset and contract liability balances. Under the practical expedients permitted by the rules of the adoption, the Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less.

Transaction Price and Variable Consideration

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). The transaction price for product sales includes variable consideration related to chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns. The Company estimates the amount of variable consideration that should be included in the transaction price under the expected value method. These estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. These provisions reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in net sales only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. In general, performance obligations do not include any estimated amounts of variable consideration that are constrained. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following table summarizes activity in each of the Company's product revenue provision and allowance categories for the nine months ended September 30, 2019:

	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2018	$ 129,318	$ 15,465	$ 14,841
Provision related to current period sales	192,794	13,313	48,242
Changes in estimate related to prior period sales	(2,865)	—	—
Credits/payments made	(180,738)	(2,024)	(49,462)
Balance at September 30, 2019	$ 138,509	$ 26,754	$ 13,621

(1) Rebates and incentives includes managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances. Provisions for rebates and discounts are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Condensed Consolidated Balance Sheets.

(2) Provisions for product returns are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Condensed Consolidated Balance Sheets.

(3) Trade allowances and chargebacks include fees for distribution service fees, prompt pay discounts, and chargebacks. Trade allowances and chargebacks are deducted from gross revenue at the time revenues are recognized and are recorded as a reduction to accounts receivable in the Company's Condensed Consolidated Balance Sheets.

As of September 30, 2019, the Company did not have any transaction price allocated to remaining performance obligations and any costs to obtain contracts with customers, including pre-contract costs and set up costs, were immaterial.

Disaggregation of Revenue

Product revenues, net consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Xtampza ER	$ 26,480	$ 17,034	$ 77,632	$ 50,945
Nucynta Products	46,462	53,142	144,866	156,041
Total product revenues, net	$ 72,942	$ 70,176	$ 222,498	$ 206,986

4. License Agreements

The Company periodically enters into license agreements to develop and commercialize its products. The Company's license agreements as of September 30, 2019 are as follows:

Nucynta Commercialization Agreement

On January 9, 2018 (the "Nucynta Commercialization Closing Date"), the Company consummated the transactions contemplated by the Nucynta Commercialization Agreement, pursuant to which Assertio agreed to grant a sublicense of certain of its intellectual property related to the Nucynta Products for commercialization in the United States. The Company began recording revenues from sales of the Nucynta Products on the Nucynta Commercialization Closing Date and began commercial promotion of the Nucynta Products in February 2018. Pursuant to the Nucynta Commercialization Agreement, the Company paid a one-time, non-refundable license fee of $10,000 to Assertio on the Nucynta Commercialization Closing Date, $6,223 for transferred inventory and $1,987 as reimbursement for prepaid expenses. The Company also assumed the existing liabilities of the Nucynta Products, including $22,660 related to sales of Nucynta Products that occurred prior to the Nucynta Commercialization Closing Date. The Nucynta Commercialization Agreement initially required the Company to pay a guaranteed minimum royalty of $135,000 per year through December 2021, payable in quarterly payments of $33,750, prorated in 2018 for the Nucynta Commercialization Closing Date, as well as a variable royalty based on annual net sales over $233,000. Beginning January 2022 and for each year of the

Nucynta Commercialization Agreement term thereafter, the Company was required to pay a variable royalty on annual net sales of the Nucynta Products, but without a guaranteed minimum.

Effective August 2018, the Company entered into a Second Amendment to the Nucynta Commercialization Agreement to clarify the mechanism for transferring title of products to be sold by the Company pursuant to the agreement and various related matters. The Second Amendment did not have an impact on the Company's financial statements.

Effective November 2018, the Company entered into the Third Amendment to the Nucynta Commercialization Agreement to adjust the royalty structure and termination clauses. Pursuant to the amended Nucynta Commercialization Agreement, the $135,000 guaranteed minimum annual royalties are eliminated, and the Company is no longer required to secure its royalty payment obligations with a standby letter of credit. Beginning on January 1, 2019 and thereafter, the Company will be conditionally obligated to make royalty payments to Assertio conditional upon net sales and based on the following royalty structure for the period between January 1, 2019 and December 31, 2021:

(i) 65% of annual net sales of the Nucynta Products up to $180,000, plus
(ii) 14% of annual net sales of the Nucynta Products between $180,000 and $210,000, plus
(iii) 58% of annual net sales of the Nucynta Products between $210,000 and $233,000, plus
(iv) 20% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(v) 15% of annual net sales of the Nucynta Products in excess of $258,000.

The Amendment does not modify the royalties payable on sales of the Nucynta Products on and after January 1, 2022, which will remain as contemplated by the Nucynta Commercialization Agreement as in effect on January 9, 2018, based on the following royalty structure:

(i) 58% of annual net sales of the Nucynta Products up to $233,000, plus
(ii) 25% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(iii) 17.5% of annual net sales of the Nucynta Products in excess of $258,000.

In addition, prior to January 1, 2022, if the annual net sales of the Nucynta Products are in the range of $180,000 to $243,000, the Company will be required to pay a supplemental royalty to Assertio, for ultimate payment to Grünenthal GmbH, not to exceed a maximum of 4.9% of net sales of the Nucynta Products. If annual net sales of Products are less than $180,000 in any 12-month period through January 1, 2022, or if they are less than $170,000 in any 12-month period commencing on January 1, 2022, then Assertio will have the right to terminate the Nucynta Commercialization Agreement without penalty. The Amendment further provides that the Company does not have a right to terminate the Nucynta Commercialization Agreement prior to December 31, 2021. The Company will be required to pay a $5,000 termination fee to Assertio in connection with any termination by the Company with an effective date between December 31, 2021 and December 31, 2022. In connection with execution of the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company (the "Warrant") at an exercise price of $19.20 per share. The Warrant will expire in November 2022 and includes customary adjustments for changes in the Company's capitalization.

The assets acquired, liabilities assumed, and equity interests issued by the Company in connection with the Nucynta Commercialization Agreement are further described in Note 8.

5. Loss per Common Share

The following table presents the computations of basic and dilutive net loss per share:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net loss	$ (6,109)	$ (16,502)	$ (20,521)	$ (48,214)
Weighted-average number of common shares used in net loss per share - basic and diluted	33,481,923	33,012,174	33,360,272	32,950,584
Loss per share - basic and diluted	$ (0.18)	$ (0.50)	$ (0.62)	$ (1.46)

The following potentially dilutive securities, which represent all outstanding potentially dilutive securities, were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in common stock equivalent shares):

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Outstanding stock options	4,140,629	3,693,400	4,140,629	3,693,400
Warrants	1,041,667	—	1,041,667	—
Unvested restricted stock (1)	—	7,545	—	7,545
Restricted stock units	868,075	532,787	868,075	532,787
Performance share units	99,400	—	99,400	

(1) - Includes shares of unvested restricted stock remaining from the early exercise of stock options.

6. Fair Value of Financial Instruments

Disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for financial instruments with respect to which it is practicable to estimate that value. Fair value measurements and disclosures describe the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, as follows:

Level 1 inputs: Quoted prices (unadjusted) in active markets for identical assets or liabilities
Level 2 inputs: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
Level 3 inputs: Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability

Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the nine months ended September 30, 2019 and 2018.

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at September 30, 2019 and December 31, 2018:

September 30, 2019	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market funds, included in cash equivalents	$ 94,461	$ 94,461	$ —	$ —
December 31, 2018				
Money market funds, included in cash equivalents	$ 92,914	$ 92,914	$ —	$ —

As of September 30, 2019, the carrying amounts of the Company's other assets and liabilities approximated their estimated fair values.

7. Inventory

Inventory consisted of the following:

	As of September 30, 2019	As of December 31, 2018
Raw materials	$ 1,531	$ 496
Work in process	889	671
Finished goods	6,340	6,650
Total inventory	$ 8,760	$ 7,817

The aggregate charges related to excess inventory for the three and nine months ended September 30, 2019 and 2018 were immaterial. These expenses were recorded as a component of cost of product revenues.

8. Intangible Assets

As of September 30, 2019 and December 31, 2018, the Company's only intangible asset is related to the Nucynta Intangible Asset.

Nucynta Intangible Asset

The Company determined the Nucynta Commercialization Agreement should be accounted for as an asset acquisition in accordance with ASC Topic 805-50 as substantially all of the fair value of the gross assets acquired is concentrated in the sublicense of the Nucynta Products, which is a single identifiable asset. The Company concluded that the fair value estimates of the assets surrendered, liabilities incurred, and equity interests issued were more clearly evident than the fair value of the assets received, and therefore followed a cost accumulation model to determine the consideration transferred in the asset acquisition.

The table below represents the costs accumulated to acquire the sublicense of the Nucynta Products based on the terms of the Nucynta Commercialization Agreement, as amended:

Acquisition consideration:	
Upfront cash paid	$ 18,877
Minimum royalty payment obligation (1)	112,719
Rebates, incentives, trade allowances and chargebacks assumed	22,660
Warrant issued	8,043
Total acquisition consideration:	$ 162,299

(1) Represents $132,000 of minimum royalty payments owed under the Nucynta Commercialization Agreement discounted for present value adjustments of $19,281.

The Company then allocated the consideration transferred to the individual assets acquired on a relative fair value basis as summarized in the table below:

Assets acquired:	
Nucynta Intangible Asset	$ 154,089
Inventory	6,223
Prepaid expenses	1,987
Total consideration allocated to assets acquired:	$ 162,299

Under the original terms of the Nucynta Commercialization Agreement, the Company was obligated to make guaranteed annual minimum royalty payments of $537,000 to Assertio, which consisted of scheduled payments of $132,000 in 2018, $135,000 in 2019, $135,000 in 2020, and $135,000 in 2021. Due to the nature of the guaranteed minimum royalty payment obligation and the fact that it was required to be settled in cash, the Company determined that the future minimum royalty payments represented a liability that should be recorded at its fair value as of the Nucynta Commercialization Closing Date. The Company calculated the fair value of the future minimum royalty payments to be

$482,300 using a discount rate of 5.7%. The discount rate was determined based on a review of observable market data relating to similar liabilities. The fair value of the future minimum royalty payments was recorded as a component of the intangible asset. The Company determined the $54,700 discount should be recognized as interest expense in the Statement of Operations using the effective interest method and over the repayment period from January 9, 2018 through December 2021. Prior to the Third Amendment to the Nucynta Commercialization Agreement in November 2018, the Company recognized interest expense of $19,281 relating to the minimum royalty payments and amortization expense of $107,662 related to the intangible asset.

Effective November 8, 2018 (the "Third Amendment Date"), the Company entered into the Third Amendment to the Nucynta Commercialization Agreement, which eliminated the guaranteed minimum royalty payment obligations for years 2019, 2020 and 2021. As a result, the Company remeasured the remaining contractual obligation as of the Third Amendment Date and recorded a reduction of the acquired intangible asset and obligation.

The gross carrying amount and accumulated amortization of the Nucynta Intangible Asset were as follows:

	As of September 30, 2019	As of December 31, 2018
Gross carrying amount	$ 154,089	$ 154,089
Accumulated amortization	(120,898)	(109,834)
Intangible assets, net	$ 33,191	$ 44,255

Warrant

In November 2018, in connection with the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company at an exercise price of $19.20 per share. The terms of the warrant are fixed, with the exception of customary adjustments for changes in the Company's capitalization. The warrant may only be settled with the issuance of shares of common stock upon exercise and will expire in November 2022. The Company has recorded the relative fair value of the warrant as a component of equity interest issued by the Company as consideration transferred in the cost accumulation model for the asset acquisition. The Company estimated the fair value of the warrant on the date of issuance to be approximately $8,043 using the Black-Scholes option-pricing model. The Company concluded that the warrant met the definition of an equity instrument and was recorded as a component of additional paid-in capital in the Company's Condensed Consolidated Balance Sheet as of the issuance date.

Amortization

The Company has been amortizing the Nucynta Intangible Asset over its useful life, which is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of the Company. The Company determined that the useful life for the intangible asset was approximately 4.0 years from the Nucynta Commercialization Closing Date. The Company recognizes amortization expense as a component of cost of product revenues in the Statement of Operations on a straight-line basis over its useful life as it approximates the period of economic benefits expected to be realized from future cash inflows from sales of the Nucynta Products. Prior to the Third Amendment to the Nucynta Commercialization Agreement, the Company had recognized $107,662 of amortization expense. As the accumulated cost basis of the intangible asset was reduced with the Third Amendment to the Nucynta Commercialization Agreement, the Company will continue to prospectively amortize the residual net intangible asset on a straight-line basis over the remaining useful life.

For the three months ended September 30, 2019 and 2018, the Company recognized amortization expenses of $3,688 and $32,407 respectively. For the nine months ended September 30, 2019 and 2018, the Company recognized amortization expenses of $11,064 and $94,340 respectively. As of September 30, 2019, the remaining amortization period is approximately 2.3 years and the remaining estimated amortization for 2019, 2020 and 2021 is expected to be $3,688, $14,752, and $14,751, respectively.

9. Accrued Expenses

Accrued expenses consisted of the following:

	As of September 30, 2019	As of December 31, 2018
Accrued royalties	$ 9,464	$ 15,138
Accrued bonuses	3,289	4,286
Accrued payroll and related benefits	1,949	1,544
Accrued incentive compensation	1,354	1,806
Accrued audit and legal	716	480
Accrued sales and marketing	651	2,193
Accrued interest	429	274
Accrued inventory	222	3,745
Accrued other operating costs	2,540	1,085
Total accrued expenses	$ 20,614	$ 30,551

10. Term Loan Payable

On August 28, 2012, the Company entered into a loan agreement with Silicon Valley Bank ("SVB") to borrow up to a maximum amount of $1,000. The loan agreement was subsequently amended in 2014 and 2015 to provide for additional borrowings (as amended, the "Existing Term Loan").

In January 2018, in connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement with Assertio, the Company entered into a Consent and Amendment to Loan and Security Agreement (the "Consent and Amendment") with SVB to amend the Existing Term Loan. The Consent and Amendment provided the Company with a new term loan facility in an original principal amount of $11,500, which replaced the Existing Term Loan and the proceeds of which were used by the Company to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay the balance of the Existing Term Loan. The Existing Term Loan also provided SVB's consent with respect to the Nucynta Commercialization Agreement.

The Consent and Amendment bears interest at a rate per annum of 0.75% above the prime rate (as defined in the Consent and Amendment). The Company will repay the Consent and Amendment in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in January 2020. All outstanding principal and accrued and unpaid interest under the Consent and Amendment, and all other outstanding obligations with respect to the Consent and Amendment, are due and payable in full in December 2022. The Company may prepay the Consent and Amendment, in full but not in part, with a prepayment fee of (i) 3.0% of the outstanding principal balance prior to the first anniversary of the Consent and Amendment, (ii) 2.0% of the outstanding principal balance following the first anniversary of the Consent and Amendment and prior to the second anniversary of the Consent and Amendment and (iii) 1.0% of the outstanding principal balance following the second anniversary of the Consent and Amendment, plus, in each case, a final payment fee of $719.

In November 2018, the Company entered into an amended and restated Loan and Security Agreement ("New Term Loan") with SVB, that supersedes the Company's original loan agreement and subsequent amendments with SVB. The New Term Loan amended and restated the loan documentation between the Company and SVB and modified the minimum liquidity ratio to be at least 1.5 to 1.0 (as defined in the New Term Loan), along with other non-material changes. The New Term Loan did not modify the Company's borrowings, interest rates, or repayment terms. Any amounts outstanding during the continuance of any event of default under the Consent and Amendment will bear additional interest at the per annum rate of 5.0%.

As of September 30, 2019, scheduled principal repayments under the Company's term loan are as follows:

2020		3,833
2021		3,833
2022		3,834
Balance	$	11,500

11. Leases

In accordance with ASC Topic 842, *Lease Accounting,* the Company records lease assets and liabilities for lease arrangements exceeding a 12-month initial term. For operating leases, the Company records a beginning lease liability equal to the present value of minimum lease payments to be made over the lease term discounted using the Company's incremental borrowing rate and a corresponding lease asset adjusted for incentives received and indirect costs. After lease commencement, the Company remeasures the operating liability at the present value of the remaining lease payments discounted using the original incremental borrowing rate and corresponding lease asset adjusted for incentives received, indirect costs and uneven lease payments. The Company records operating lease rent expense in the Statements of Operations on a straight-line basis over the lease term. Leases with an initial term of 12 months or less, or short-term leases, are not recorded on the balance sheet. Short-term lease expense is recognized on a straight-line basis over the lease term. The Company does not have any financing lease arrangements.

As of September 30, 2019, the Company had operating lease assets of $9,219 and operating lease liabilities of $10,362 primarily related to operating lease agreements for its corporate headquarters.

Adoption of ASC Topic 842, Lease Accounting

The Company adopted ASC Topic 842, as amended, on January 1, 2019, which supersedes the lease accounting requirements in ASC Topic 840, *Leases* ("legacy GAAP") and most industry-specific guidance. The Company adopted ASC Topic 842 using the modified retrospective method. Under this method, the Company applied the new standard at the adoption date and recognized a cumulative-effect adjustment. Therefore, prior period financials were not retrospectively adjusted, and comparative period disclosures will continue to be presented in accordance with legacy GAAP. In addition, the Company utilized the package of practical expedients permitted within the transition guidance, which, among other things, allowed the Company to carryforward the historical lease classification.

Adoption of the new standard resulted in the Company initially recording operating lease assets of $9,957 and corresponding operating lease liabilities of $10,691 on its Condensed Consolidated Balance Sheet, primarily related to the operating lease agreement for its corporate headquarters. In addition, the Company identified an embedded operating lease arrangement that was accounted as a service contract in prior years, as accounting for operating leases and service contracts was similar under legacy GAAP and the accounting for the embedded lease did not result in a material impact to the financial statements. The Company has also implemented new accounting policies, processes and controls to identify and account for leases, including embedded leases, going forward.

Operating Lease Arrangements

In March 2018, the Company entered into an operating lease for its new corporate headquarters (the "Stoughton Lease") pursuant to which the Company leases approximately 50,678 of rentable square feet of space, in Stoughton, Massachusetts. The Stoughton Lease commenced in August 2018 when the Company took possession of the space. After the initial four-month free rent period following possession of the space, the operating lease will continue for a term of 10 years. The Company has the right to extend the term of the Stoughton Lease for two additional five-year terms, provided that written notice is provided to the landlord no later than 12 months prior to the expiration of the then current Stoughton Lease term. The Company does not believe the exercise of the extension to be reasonably certain as of the balance sheet date and therefore did not include the extension as part of its recognized lease asset and lease liability. The annual base rent is $1,214, or $23.95 per rentable square foot, and will increase annually by 2.5% to 3.1% over the subsequent years.

The Company continues to lease 9,660 square feet of office and research space at its former corporate headquarters located in Canton, Massachusetts (the "Canton Lease"). The Canton Lease terminates in August 2020 and may be

extended for an additional five years at the Company's election. In September 2019, the Company determined it had ceased use of the space and impaired the operating lease asset and adjusted the operating lease liability to the fair value of cost that will continue to be incurred under the Canton Lease. The impact to the consolidated financial statements was immaterial and the impairment expense was recognized as a component of selling, general and administrative expense in the Statement of Operations.

In January 2016, the Company entered a non-cancellable contract with the contract manufacturing organization ("CMO") of Xtampza ER. The initial contract term continues through December 2020 and automatically renews for successive two-year terms unless either party gives written notice of termination two-years in advance. Xtampza ER production is currently conducted in an area of the manufacturing plant that is shared with other clients. Pursuant to the terms of the agreement, since 2016 the CMO has reserved 3,267 square feet of existing manufacturing space for a dedicated production suite for Xtampza ER, which is currently under construction. Upon adoption of ASC Topic 842, the Company determined that this arrangement has an embedded operating lease arrangement as the Company can direct the use of the dedicated space and obtain substantially all the economic benefits. The Company expects the lease term to continue at least through December 2026 and separated the agreement's lease and non-lease components in determining the operating lease assets and liabilities. The Company determined its best estimate of stand-alone prices for each of the lease and nonlease components by considering observable information including gross margins expected to be recovered from the Company's service provider and terms of similar lease contracts.

Short-Term Lease Arrangements

In December 2018, the Company began entering into 12-month, non-cancelable vehicle leases for its field-based employees. Each vehicle lease is executed separately and will expire at varying times with automatic renewal options that are cancelable at any time. The rent expense for these leases will therefore be recognized on a straight-line basis over the lease term.

Variable lease payments associated with non-lease components of these arrangements were immaterial and expensed as incurred.

	Three months ended September 30, 2019	Nine months ended September 30, 2019
Lease Cost		
Operating lease cost	$ 452	$ 1,157
Short-term lease cost	219	531
Total lease cost	$ 671	$ 1,688

Lease Term and Discount Rate:	As of September 30, 2019
Weighted-average remaining lease term — operating leases (years)	9.7
Weighted-average discount rate — operating leases	6.1%

Other Information:	Nine months ended September 30, 2019
Cash paid for amounts included in the measurement of operating leases liabilities	$ 748
Leased assets obtained in exchange for new operating lease liabilities	—

Under ASC Topic 842, the Company's aggregate future minimum lease payments for its operating leases, including embedded operating lease arrangements, as of September 30, 2019, are as follows:

2019	$	340
2020		1,334
2021		1,290
2022		1,328
2023		1,366
After 2023		8,263
Total minimum lease payments	$	13,921
Less: Present value discount		3,559
Present value of lease liabilities	$	10,362

Under legacy GAAP, the Company's aggregate future minimum lease payments for its operating leases as of December 31, 2018 were as follows:

2019	$	1,032
2020		1,305
2021		1,261
2022		1,299
2023		1,337
After 2023		8,423
Total minimum lease payments	$	14,657

12. Equity

The changes in shareholder's equity for the three and nine months ended September 30, 2019 as follows:

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount			
Balance, December 31, 2018	33,265,629	$ 33	$ 428,729	$ (337,177)	$ 91,585
Exercise of common stock options	18,693	—	246	—	246
Issuance for employee stock purchase plan	32,826	—	444	—	444
Vesting of restricted stock units ("RSUs")	101,483	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(33,503)	—	(488)	—	(488)
Stock-based compensation	—	—	4,263	—	4,263
Net loss	—	—	—	(9,700)	(9,700)
Balance, March 31, 2019	33,385,128	$ 33	$ 433,194	$ (346,877)	$ 86,350
Exercise of common stock options	8,218	—	58	—	58
Vesting of RSUs	26,304	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(3,097)	—	(35)	—	(35)
Stock-based compensation	—	—	4,162	—	4,162
Net loss	—	—	—	(4,712)	(4,712)
Balance, June 30, 2019	33,416,553	$ 33	$ 437,379	$ (351,589)	$ 85,823
Exercise of common stock options	25,271	—	232	—	232
Issuance for employee stock purchase plan	41,316	1	372	—	373
Vesting of RSUs	57,818	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(17,100)	—	(198)	—	(198)
Stock-based compensation	—	—	4,137	—	4,137
Net loss	—	—	—	(6,109)	(6,109)
Balance, September 30, 2019	33,523,858	$ 34	$ 441,922	$ (357,698)	$ 84,258

The changes in shareholder's equity for the three and nine months ended September 30, 2018 were as follows:

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount			
Balance, December 31, 2017	32,770,678	$ 33	$ 402,096	$ (298,049)	$ 104,080
Exercise of common stock options	183,987	—	2,373	—	2,373
Issuance for employee stock purchase plan	50,151	—	510	—	510
Vesting of RSUs	32,573	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(9,810)	—	(216)	—	(216)
Stock-based compensation	—	—	2,728	—	2,728
Net loss	—	—	—	(18,652)	(18,652)
Balance, March 31, 2018	33,027,579	$ 33	$ 407,491	$ (316,701)	$ 90,823
Exercise of common stock options	137,419	—	1,532	—	1,532
Vesting of RSUs	20,887	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(6,205)	—	(140)	—	(140)
Stock-based compensation	—	—	3,526	—	3,526
Net loss	—	—	—	(13,060)	(13,060)
Balance, June 30, 2018	33,179,680	$ 33	$ 412,409	$ (329,761)	$ 82,681
Exercise of common stock options	13,619	—	182	—	182
Issuance for employee stock purchase plan	36,778	—	607	—	607
Vesting of RSUs	21,125	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(6,176)	—	(114)	—	(114)
Stock-based compensation	—	—	3,926	—	3,926
Net loss	—	—	—	(16,502)	(16,502)
Balance, September 30, 2018	33,245,026	$ 33	$ 417,010	$ (346,263)	$ 70,780

Controlled Equity Offering Sales Agreement

In March 2017, the Company entered into a Controlled Equity Offering Sales Agreement (the "ATM Sales Agreement"), with Cantor Fitzgerald & Co., as sales agent ("Cantor Fitzgerald"), pursuant to which the Company may issue and sell, from time to time, through Cantor Fitzgerald, shares of the Company's common stock, up to an aggregate offering price of $60,000 (the "ATM Shares"). The ATM Sales Agreement expired in October 2019. No ATM shares were sold in 2019 or in the year ended December 31, 2018.

Warrants

As of September 30, 2019, the warrant issued to Assertio in November 2018 was the Company's only outstanding warrant, which is described in greater detail in Note 8.

13. Stock-based Compensation

A summary of the Company's stock-based compensation expense included in the Condensed Consolidated Statements of Operations are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Research and development expenses	$ 525	$ 388	$ 1,606	$ 1,091
Selling, general and administrative expenses	3,612	3,538	10,956	9,089
Total stock-based compensation expense	$ 4,137	$ 3,926	$ 12,562	$ 10,180

At September 30, 2019, there was approximately $31,051 of unrecognized compensation expense related to unvested options, restricted stock units and performance stock units, which is expected to be recognized as expense over a weighted average period of approximately 2.6 years.

Restricted Stock Units, Performance Share Units, and Stock Options

In May 2015, the Company adopted the Amended and Restated 2014 Stock Incentive Plan (the "Plan"), under which an aggregate of 2,700,000 shares of common stock were authorized for issuance to employees, officers, directors, consultants and advisors of the Company, plus an annual increase on the first day of each fiscal year until the expiration of the Plan equal to 4% of the total number of outstanding shares of common stock on December 31st of the immediately preceding calendar year (or a lower amount as otherwise determined by the board of directors prior to January 1st). As of September 30, 2019, there were 1,251,722 shares of common stock available for issuance pursuant to the Plan. The Plan provides for granting of both Internal Revenue Service qualified incentive stock options and non-qualified options, restricted stock awards, restricted stock units and performance stock units. The Company's qualified incentive stock options and non-qualified options, restricted stock awards, restricted stock units generally vest ratably over a four-year period of service. The stock options generally have a ten-year contractual life and, upon termination, vested options are generally exercisable between one and three months following the termination date, while unvested options are forfeited immediately upon termination.

In January 2019, the Company granted performance share units ("PSUs") to certain members of the Company's senior management team. The PSUs will vest following a three-year performance period, subject to the satisfaction of annual and cumulative performance criteria and the executive's continued employment through the performance period. No shares will be issued if the minimum applicable performance metric is not achieved. The Company recognizes compensation expense ratably over the required service period based on its estimate of the number of shares that will vest based upon the probability of achieving performance metrics. If there is a change in the estimate of the number of shares that are likely to vest, the Company will cumulatively adjust compensation expense in the period that the change in estimate is made. Achievement of the annual and cumulative performance criteria for PSU grants will be determined by the compensation committee. For PSUs granted in 2019, the performance criteria relate to Xtampza ER 2019, 2020, 2021 and three-year cumulative revenue goals. The expense for the three and nine months ended September 30, 2019 was $21 and $63, respectively.

A summary of the Company's performance share units activity for the nine months ended September 30, 2019 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2018	—	$ —
Granted	99,400	15.90
Outstanding at September 30, 2019	99,400	$ 15.90

A summary of the Company's restricted stock units activity for the nine months ended September 30, 2019 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2018	514,603	$ 20.67
Granted	634,708	15.48
Vested	(185,605)	21.44
Forfeited	(95,631)	18.19
Outstanding at September 30, 2019	868,075	$ 16.98

A summary of the Company's stock option activity for the nine months ended September 30, 2019 and related information is as follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	3,585,856	$ 16.20	8.0	$ 11,170
Granted	1,045,658	15.08		
Exercised	(52,182)	10.27		
Cancelled	(438,703)	17.96		
Outstanding at September 30, 2019	4,140,629	$ 15.81	7.7	$ 3,611
Exercisable at September 30, 2019	2,147,473	$ 14.61	6.7	$ 3,108

The fair value of each stock option is estimated on the grant date using the Black-Scholes option-pricing model using the following assumptions:

	Nine months ended September 30,	
	2019	2018
Risk-free interest rate	2.4 %	2.6 %
Volatility	63.2 %	65.0 %
Expected term (years)	6.06	6.11
Expected dividend yield	— %	— %

Employee Stock Purchase Plan

The Company's 2015 Employee Stock Purchase Plan allows employees to purchase shares of the Company's common stock. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on (1) the first day of the purchase period or (2) the last day of the purchase period. During the three months ended September 30, 2019, 41,316 shares of common stock were purchased for total proceeds of $373. During the nine months ended September 30, 2019, 74,142 shares of common stock were purchased for total proceeds of $817. The expense for the three months ended September 30, 2019 and 2018 was $120 and $156, respectively. The expense for the nine months ended September 30, 2019 and 2018 was $293 and $398, respectively.

14. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may face legal claims or actions in the normal course of business. Except as disclosed below, the Company is not currently a party to any litigation and, accordingly, does not have any amounts recorded for any litigation related matters.

Xtampza ER Litigation

The Company filed the NDA for Xtampza ER as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), in this case OxyContin OP. The 505(b)(2) process requires that the Company certifies to the FDA and notify Purdue Pharma, L.P ("Purdue"), as the holder of the NDA and any other Orange Book-listed patent owners, that the Company does not infringe any of the patents listed for OxyContin OP in the Orange Book, or that the patents are invalid. The Company made such certification and provided such notice on February 11, 2015 and such certification documented why Xtampza ER does not infringe any of the 11 Orange Book listed patents for OxyContin OP, five of which have been invalidated in court proceedings. Under the Hatch-Waxman Act of 1984, Purdue had the option to sue the Company for infringement and receive a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

Purdue exercised its option and elected to sue the Company for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (Patent Nos. 7,674,799, 7,674,800, and 7,683,072) and a non-Orange Book-listed patent (Patent No. 8,652,497), and accordingly, received a 30-month stay of FDA approval.

The Delaware court transferred the case to the District of Massachusetts. After the Company filed a partial motion for judgment on the pleadings relating to the Orange Book-listed patents, the District Court of Massachusetts ordered judgment in the Company's favor on those three patents, and dismissed the claims asserting infringement of those patents with prejudice. Upon dismissal of those claims, the 30-month stay of FDA approval was lifted. As a result, the Company was able to obtain final approval for Xtampza ER and launch the product commercially.

In November 2015, Purdue filed a follow-on suit asserting infringement of another patent, Patent No. 9,073,933, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. In June 2016, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,155,717. In April 2017, Purdue filed another follow-on suit asserting infringement of another patent, Patent No. 9,522,919, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. Then, in September 2017, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,693,961.

On March 13, 2018, the Company filed a Petition for Post-Grant Review ("PGR") of the ′961 patent with the Patent Trial and Appeal Board ("PTAB"). The PGR argues that the ′961 patent is invalid for lack of a written description, for lack of enablement, for indefiniteness, and as being anticipated by prior art. Purdue filed its Patent Owner Preliminary Response on July 10, 2018. The PTAB entered an order to institute post-grant review of all claims of the ’961 patent on October 4, 2018, upon a finding that it is more likely than not that the claims of the ′961 patent are unpatentable. Purdue filed its Patent Owner Response on January 30, 2019. The Company filed its reply on April 12, 2019, and Purdue filed a sur-reply on May 10, 2019. The PTAB held oral argument on the proceedings on July 10, 2019 and was scheduled to issue a decision on the patentability of the ′961 patent by no later than October 4, 2019. On September 15, 2019, Purdue commenced a voluntary case under chapter 11 of title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York. On September 24, 2019, Purdue gave the PTAB notice of its bankruptcy filing and sought the imposition of an automatic stay of the PGR proceedings. On October 2, 2019, the PTAB extended the one-year period for issuing its decision by up to six months.

In October 2017, and in response to the filing of the Company's Supplemental NDA ("sNDA") seeking to update the drug abuse and dependence section of the Xtampza ER label, Purdue filed another suit asserting infringement of the ′933 and ′919 patent. The Company filed a motion to dismiss that action, and the Court granted its motion on January 16, 2018.

The current suits have been consolidated by the District of Massachusetts, where Purdue asserted infringement of five patents: the ′497 patent, the ′933 patent, the ′717 patent, the ′919 patent, and the ′961 patent. The Court issued an order on September 28, 2018 in which it granted in part a motion for summary judgment filed by the Company, and in which the Court ruled that the ′497 and ′717 patents are not infringed by the Company. As a result, only the ′933, the ′919, and the ′961 patents remain in dispute. On October 16, 2018, the Company filed a motion to stay proceedings in the district court on the ‘961 patent pending the PGR. None of these suits are associated with any stay of FDA approval for Xtampza ER. Purdue has made a demand for monetary relief but has not quantified its alleged damages. Purdue has also requested a judgment of infringement, an adjustment of the effective date of FDA approval, and an injunction on the sale of the

Company's products accused of infringement. The Company has denied all claims and seeks a judgment that the patents are invalid and/or not infringed by the Company; the Company is also seeking a judgment that the case is exceptional, with an award to the Company of its fees for defending the case.

A claim construction hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the '933, '497, and '717 patents. No trial date has been scheduled. On September 18, 2019, Purdue gave the Court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. On September 20, the matter was stayed pending further order of the Court.

Once the stay is lifted, the Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Nucynta Litigation

On February 7, 2018, Purdue filed a patent infringement suit against the Company in the District of Delaware. Specifically, Purdue argues that the Company's sale of immediate-release and extended-release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in its complaint but has not quantified its alleged damages.

On December 6, 2018, the Company filed an Amended Answer asserting an affirmative defense for patent exhaustion. On December 10, 2018, the Court granted the parties' stipulation for resolution of the Company's affirmative defense of patent exhaustion and stayed the action, with the exception of briefing on and resolution of the Company's Motion for Judgment on the Pleadings related to patent exhaustion and any discovery related to that Motion. Also, on December 10, 2018, the Company filed a Rule 12(c) Motion for Judgment on the Pleadings, arguing that the Purdue's claims were barred by the doctrine of patent exhaustion. Purdue filed its response on January 11, 2019 and the Company filed a reply on January 25, 2019. On June 18, 2019, the court heard oral argument on the Company's Rule 12(c) Motion for Judgment on the Pleadings. On June 19, 2019, the court issued an order stating that "judgment in Collegium's favor is warranted under the doctrine of patent exhaustion to the extent Collegium's alleged infringing activities resulted from sales that fall within the scope of that covenant." The court explained, however, that based on the current record, it was not possible "to determine whether title of the Nucynta Products was transferred to Collegium" from sales authorized by Purdue's covenant not to sue. The court ordered discovery on this issue and the case remained "stayed with the exception of discovery and briefing on and resolution of the Company's anticipated motion for summary judgment based on patent exhaustion."

On September 19, 2019, Purdue gave the court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. The Nucynta litigation is subject to the automatic bankruptcy stay.

Pending resolution of the bankruptcy action, the Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Teva Litigation

The Company has fifteen patents listed in the FDA Orange Book as covering the Company's abuse-deterrent product and methods of using it to treat patients: Patents Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530, 9,763,883; 9,968,598; 10,004,729; and 10,188,644 (the "Orange Book Patents").

Teva Pharmaceuticals USA, Inc. ("Teva") filed Notice Letters of Patent Certification against all of the fifteen listed Orange Book Patents alleging that they were invalid and/or not infringed by the proposed oxycodone products that are the subject of Teva's Abbreviated New Drug Application ("ANDA"). On February 22, 2018—within the 45-day period that gives the Company a 30-month stay on FDA approval of Teva's ANDA while the parties have an opportunity to litigate—the Company sued Teva in the District of Delaware on eleven of the Orange Book Patents. Teva responded to the Company's complaint on May 14, 2018, alleging that the Orange Book Patents are invalid and are not infringed by Teva's proposed ANDA products and asserting counterclaims of non-infringement and invalidity of the Orange Book Patents. The Company answered Teva's counterclaims on June 4, 2018. The parties briefed claim construction and the court heard argument on April 12, 2019. On September 11, 2019, the Court issued a Report and Recommendation

construing two of the six terms or sets of terms that are in dispute. The remaining terms will be addressed in one or more forthcoming Report and Recommendations. Fact discovery was scheduled to close on September 20, 2019 and expert discovery was scheduled to close on January 24, 2020.

The Company filed a second lawsuit in the District of Delaware, asserting two additional Orange Book Patents, on November 30, 2018. Teva responded to the Company's complaint on January 11, 2019, alleging that the asserted patents are invalid and are not infringed by Teva's proposed ANDA products, and asserting counterclaims of non-infringement and invalidity of the asserted patents. The Company answered Teva's counterclaims on February 1, 2019. The court consolidated the second suit with the first suit, and thus both suits are proceeding on the same schedule.

The Company filed a third lawsuit in the District of Delaware, asserting one additional Orange Book Patent, on May 9, 2019. Teva responded to the Company's complaint on June 6, 2019, alleging that the asserted patent is invalid and is not infringed by Teva's proposed ANDA products, and asserting counterclaims of non-infringement and invalidity of the asserted patent. The Company answered Teva's counterclaims on June 27, 2019. The parties filed a proposed Scheduling Order, which the Court entered on September 4, 2019. The parties have exchanged initial disclosures pursuant to that Order.

On September 20, 2019, the parties jointly agreed to stay both litigations, which the Court so ordered. Once the stay is lifted, the Company plans to continue defending this case vigorously.

Opioid Litigation

On March 19, 2018, a lawsuit was filed by multiple local governments in the Circuit Court of Crittenden County, Arkansas, against the Company and other pharmaceutical manufacturers and distributors alleging a variety of claims related to opioid marketing and distribution practices. On January 29, 2019, the Company was dismissed from this litigation without prejudice.

On March 21, 2018, the Company, along with other pharmaceutical manufacturers and distributors, were named in a class-action lawsuit filed in the Eastern District of Kentucky by a family practice clinic, on behalf of other similarly-situated healthcare providers. The action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") relating to opioid marketing and distribution practices. On April 14, 2018, the lawsuit was conditionally transferred by the Judicial Panel on Multi-District Litigation to the federal Prescription Opiate Multi District Litigation (the "MDL") in the Southern District of Ohio. On April 10, 2018, the conditional transfer was finalized, and the lawsuit was docketed in the MDL on April 11, 2018. On May 4, 2018, the Company, along with other pharmaceutical manufacturers and distributors, were named in two lawsuits filed in the MDL by the Fiscal Court of Bourbon County, Kentucky and the Fiscal Court of Owen County, Kentucky, relating to opioid marketing and distribution practices. On June 11 and 12, 2018, the Company was named in four lawsuits filed in the MDL by a health system and various member hospitals. On September 26, 2018, the Company was named in two lawsuits filed in the MDL by the Fiscal Court of Lee County, Kentucky and the Fiscal Court of Wolfe County, Kentucky. On March 15, 2019, the plaintiffs in all of the MDL cases in which the Company was named, except for the City of Paterson case, discussed below, filed amended complaints which no longer name the Company as a defendant, effectively terminating these lawsuits as to the Company.

On March 15, 2019, the Company was named in a lawsuit in the MDL by the City of Paterson, New Jersey that alleges violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws, and seeks, generally, penalties and/or injunctive relief. In April 2019, the City of Norwich, Connecticut and the Town of Enfield, Connecticut filed lawsuits in Connecticut Superior Court. The lawsuits allege violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws. On June 28, 2019, both cases were transferred to the MDL. On January 11, 2019, the City of Portsmouth filed a lawsuit in Virginia Circuit Court against the Company and other pharmaceutical manufacturers and distributors. The lawsuit alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, and violations of state consumer protection laws. On October 3, 2019, the case was transferred the MDL. On September 6, 2019, Triad Health Systems filed a class action lawsuit in the MDL on behalf of itself and similarly situated health care systems (the "Triad case"). On October 18, 2019, three counties in Kentucky filed lawsuits in the MDL, naming the Company: the Fiscal Court of Casey County Kentucky; the Fiscal Court of Gallatin County Kentucky; and the Fiscal Court of Lewis County Kentucky. On November 6, 2019, the plaintiffs in these three lawsuits, as well as the Triad case, dismissed the Company from these suits. Each of the remaining lawsuits

in the MDL naming the Company seeks, generally, penalties and injunctive relief. None of the remaining lawsuits naming the Company are designated as representative cases in the MDL, and therefore, are effectively currently stayed.

On May 29, 2018, a lawsuit was filed by Bucks County, Pennsylvania against the Company and other pharmaceutical manufacturers and on June 12, 2018, a lawsuit was filed by Clinton County, Pennsylvania, against the Company and other pharmaceutical manufacturers and distributors. On June 6, 2018, a lawsuit was filed by Mercer County, Pennsylvania, against the Company and other pharmaceutical manufacturers and distributors. These lawsuits allege claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws. These cases have been consolidated for discovery purposes in the Delaware County Court of Common Pleas as part of a consolidated proceeding of similar lawsuits brought by numerous Pennsylvania counties against other pharmaceutical manufacturers and distributors. In March 2019, three additional cases were filed in Pennsylvania by two payor groups and Warminster Township. The Company has been dismissed from one of the payor group cases. In July 2019, the Company learned of additional lawsuits alleging similar claims which were filed by Warrington Township in the Bucks County Court of Common Pleas, and filed by the City of Lock Haven in the Clinton County Court of Common Pleas. The City of Lock Haven and the Warrington Township cases have been coordinated into the consolidated proceeding before the Delaware County Court of Common Pleas. None of these cases have been designated a Track One case in which discovery would commence, and therefore are effectively stayed at present.

On July 30, 2018, a lawsuit was filed by the City of Worcester, Massachusetts against the Company and other pharmaceutical manufacturers and distributors. The action alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, violations of Mass Gen. Laws ch. 93A, *Section 11*, unjust enrichment and civil conspiracy. In February 2019, the City of Worcester case was transferred to the Business Litigation Session of the Superior Court. Additional lawsuits brought by the following cities and counties Massachusetts were filed between October 2018 and April 2019: City of Salem, City of Framingham, Town of Lynnfield, City of Springfield, City of Haverhill, City of Gloucester, Town of Canton, Town of Wakefield, City of Chicopee; Town of Natick; City of Cambridge, and Town of Randolph. With the exception of the City of Cambridge and the Town of Randolph, each of these additional lawsuits has been coordinated before the Business Litigation Session; the City of Cambridge and Town of Randolph are pending transfer into the Business Litigation Session. The case brought by the City of Springfield has been selected to advance for the purpose of motions practice. The Company and other pharmaceutical manufacturers and distributors filed motions to dismiss the case and the plaintiffs filed oppositions to these motions to dismiss. These motions are currently pending before the Court. The other cases pending before the Business Litigation Session are effectively stayed at present.

On June 14, 2019, the City of Trenton filed a lawsuit in New Jersey Superior Court against the Company and other pharmaceutical manufacturers and distributors. The lawsuit alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, and violations of state consumer protection laws and the New Jersey Drug Dealer Liability Act. On August 23, 2019, the case was removed to the District Court of New Jersey, where it awaits either coordination in the federal MDL or remand to state court. The plaintiff has filed its opposition to coordination and requested remand to New Jersey Superior Court.

The Company disputes the allegations in these lawsuits and intends to vigorously defend these actions. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Opioid-Related Request and Subpoenas

The Company, like a number of other pharmaceutical companies, has received subpoenas or civil investigative demands related to opioid sales and marketing. The Company has received such subpoenas or civil investigative demands from the Offices of the Attorney General of each of Washington, New Hampshire, and Massachusetts. The Company is currently cooperating with each of the foregoing states in their respective investigations.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements that involve risks uncertainties and assumptions. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Quarterly Report on Form 10-Q, including those set forth under "Forward-looking Statements" and "Risk Factors", as revised and supplemented by those risks described from time to time in other reports which we file with the SEC.

OVERVIEW

We are a specialty pharmaceutical company committed to being the leader in responsible pain management. Our first product, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the FDA approved our NDA for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, we announced the commercial launch of Xtampza ER.

Xtampza ER, OxyContin OP from Purdue, and the authorized generic version of OxyContin OP (which is identical to the branded version) are the only extended-release oxycodone products marketed in the United States as of September 2019. In 2018, the extended-release oxycodone market generated approximately $1.8 billion in U.S. sales and there were approximately 3.4 million prescriptions written. OxyContin OP is the largest selling extended-release oxycodone (and largest-selling branded extended-release opioid) in the United States by dollars and prescription volume, with approximately $1.5 billion in U.S. sales in 2018. We conducted a comprehensive preclinical and clinical program for Xtampza ER consistent with FDA guidance on abuse-deterrence. These studies and clinical trials demonstrated, among other things, that chewing, and crushing Xtampza ER, and then taking it orally, did not meaningfully change its drug release profile or safety characteristics. On the basis of these studies and clinical trials, the FDA concluded that Xtampza ER has properties that are expected to reduce abuse via the oral and intranasal routes and that are expected to make abuse by injection difficult. By contrast, clinical trials performed by us and others — including head-to-head clinical trials comparing Xtampza ER with OxyContin OP — have shown that drug abusers could achieve rapid release and absorption of the active ingredient by manipulating OxyContin OP using common household tools and methods commonly available on the Internet. In November 2017, we announced the approval of a Supplemental New Drug Application by the FDA for Xtampza ER to include comparative oral pharmacokinetic data from the clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim.

Our product portfolio also includes the Nucynta Products. In December 2017, we entered into the Nucynta Commercialization Agreement with Assertio, pursuant to which we acquired the right to commercialize the Nucynta Products in the United States. Nucynta ER is an extended-release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of moderate to severe acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and began marketing the Nucynta Products in February 2018. Effective August 2018, we entered into a Second Amendment to the Commercialization Agreement to primarily clarify the mechanism for transferring title to products to be sold by the Company pursuant to the agreement and various related matters. Effective November 2018, we entered into a Third Amendment to the Nucynta Commercialization Agreement, which primarily eliminated the guaranteed minimum royalty payment obligations for years 2019, 2020 and 2021. We began shipping and recognizing product sales on the Nucynta Products in January 2018.

Outlook

We expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities. We are promoting Xtampza ER to approximately 11,000 health care professionals who write approximately 65% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 150 sales representatives and managers. We are promoting the Nucynta Products to the same health care professionals to whom we promote Xtampza ER, leveraging our existing sales organization. We pay a royalty to Assertio on all revenues from the sale of Nucynta Products based on certain net sales thresholds.

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $20.5 million and $48.2 million for the nine months ended September 30, 2019 and 2018 respectively. As of September 30, 2019, we had an accumulated deficit of $357.7 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We expect to continue to incur net losses in the near future as we continue to commercialize our products. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We believe that our cash and cash equivalents at September 30, 2019, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as “critical” because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used, which would have resulted in different financial results.

The critical accounting policies we identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (“Annual Report”), relate to revenue recognition and impairment of intangible assets. Estimates include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of our products, estimates utilized in the valuation of inventory, accounting for stock-based compensation, contingencies, and tax valuation reserves. We also estimate the useful life of our intangible asset and periodically evaluative it for impairment whenever events or circumstances indicate a potential reduction in the fair value. We base our estimates and assumptions on historical experience when available and on various factors that we believe are reasonable under the circumstances, and we evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in our Annual Report.

RESULTS OF OPERATIONS
(in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
	(in thousands)			
Product revenues, net	$ 72,942	$ 70,176	$ 222,498	$ 206,986
Costs and expenses				
Cost of product revenues	46,754	46,007	144,572	135,951
Research and development	2,491	1,907	7,942	6,412
Selling, general and administrative	30,072	33,448	91,359	96,309
Total costs and expenses	79,317	81,362	243,873	238,672
Loss from operations	(6,375)	(11,186)	(21,375)	(31,686)
Interest expense	(228)	(5,868)	(698)	(17,726)
Interest income	494	552	1,552	1,198
Net loss	$ (6,109)	$ (16,502)	$ (20,521)	$ (48,214)

Comparison of the three months ended September 30, 2019 and September 30, 2018

Product revenues, net were $72.9 million for the three months ended September 30, 2019 (the "2019 Quarter"), compared to $70.2 million for the three months ended September 30, 2018 (the "2018 Quarter"). The $2.7 million increase was related to an increase in revenue for Xtampza ER of $9.4 million, partially offset by a decrease in revenue for the Nucynta Products of $6.7 million. In the 2019 Quarter, Xtampza ER product revenues, net were $26.5 million, compared to $17.0 million for the 2018 Quarter. The increase in revenue for Xtampza ER was primarily related to an increase in sales volume due to increasing demand. In the 2019 Quarter, Nucynta IR and ER product revenues, net were $28.1 million and $18.3 million, respectively, compared to $34.3 million and $18.9 million, respectively, for the 2018 Quarter. The decrease in revenue for the Nucynta Products was primarily related to lower sales volume, partially offset by an increase in price.

Cost of product revenues was $46.8 million for the 2019 Quarter, compared to $46.0 million for the 2018 Quarter. The $747,000 increase was primarily related to the recognition of royalty expense for the Nucynta Products, as royalty expense in the 2019 Quarter was recognized as incurred under the terms of the Commercialization Agreement as amended in November 2018, while the expense for the 2018 Quarter was recognized on a straight-line basis through the amortization of the Nucynta Intangible Asset.

Research and development expenses were $2.5 million for the 2019 Quarter, compared to $1.9 million for the 2018 Quarter. The $584,000 increase was primarily related to an increase in salaries, wages and benefits, including stock-based compensation expense.

Selling, general and administrative expenses were $30.1 million for the 2019 Quarter, compared to $33.4 million for the 2018 Quarter. The $3.3 million decrease was primarily related to:

- a decrease in sales, marketing and consulting costs of $3.8 million, primarily due to higher one-time costs incurred in the 2018 Quarter to commercialize the Nucynta Products;
- a decrease in salaries, wages and benefits of $471,000, primarily due to lower incentive compensation expense; offset by
- an increase in fees, permits and other regulatory costs of $539,000; and
- an increase in rent expense of $383,000, primarily related to us taking possession of our new corporate headquarters in mid-2018.

Interest expense was $228,000 for the 2019 Quarter, compared to $5.9 million in the 2018 Quarter. The decrease was primarily due to $5.6 million of interest expense recognized in the 2018 Quarter associated with the minimum royalty

payments related to the Nucynta Commercialization Agreement. In November 2018, the minimum royalty payments were eliminated upon the execution of the Third Amendment to the Nucynta Commercialization Agreement.

Interest income was $494,000 for the 2019 Quarter, compared to $552,000 in the 2018 Quarter. The $58,000 decrease was primarily due to a lower balance invested in money market funds partially offset by higher interest rates earned in the 2019 Quarter.

Comparison of the nine months ended September 30, 2019 and September 30, 2018

Product revenues, net were $222.5 million for the nine months ended September 30, 2019 (the "2019 Period"), compared to $207.0 million for the nine months ended September 30, 2018 (the "2018 Period"). The $15.5 million increase was related to an increase in revenue for Xtampza ER of $26.7 million, partially offset by a decrease in revenue for the Nucynta Products of $11.2 million. In the 2019 Period, Xtampza ER product revenues, net were $77.6 million compared to $51.0 million for the 2018 Period. The increase in revenue for Xtampza ER was primarily related to an increase in sales volume due to increasing demand. In the 2019 Period, Nucynta IR and ER product revenues, net were $87.5 million and $57.4 million, respectively, compared to $95.7 million and $60.3 million, respectively, for the 2018 Period. The decrease in revenue for the Nucynta Products was primarily related to lower sales volume, partially offset by an increase in price.

Cost of product revenues was $144.6 million for the 2019 Period, compared to $136.0 million for the 2018 Period. The $8.6 million increase was primarily related to the recognition of royalty expense for the Nucynta Products, as royalty expense in the 2019 Period was recognized as incurred under the terms of the Commercialization Agreement as amended in November 2018, while the expense for the 2018 Period was recognized on a straight-line basis through the amortization of the Nucynta Intangible Asset.

Research and development expenses were $7.9 million for the 2019 Period, compared to $6.4 million for the 2018 Period. The $1.5 million increase was primarily due to related to an increase in salaries, wages and benefits, including stock-based compensation expense.

Selling, general and administrative expenses were $91.4 million for the 2019 Period, compared to $96.3 million for the 2018 Period. The $4.9 million decrease was primarily related to:

- a decrease in sales, marketing and consulting costs of $5.4 million, primarily due to higher one-time costs incurred in the 2018 Period to commercialize the Nucynta Products;
- a decrease in salaries, wages and benefits of $1.7 million, primarily due to lower incentive compensation expense;
- a decrease in fees and permits, including post-marketing requirements, of $1.3 million; offset by
- an increase in professional fees of $1.7 million, including audit and legal expenses; and
- an increase in rent expense of $1.3 million, primarily related to us taking possession of our new corporate headquarters in mid-2018.

Interest expense was $698,000 for the 2019 Period, compared to $17.7 million in the 2018 Period. The decrease was primarily due to $17.1 million interest expense recognized in the 2018 Period associated with the minimum royalty payments related to the Nucynta Commercialization Agreement. In November 2018, the minimum royalty payments were eliminated upon the execution of the Third Amendment to the Nucynta Commercialization Agreement.

Interest income was $1.6 million for the 2019 Period, compared to $1.2 million in the 2018 Period. The increase was primarily due to higher interest rates earned on money market funds.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We have incurred net losses from operations since inception. Since inception, we have funded our operations primarily through the private placements of our preferred stock and convertible notes, public offerings of common stock, and commercial bank debt. As of September 30, 2019, we had $153.8 million in cash and cash equivalents.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents at September 30, 2019, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

Borrowing Arrangements and Equity Offerings

Other than the expiration of the ATM Sales Agreement in October 2019, there have not been any material changes in borrowing arrangements and equity offerings that were previously disclosed in our most recent Annual Report.

Cash Flows

	Nine months ended September 30,	
	2019	**2018**
Net cash provided by operating activities	$ 12,127	$ 127,102
Net cash used in investing activities	(5,549)	(22,581)
Net cash provided by (used in) financing activities	627	(83,525)
Net increase in cash, cash equivalents and restricted cash	$ 7,205	$ 20,996

Operating activities. Cash provided by operating activities was $12.1 million in the 2019 Period, compared to cash provided by operating activities of $127.1 million in the 2018 Period. The $115.0 million decrease was primarily due to lower non-cash adjustments related to the Nucynta Commercialization Agreement, as in 2018 we were required to make guaranteed minimum royalty payments which were classified as outflows from financing activities, while in 2019 royalty payments were conditional on net sales and therefore classified as outflows from operating activities. Further, there was lower amortization from the Nucynta Intangible Asset in 2019 compared to 2018 as a result of the Third Amendment to the Nucynta Commercialization Agreement and non-cash interest was reduced to zero. In addition, cash provided by operating activities decreased due to changes in the working capital accounts, partially offset by a benefit from the change in net loss.

Investing activities. Cash used in investing activities was $5.5 million in the 2019 Period, compared to cash used in investing activities of $22.6 million in the 2018 Period. The $17.1 million decrease in cash used in investing activities was primarily related to the Nucynta Commercialization Agreement, as in 2018 we made a one-time upfront payment of $18.9 million to Assertio to consummate the Nucynta Commercialization Agreement. This decrease was partially offset by an increase of $1.8 million paid for purchases of property, plant, and equipment primarily for the dedicated production suite at our contract manufacturing organization in the 2019 Period.

Financing activities. Cash provided by financing activities was $627,000 for the 2019 Period, compared to cash used by financing activities of $83.5 million in the 2018 Period. The $84.2 million increase in cash provided by financing activities was primarily related to the Nucynta Commercialization Agreement. In 2018 we were required to make guaranteed minimum royalty payments which were classified as outflows from financing activities, while in 2019, royalty payments were conditional on net sales and therefore classified as outflows from operating activities. The guaranteed minimum royalty payments paid in the 2018 Period were partially offset by term loan proceeds of $10.0 million. The remaining change is primarily related to changes in proceeds from the issuance of shares under our employee stock purchase plan and proceeds from exercises of stock options, offset by payments made for employee restricted stock tax withholdings.

Funding Requirements

We believe that our cash and cash equivalents at September 30, 2019 together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future. However, we are subject to all the risks common to the commercialization and development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Certain economic or strategic considerations may cause us to seek additional cash through private or public debt or equity offerings. Such funds may not be available when needed, or, we may not be able to obtain funding on favorable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast that our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the generation of reasonable levels of revenue from products sales;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products;
- the timing and costs associated with manufacturing our products, for commercial sale and clinical trials
- the cost of patent infringement litigation, including our litigation with each of Purdue and Teva, relating to Xtampza ER and the Nucynta Products, which may be expensive to defend;
- the cost of litigation related to opioid marketing and distribution practices;
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

If we cannot capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

ADDITIONAL INFORMATION

To supplement our financial results presented on a GAAP basis, we have included information about non-GAAP adjusted income/loss. We internally use this non-GAAP financial measure to understand, manage and evaluate the Company as we believe it represents the performance of our core business. Because this non-GAAP financial measure is an important internal measure for the Company, we believe that the presentation of the non-GAAP financial measure provides analysts, investors and lenders insight into management's view and assessment of the Company's ongoing operating performance. In addition, we believe that the presentation of this non-GAAP financial measure, when viewed with our results under GAAP and the accompanying reconciliation, provides supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing the Company's performance and results from period to period. We report this non-GAAP financial measure in order to portray the results of our major operations – commercializing innovative, differentiated products for people suffering from pain – prior to considering certain income statement elements. This non-GAAP financial measure should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP. The Non-GAAP financial measure is not based on any standardized methodology prescribed by GAAP and represents GAAP net income/loss adjusted to exclude stock-based compensation expense, amortization expense for the Nucynta intangible asset, non-cash interest expense recognized on the Nucynta minimum royalty payments, and minimum royalty payments due and payable in connection with the Nucynta Commercialization Agreement. Any non-GAAP financial measures used by us

may be calculated differently from, and therefore may not be comparable to, a non-GAAP measure used by other companies.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
GAAP net loss	$ (6,109)	$ (16,502)	$ (20,521)	$ (48,214)
Non-GAAP adjustments:				
Stock-based compensation expense	4,137	3,926	12,562	10,180
Nucynta related amortization expense (1)	3,688	32,407	11,064	94,340
Nucynta non-cash interest expense (2)	—	5,641	—	17,112
Nucynta minimum royalty payment due (3)	—	(33,750)	—	(98,250)
Total non-GAAP adjustments	$ 7,825	$ 8,224	$ 23,626	$ 23,382
Non-GAAP adjusted income (loss)	$ 1,716	$ (8,278)	$ 3,105	$ (24,832)

	First Quarter 2019	Second Quarter 2019	Third Quarter 2019
GAAP net loss	$ (9,700)	$ (4,712)	$ (6,109)
Non-GAAP adjustments:			
Stock-based compensation expense	4,263	4,162	4,137
Nucynta related amortization expense (1)	3,688	3,688	3,688
Nucynta non-cash interest expense (2)	—	—	—
Nucynta minimum royalty payment due (3)	—	—	—
Total non-GAAP adjustments	$ 7,951	$ 7,850	$ 7,825
Non-GAAP adjusted income (loss)	$ (1,749)	$ 3,138	$ 1,716

	First Quarter 2018	Second Quarter 2018	Third Quarter 2018	Fourth Quarter 2018
GAAP net income (loss)	$ (18,652)	$ (13,060)	$ (16,502)	$ 9,086
Non-GAAP adjustments:				
Stock-based compensation expense	2,728	3,526	3,926	3,598
Nucynta related amortization expense (1)	29,526	32,407	32,407	15,494
Nucynta non-cash interest expense (2)	5,528	5,943	5,641	2,169
Nucynta minimum royalty payment due (3)	(30,750)	(33,750)	(33,750)	(33,750)
Total non-GAAP adjustments	$ 7,032	$ 8,126	$ 8,224	$ (12,489)
Non-GAAP adjusted loss	$ (11,620)	$ (4,934)	$ (8,278)	$ (3,403)

(1) Represents amortization expense of the Nucynta Intangible Asset.

(2) Represents non-cash interest expense associated with the minimum royalty payments of the Nucynta Commercialization Agreement.

(3) Represents minimum royalty payment due and payable in connection with the Nucynta Commercialization Agreement.

CONTRACTUAL OBLIGATIONS

There have been no material changes to the contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our most recent Annual Report.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the periods presented any off-balance sheet arrangements, as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

For information regarding our exposure to certain market risks, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report. There have been no significant changes in our financial instrument portfolio or market risk exposures since our fiscal year ended December 31, 2018.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Except as set forth in Note 14 to our financial statements, which is incorporated herein by reference to the extent applicable, there are no material changes from the legal proceedings previously disclosed in our Annual Report.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, as well as all other information included in this Quarterly Report on Form 10-Q, including our financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and investors could lose all or part of their investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position and Capital Needs

Although we currently generate revenue from the sale of products, we may never become profitable. Our ability to generate sufficient revenue to become profitable is dependent upon our ability to successfully commercialize our products and any products and product candidates that we may develop or acquire in the future on a timely basis, and to address all regulatory requirements applicable to the development and commercialization of our products and any product candidates. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results.

We began the commercial sale of our first product, Xtampza ER, in June 2016 and assumed responsibility for the sales and marketing of the Nucynta Products in January 2018. Our ability to generate sufficient revenue to become profitable depends upon our ability to successfully commercialize our products and any other products and product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from our current or future products depends on a number of factors, including our ability to:

- successfully commercialize our products;
- successfully satisfy FDA post-marketing requirements for our products, including studies and clinical trials that have been required for other extended-release/long acting opioid analgesics and individual studies and clinical trials of our products;
- set a commercially viable price for our products;
- manufacture commercial quantities of our products at acceptable cost levels;
- grow and sustain a commercial organization capable of sales, marketing and distribution for the products we sell;
- obtain coverage and adequate reimbursement from third parties, including government payors;
- complete and submit regulatory submissions to the FDA; and
- comply with existing and changing laws and regulations that apply to the pharmaceutical industry, including opioid manufacturers.

In addition, because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability.

Even though we are generating revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

If we require additional capital to fund our operations and we fail to obtain necessary financing, we may be unable to complete the commercialization of our products or the development and commercialization of our future product candidates.

Our operations have consumed substantial amounts of cash. We believe that our cash and cash equivalents at September 30, 2019 together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future. However, certain economic or strategic factors may require us to seek additional cash through private or public debt or equity offerings.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts, when required or on acceptable terms, we also could be required to:

- significantly delay, scale back or discontinue the development and/or the commercialization of our products or our other research and development initiatives;
- seek collaborators for our products and/or one or more of our future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies, products or future product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail operations.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the generation of sufficient levels of revenue from the sale of our products;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products and any other products we may acquire or develop;
- the outcome, timing and cost of regulatory approvals by the FDA, including the potential for the FDA to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;
- the timing and costs associated with manufacturing (1) our products, for commercial sale and clinical trials, and (2) our future product candidates for preclinical studies, clinical trials and, if approved, for commercial sale;
- the cost of litigation relating to our products or future product candidates, including our patent infringement litigation with each of Purdue and Teva, and ongoing litigation related to opioid marketing and distribution practices, which may be expensive to defend;
- the cost of implementing additional infrastructure and internal systems and hiring additional employees as our organization grows;
- our need to expand our regulatory and compliance functions; and

- the effect of competing technological and market developments.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our products or technologies.

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing shareholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing shareholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing shareholders' ownership. The incurrence of additional indebtedness could result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur further debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could have a material adverse effect on our ability to conduct our business and may result in additional liens being placed on our assets and intellectual property. If we were to default on any of our indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic collaborations and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our products, technologies or revenue streams or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our commercialization or product development efforts or grant rights to develop and market our technologies that we would otherwise prefer to develop and market ourselves.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our predecessor was originally incorporated in Delaware in April 2002 under the name Collegium Pharmaceuticals, Inc. and in October 2003, our predecessor changed its name to Collegium Pharmaceutical, Inc. In July 2014, we reincorporated in the Commonwealth of Virginia pursuant to a merger whereby Collegium Pharmaceutical, Inc., a Delaware corporation, merged with and into Collegium Pharmaceutical, Inc., a Virginia corporation, with the Virginia corporation surviving the merger. From 2002 until 2010, our operations focused primarily on marketing proprietary therapies to the wound care and dermatology industry through our former subsidiary, Onset Therapeutics, LLC, which was spun off and became a part of PreCision Dermatology, Inc. in 2010. Since 2010, our operations have focused primarily on developing the DETERx technology platform and identifying and developing product candidates that utilize the DETERx technology, including our first product, Xtampza ER. Although we began the commercial sale of Xtampza ER in June 2016 and acquired the right to commercialize the Nucynta Products in the United States in January 2018, we have a limited track record of successful commercialization of these products. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history.

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

As of December 31, 2018, we had a federal net operating loss ("NOL"), carryforward of approximately $324.5 million and state NOL carryovers of approximately $285.2 million, which are available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022, and the state NOL carryforwards begin to expire in 2030. We also had U.S. federal tax credits of approximately $3.6 million, and state tax credits of approximately $885,000. These tax attributes are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382").

The federal R&D credit generally has a twenty-year carryover term, and our state R&D credit is generally available for a fifteen-year carryover.

Under Section 382, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership some of which are outside our control. We have not completed a current study to assess whether an ownership change has occurred or

whether there have been multiple ownership changes since our formation. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

As of December 31, 2018, and December 31, 2017, we have provided a full valuation allowance for deferred tax assets including NOL and tax credit carryovers.

Risks Related to our Products

If we are unable to successfully commercialize Xtampza ER or the Nucynta Products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

To date, we have invested substantial resources in the development of Xtampza ER, which has been approved by the FDA. In February 2018, we began marketing the Nucynta Products. Our business and future success are substantially dependent on our ability to successfully and timely commercialize these products. We may never be able to successfully commercialize our products.

Our ability to successfully commercialize Xtampza ER will depend on many factors, including but not limited to:

- our ability to successfully satisfy FDA post-marketing requirements, including studies and clinical trials that have been required for other extended-release/long acting opioid analgesics and individual studies of Xtampza ER and its components;
- our ability to manufacture commercial quantities of Xtampza ER at reasonable cost and with sufficient speed to meet commercial demand;
- our ability to continue to build and retain a sales and marketing organization to market Xtampza ER;
- our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of Xtampza ER;
- the perceived availability and advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments with similar indications;
- our ability to successfully defend any challenges to our intellectual property or suits asserting patent infringement relating to Xtampza ER;
- the availability of coverage and adequate reimbursement for Xtampza ER;
- a continued acceptable safety profile of Xtampza ER; and
- our ability to comply with applicable legal and regulatory requirements, including any additional manufacturing or packaging requirements that may become applicable to certain opioid products.

Our ability to successfully commercialize the Nucynta Products will depend on many factors including, but not limited to, our ability to:

- develop and execute our sales and marketing strategies for the Nucynta Products;

- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers;
- maintain and manage the necessary sales, marketing, supply chain, managed markets and other capabilities and infrastructure that are required to successfully integrate and commercialize the Nucynta Products;
- successfully defend any challenges to intellectual property or suits asserting patent infringement relating to the Nucynta Products;
- obtain adequate supply of Nucynta ER and Nucynta IR; and
- comply with applicable legal and regulatory requirements.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will be able to successfully commercialize or generate sufficient revenue from our products. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

Despite receiving approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling of Xtampza ER and our ability to successfully market Xtampza ER may be adversely affected.

Xtampza ER was approved with label language describing abuse-deterrent properties of the formulation with respect to the nasal and IV routes of abuse, consistent with Guidance for Industry, "Abuse-Deterrent Opioids- Evaluation and Labeling". In November 2017, the FDA approved an sNDA for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim. Per FDA guidance, data that emerges from post-marketing studies or other sources could prompt the FDA to withdraw or amend its approval of the product labeling describing the abuse deterrent properties of the formulation, which withdrawal or amendment could adversely impact our ability to successfully commercialize Xtampza ER.

The FDA can change the product labeling for Xtampza ER at any time. Per FDA guidance, data that emerges from post-marketing studies or other sources could prompt the FDA to withdraw or amend its approval of the product labeling describing the abuse deterrent properties of the formulation. If the product label for Xtampza ER is modified in the future so that the FDA requires us to have additional boxed warning language similar to competitor product labeling stating that "crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug" or to exclude the flexible dose administration options, it will limit our ability to differentiate Xtampza ER from other abuse-deterrent opioid and this may have an adverse effect on our business and our prospects for future growth.

Xtampza ER and the Nucynta Products are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products.

The FDA has approved REMS for extended-release and long acting ("LA"), opioid drugs formulated with the active pharmaceutical ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and others as part of a federal initiative to address prescription drug abuse and misuse, or the ER/LA opioid REMS. In September 2018, the FDA announced that immediate-release ("IR"), opioid drugs will be subject to the same REMS as ER/LA opioids (now called the Opioid Analgesic REMS). One of the primary goals of the REMS is to ensure that the benefits of these drugs continue to outweigh the risks.

The REMS introduces new safety measures designed to reduce risks and improve the safe use of opioids, while continuing to provide access to these medications for patients in pain. The REMS applies to more than 20 companies that manufacture opioid analgesics. Under the REMS, companies are required to make education programs available to prescribers based on the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the

Treatment and Monitoring of Patients with Pain. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. The REMS also requires companies to distribute FDA-approved educational materials to prescribers and patients on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program. At present, a physician does not have to complete the training offered under REMS as a prerequisite for ability to prescribe opioids; however, the FDA is considering circumstances where it would require some type of mandatory training as a precondition. Congress has also considered legislation that would require prescribers to have continuing medical education on best practices in prescribing opioids. These requirements, if enacted, could impact the number of prescriptions written by physicians for our products.

Additionally, drug products that fall under the Opioid Analgesic REMS may be subject to class-wide safety labelling changes when FDA determines such changes are warranted. Such labeling has the potential to adversely impact prescribing or market acceptance of these products.

If the FDA determines that a REMS is necessary during review of an application, the drug sponsor must agree to the REMS plan at the time of approval. Xtampza ER and the Nucynta Products have been subject to the REMS requirement since their approval. REMS includes a Medication Guide that is dispensed with each prescription, physician training based on FDA-identified learning objectives, audits to ensure that the FDA's learning objectives are addressed in the physician trainings, letters to prescribing physicians, professional organizations and state licensing entities alerting each to the REMS, and the establishment of a call center to provide more information about the REMS. We anticipate that our future product candidates will also be subject to these REMS requirements. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of product candidates subject to the REMS requirements, which could reduce the commercial benefits to us from the sale of these product candidates.

If we fail to comply with our obligations in the Nucynta Commercialization Agreement or otherwise experience disruptions to our business relationship with Assertio, we could lose license rights that are important to our business.

The Nucynta Commercialization Agreement imposes various diligence, milestone, royalty and other obligations on us. If we fail to comply with the obligations under the Nucynta Commercialization Agreement, Assertio may have the right to terminate the license, in which event we would not be able to market the Nucynta Products.

In addition, Assertio may terminate the Nucynta Commercialization Agreement under certain circumstances, regardless of whether we are compliant with the terms of such agreement. If annual net sales of the Nucynta Products are less than $180.0 million in any 12-month period through January 1, 2022, or if they are less than $170.0 million in any 12-month period commencing on January 1, 2022, then Assertio will have the right to terminate the Nucynta Commercialization Agreement without penalty.

Conversely, if Assertio, upon whom we rely for commercial supply of the Nucynta Products and other forms of support for the commercialization of the Nucynta Products pursuant to the terms of the Nucynta Commercialization Agreement, experiences a disruption of its ordinary course of business for any reason, such disruption may impair our ability to obtain and effectively commercialize the Nucynta Products and may therefore have an adverse impact on our financial condition.

Although Xtampza ER has been approved with abuse deterrent labeling, the FDA could require changes to such labeling or we could fail to promote such abuse deterrent labeling in compliance with FDA regulations.

Xtampza ER was developed in compliance with the FDA's April 2015 guidance regarding opioid abuse deterrence and has received FDA-approved product labeling that describes its abuse deterrent features, which allows us to promote those features and differentiate Xtampza ER from other opioid products containing the same active pharmaceutical ingredients. Because the FDA closely regulates promotional materials and other promotional activities, even though the FDA approved product labeling that includes a description of the abuse deterrent characteristics of Xtampza ER, the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the

commercial success of Xtampza ER. In addition, the April 2015 final FDA guidance on abuse-deterrent opioids is not binding law and may be superseded or modified at any time. Also, if the FDA determines that our post-marketing data do not demonstrate that the abuse-deterrent properties result in reduction of abuse, or demonstrate a shift to routes of abuse that present a greater risk, the FDA may find that product labeling revisions are needed, and potentially require the removal of our abuse-deterrence claims, which would have a material adverse effect on our ability to successfully commercialize Xtampza ER.

Failure to comply with ongoing governmental regulations for marketing any product, including Xtampza ER and the Nucynta Products, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.

Advertising and promotion of any product that has obtained approval in the United States, including Xtampza ER and the Nucynta Products, is heavily scrutinized by, among others, the FDA, the Department of Justice, the Office of Inspector General for the U.S. Department of Health and Human Services ("HHS"), state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies.

In the United States, engaging in off-label promotion of our products, can also subject us to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal 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 prevails in the lawsuit, the individual will share in any fines or settlement funds. False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth in recent years, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This increased focus and scrutiny 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 the Medicare, Medicaid and other federal and state healthcare programs.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our products, we could become subject to significant liability, which could materially adversely affect our business and financial condition.

In addition, later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. The failure to obtain or maintain requisite governmental approvals, or FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects, could delay or preclude us from further developing, marketing or realizing the full commercial potential of our products.

Risks Related to Intellectual Property

Unfavorable outcomes in intellectual property litigation could result in costly litigation and potentially limit our ability to commercialize our products.

Our commercial success depends upon our ability to commercialize products without infringing the intellectual property rights of others. Our current or future products, or any uses of them, may now or in the future infringe third-party patents or other intellectual property rights. This is due in part to the considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the United States and, to date, there is no consistency regarding the breadth of claims allowed in pharmaceutical patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be

asserted to be infringed by the manufacture, use and sale of our products. In part as a result of this uncertainty, there has been, and we expect that there will continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights.

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. We are aware of third-party patents and patent applications related to oxycodone formulations, including those listed in the FDA's Orange Book for oxycodone products. Because of the delay between filing and publication of patent applications, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Because of the uncertainty inherent in intellectual property litigation, we could lose, even if the case against us was weak or flawed.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing or commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, 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 products or force us to cease some of our business operations.

In connection with any NDA that we file under Section 505(b)(2), we are required to notify the patent holder of the reference listed drug that we identify in our NDA, that we have certified to the FDA that any patents listed for the listed drug in the FDA's Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our drug. If the patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months after the lawsuit is filed, expiration of the patents, settlement of the lawsuit and a court decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our products only to be subject to significant delay and patent litigation before our products may be commercialized.

If we are found by the court to have infringed a valid patent claim, we could be prevented from using the patented technology or be required to pay the patent holder for the right to license the patented technology. If we decide to pursue a license to use one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, such as Purdue, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

Even if we are found not to infringe or patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time consuming, and could delay the commercialization of our products and distract management from their normal responsibilities.

Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the United States, or litigation against our collaborators may be costly and time consuming and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. We expect that litigation may be necessary in some instances to determine the validity and scope of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation, including our pending litigation with Purdue, could compromise the validity and scope of our patents or other proprietary rights or hinder our ability to manufacture and market our products.

If we are unable to obtain or maintain intellectual property rights for our technologies, products or any future product candidates which we may develop, we may lose valuable assets or be unable to compete effectively in our market.

We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know-how, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights in the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking.

The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products identical, similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, our patent applications may not issue into patents, and any issued patents may not provide protection against competitive technologies, may be held invalid or unenforceable if challenged or may be interpreted in a manner that does not adequately protect our technology or future product candidates. Even if our patent applications issue into patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The examination process may require us to narrow the claims in our patents, which may limit the scope of patent protection that may be obtained. Our competitors may design around or otherwise circumvent patents issued to us or licensed by us.

The scope of patent protection in the United States is highly uncertain, and changes in U.S. patent law have increased that uncertainty and could diminish the value of patents in general, thereby impairing our ability to protect our products or future product candidates.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Changes in either the patent laws or interpretation of the patent laws in the United States may diminish the value of our patents or narrow the scope of our patent protection.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States typically are not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, in the United States, are highly uncertain.

Patent reform legislation could increase the uncertainties and costs associated with the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act (the “Leahy-Smith Act”), which was signed into law on September 16, 2011, made significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and litigated. Many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the “first to file” provisions described below, became

effective in 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Pursuant to the Leahy-Smith Act, the United States transitioned to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. In addition, third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office (the "USPTO"), and may become involved in opposition, derivation, reexamination, or inter partes review challenging our patent rights or the patent rights of others. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness and enablement. It is possible that prior art of which both we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, there may exist prior art of which we were or are aware, and which we did not or do not consider relevant to our patents, but which could nevertheless be determined to render our patents invalid. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could have a material adverse effect on our competitive position with respect to third parties.

Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or license from third parties may be challenged in the courts or patent offices in the United States. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and, may in some cases not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We may be forced to litigate to enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful, and result in the loss of valuable assets.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable or limited or narrowed in scope.

Further, this can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In addition, an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. 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 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 shares of our common stock.

We may not be responsible for or have control over the prosecution or enforceability of our licensed technology and have to rely on the licensor to enforce or defend our intellectual property.

In some cases, patent prosecution of our licenses is controlled solely by the licensor, like in certain circumstances under the Nucynta Commercialization Agreement. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual

property. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license prevent or impair our ability to maintain such licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products.

We may be subject to claims by third parties of ownership of what we regard as our own intellectual property or obligations to make compensatory payments to employees or others.

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 or obtaining such an agreement with each party who, in fact, develops intellectual property that we regard as our own. In addition, they may breach the assignment agreements or such agreements may not be self-executing, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. 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. 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 may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. 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. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may 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 in the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor, or those to whom they communicate with, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed, our competitive position would be harmed.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including potential competitors. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs, damage our reputation and be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, 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.

The USPTO requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO in several stages over the lifetime of the patents. 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, but are not limited to, 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 fail to maintain the patents and patent applications covering our products, our competitive position would be adversely affected.

Risks Related to the Commercialization of Our Products

If we are unable to successfully develop and utilize our own sales and marketing capabilities or enter into strategic alliances with marketing collaborators, we may not be successful in commercializing our products and may be unable to generate sufficient product revenue.

Our commercial organization continues to evolve, and in light of its short history and limited track record, we cannot guarantee that we will be successful in marketing our products that may be approved for marketing. In addition, we compete with other pharmaceutical and biotechnology companies with extensive and well-funded sales and marketing operations to recruit, hire, train and retain sales and marketing personnel. If we are unable to continue to grow and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. Factors that may inhibit our efforts to commercialize our products in the United States include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to reach adequate numbers of physicians who may prescribe our products; and
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization.

If we are not successful in recruiting and retaining sales and marketing personnel or in maintaining our sales and marketing infrastructure or if we do not preserve strategic alliances with marketing collaborators, agreements with contract sales organizations or collaboration arrangements, we will have difficulty commercializing our products.

If physicians, patients, healthcare payors and the medical community do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Physicians, patients, healthcare payors and the medical community may not accept and use our products. Acceptance and use of our products will depend on a number of factors including:

- the timing of market introduction of our products as well as the availability of competitive products;
- approved indications, warnings and precautions language that may be less desirable than anticipated;
- perceptions by members of the healthcare community, including physicians, about the safety and efficacy of our products;
- perceptions by members of the healthcare community, including physicians, about the relevance and efficacy of our abuse deterrent technology;
- the pricing and cost-effectiveness of our products relative to competing products;
- the potential and perceived advantages of our products over alternative treatments;
- the convenience and ease of administration to patients of our products;
- actual and perceived availability of coverage and reimbursement for our products from government or other third-party payors;
- any negative publicity related to our or our competitors' products;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA approved product labeling;
- FDA's and HHS's policy initiatives of regarding opioids;
- our ability to implement a REMS; and
- effectiveness of marketing and distribution efforts by us and any licensees and distributors.

If our products fail to have an adequate level of acceptance by physicians, healthcare payors, patients or the medical community, we will not be able to generate sufficient revenue to become or remain profitable. Since we expect to rely on sales generated by Xtampza ER and the Nucynta Products for substantially all of our revenues for the foreseeable future, the failure of Xtampza ER or the Nucynta Products to maintain market acceptance would harm our business prospects.

Our products contain and our future product candidates may contain controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies.

Our products contain and our future product candidates may contain, controlled substances that are subject to state and federal laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza ER's active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as Schedule II controlled substances under the CSA and regulations of the DEA. A number of states also independently regulate these drugs, including oxycodone and tapentadol, as controlled substances.

We and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state and federal law enforcement and regulatory agencies and comply with state and federal laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. In July 2018, the DEA published final guidelines strengthening the process for setting controls over diversion of controlled substances and making other improvements in the quota management regulatory system. For 2019, the DEA has proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas; and DEA has proposed further decreasing manufacturing quotas in 2020 five of the six opioids fentanyl, hydrocodone, hydromorphone, oxycodone, oxymorphone), by an average of 28%. Together with reductions in morphine, this is a 53% decrease since 2016. In October 2019, the DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. The proposed regulations will establish use-specific quotas, including commercial sales, product development, transfer, replacement, and packaging. To decrease the risk of diversion and increase accountability, inventory allowances will be reduced, and procurement quota certifications will be required. We may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand. If commercial demand for Xtampza ER, or any of our other approved products, increases and we cannot meet such demand in a timely fashion because of our limited supply of its active pharmaceutical ingredient (in the case of Xtampza ER, oxycodone) then physicians may perceive such product as unavailable and may be less likely to prescribe it in the future.

In addition, controlled substances are also subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of our products that include controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances.

Failure to obtain and maintain required registrations or to comply with any applicable regulations could delay or preclude us from developing and commercializing our products that contain controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of our products containing controlled substances.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our products and may reduce the prices we are able to obtain for our products.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system generally, and the manufacturing, distribution, and marketing of opioids in particular, that could prevent or delay marketing approval of future product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell our products for which we obtain marketing approval.

Effective July 2019, New York imposed an excise tax on the first sale of an opioid unit by a registrant in New York based on morphine milligram equivalents. In addition, in 2019 several other states, including Delaware, Minnesota, and Rhode Island, enacted laws that imposed similar taxes or fees on the sale of opioids. Other states could impose similar taxes or fees, and such laws and proposals can vary in the tax and fee amounts imposed and the means of calculation. Liabilities for taxes or assessments under any such laws could have an adverse impact on our results of operations.

Laws intended 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 may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing of our products 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.

On February 27, 2018, a bipartisan group of senators introduced Senate Bill 2456 (S.2456). S.2456 is characterized as "CARA 2.0," in reference to the Comprehensive Addiction and Recovery Act of 2016. CARA 2.0 would limit initial prescriptions for opioids to three days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 would also increase civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids. The bill would increase civil fines from $10,000 to $100,000, and if a manufacturer fails to maintain effective controls or report suspicious orders with knowledge or willful disregard, the bill would double criminal penalties from $250,000 to $500,000. If this bill were signed into law, it could adversely affect our ability to successfully commercialize our products. In addition, in 2017 several states, including Indiana, Louisiana, and Utah, enacted laws that further limit or restrict opioid prescriptions.

In October 2018, President Trump signed the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. Among other things, this legislation provides funding for research and development of non-addictive painkillers that could potentially compete with our products. It also clarifies FDA's authority to require that certain opioids be dispensed in packaging that limits their abuse potential, makes changes to Medicare and Medicaid in an effort to limit over-prescription of opioid painkillers, and increases penalties against manufacturers and distributors related to the over-prescription of opioids, including the failure to report suspicious orders and keep accurate records. The ultimate effect of this legislation is currently not known, but could potentially have a material adverse effect on our business.

In addition, state pharmacy laws may permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents, or may permit pharmacists and pharmacy benefit managers to seek prescriber authorization to substitute generics in place of our products, which could significantly diminish demand for them and significantly impact our ability to successfully commercialize our products and generate revenues.

Our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business. Such pricing regulations may address the rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products can vary widely. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Pricing limitations may hinder our ability to recoup our investment in our products.

Our ability to commercialize any product successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with discounts and rebates from list prices and are challenging the prices charged for medical products. We have agreed to provide such discounts and rebates to certain third-party payors. We expect increasing pressure to offer larger discounts and rebates. Additionally, a greater number of third-party payors may seek discounts and rebates in order to offer or maintain access for our products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory.

In January 2019, as part of its cost containment efforts for government-reimbursed prescription medications, HHS released a proposed rule that (1) eliminates federal anti-kickback statue safe harbor protection for rebates paid to prescription benefit managers; (2) creates a new safe harbor for discounts provided to beneficiaries at the point of sale; and (3) creates a new safe harbor for administrative fees paid by manufacturers to prescription benefit managers. The goal of the proposed safe harbor changes is to eliminate rebates from manufacturers to prescription benefit managers and replace them with point-of-sale discounts to beneficiaries. The proposed new rule only applies to Medicare, Medicare Advantage and Medicaid plans, not to private commercial insurance plans. The proposed regulation faces opposition from pharmacy benefit managers and others who do not believe it will have its intended effect of reducing overall costs to government beneficiaries. We cannot be sure whether the proposed rule will be adopted either in its current form or in an amended form, and do not know what impact the uncertainty will have on our agreements and relationships with pharmacy benefit managers and other pertinent parties. If the rule is finalized, we will likely be required to alter our agreements with these parties to come into compliance with the new rule, and it is uncertain what financial impact these alterations will have on our list prices, discounts, and reimbursement levels for our products

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. Moreover, eligibility for coverage and reimbursement does not imply that any 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 may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for our products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory efforts to combat abuse, could decrease the potential market for our products and may adversely impact external investor perceptions of our business.

Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Law enforcement and regulatory agencies may apply policies and guidelines that seek to limit the availability or use of opioids. Such efforts may inhibit our ability to commercialize our products.

Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse-resistant formulations; the ability of drug abusers to discover previously unknown ways to abuse opioid drugs, including Xtampza ER and the Nucynta Products; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for our products, decrease the revenues we are able to generate from their sale and adversely impact external investor perceptions of our business. Similarly, to the extent opioid abuse becomes less prevalent or less urgent of a public health issue, regulators and third party payers may not be willing to pay a premium for abuse-deterrent formulations of opioid.

Many state legislatures have enacted legislation intended to reduce opioid abuse, for example by establishing prescription drug monitoring programs and mandating prescriber education. The SUPPORT Act allows for sharing of this type of data across state lines. Efforts by the FDA and other regulatory and legislative bodies to combat abuse of opioids may negatively impact the market for our products. In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The plan identifies the FDA's focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA's plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the REMS requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic-abuse deterrent opioid formulations, and seeking input from the FDA's Science Board to broaden the understanding of the public risks of opioid abuse. The FDA's

Science Board met to address these issues on March 1, 2016. In November 2017, FDA issued a final guidance addressing approval standards for generic abuse-deterrent opioid formulations, which included recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. In September 2018, the FDA announced that IR opioid drugs will be subject to the same REMS as ER/LA opioids (now called the Opioid Analgesic REMS). One of the primary goals of the REMS is to ensure that the benefits of these drugs continue to outweigh the risks The FDA's plan is part of a broader initiative led by the HHS to address opioid-related overdose, death and dependence. The HHS initiative's focus is on improving physician's use of opioids through education and resources to address opioid over-prescribing, increasing use and development of improved delivery systems for naloxone, which can reverse overdose from both prescription opioids and heroin, to reduce overdose-related deaths, and expanding the use of Medication-Assisted Treatment, which couples counseling and behavioral therapies with medication to address substance abuse. As part of this initiative, the CDC has launched a state grant program to offer state health departments resources to assist with abuse prevention efforts, including efforts to track opioid prescribing through state-run electronic databases. In March 2016, as part of the HHS initiative, the CDC released a Guideline for Prescribing Opioids for Chronic Pain. The guideline is intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The guideline states that no treatment recommendations about the use of abuse-deterrent opioids can be made at this time. The SUPPORT Act, described above, also addresses opioid-related abuse by, among other things, seeking to increase access to and reimbursement for addiction treatment, advancing new initiatives to promote education and awareness of appropriate pain treatment among health care providers and improving coordination among federal agencies in relation to border checks.

The FDA continues to evaluate extended-release and abuse-deterrent opioids in the post-market setting. In March 2017, the FDA's Advisory Committee met to discuss OPANA ER (oxymorphone hydrochloride) extended-release tablets. A majority of the Advisory Committee voted that the benefits do not outweigh the risks of OPANA ER. Upon the FDA's subsequent request in June 2017, OPANA ER was removed from the market. Also, in July 2017, the FDA held a public workshop to discuss available data and methods to assess the impact of opioid formulations with abuse-deterrent properties on misuse, abuse, addiction, overdose, and death in the post-market context. The FDA will continue to scrutinize the impact of abuse-deterrent opioids and in the future could impose further restrictions to products currently on the market, which may include changing labeling, imposing additional prescribing restrictions, or seeking a product's removal from the market.

Recently, CVS Pharmacy announced it would only fill first-time opioid prescriptions for acute pain for a seven day supply. In July 2017, the Pharmaceutical Care Management Association, a trade association representing pharmacy benefit managers, wrote a letter to the commissioner of the FDA in which it expressed support for, among other things, the CDC guidelines and a seven-day limit on the supply of opioids for acute pain. In addition, states, including the Commonwealths of Massachusetts and Virginia and the States of New York, Ohio, Arizona, Maine, New Hampshire, Vermont, Rhode Island, Colorado, Wisconsin, Alabama, South Carolina, Washington and New Jersey, have either recently enacted, intend to enact, or have pending legislation or regulations designed to, among other things, limit the duration and quantity of initial prescriptions of immediate-release forms of opiates and mandate the use by prescribers of prescription drug databases and mandate prescriber education. FDA has announced that it will advance policies to require that immediate-release formulations of opioids be made available in fixed-quantity packaging- such as blister packs- to further encourage the writing of prescriptions for short durations for common acute pain conditions and procedures. Also, at the state and local level, a number of states and cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that market opioid pain medications. We are currently subject to such lawsuits and investigations, as discussed under the heading "Legal Proceedings" in this report. Many of these changes and others could cause us to expend additional resources in developing and commercializing our products to meet additional requirements. Advancements in development and approval of generic abuse-deterrent opioids could also compete with and potentially impact physician use of our products and cause our products to be less commercially successful.

If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products, our sales could decline.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active pharmaceutical ingredients, dosage form, strength, route of administration, and conditions of use, or product labeling, as our product and that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products. In November 2017, FDA issued a final guidance to assist industry in the development of generic versions of approved opioids with abuse-deterrent formulations, including recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. In the second half of 2018, the FDA posted three revised product-specific guidances related to generic abuse-deterrent opioid formulations, including one guidance specifically relating to Xtampza ER, which recommend specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of FDA's wider focus on assisting developers of generic abuse-deterrent formulations navigate the regulatory path to market more quickly. Earlier market entry of generic abuse-deterrent formulations could have a material adverse effect on our business.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products.

Risks Related to Our Dependence on Third Parties

If the third-party manufacturer of Xtampza ER fails to devote sufficient time and resources to Xtampza ER, or its performance is substandard, and/or we encounter challenges in completing our dedicated facility at our third-party manufacturer's site, our costs may be higher than expected and could have a material adverse effect on our business. Our commercialization partner also relies on sole suppliers to manufacture the Nucynta Products, which presents a similar risk.

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources and expertise to manufacture and test, on a commercial scale, the technical performance of Xtampza ER. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturers for our products, as well as other vendors to formulate, test, supply, store and distribute our products and we control only certain aspects of their activities. In 2016, we began to construct a dedicated facility for a portion of the Xtampza ER manufacturing process, at a site operated by our contract manufacturing organization, Patheon. This dedicated facility has required significant capital expenditures and, when operational, is likely to result in significantly increased fixed costs. This dedicated facility requires the maintenance of additional regulatory approvals and entails other costs, all of which we will need to absorb. We cannot guarantee that we will be able to successfully leverage the dedicated facility in a timely or profitable manner, or within the budget that we currently project. If the demand for Xtampza ER and any future related products never meets our expectations and forecasts, or if we do not produce the

output we plan, we may not be able to realize the return on investment we anticipated, which would have a negative impact on our financial condition and results of operations.
Although we have identified alternate sources for these services, it would be time-consuming, and require us to incur additional cost, to qualify these sources.

Our reliance on a limited number of vendors and, in particular, Patheon, Part of Thermo Fisher Scientific, as our single manufacturer for Xtampza ER, exposes us to the following risks, any of which could delay commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand (even after accounting for the increased capacity to be provided by the dedicated facility), may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment.

- Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of Xtampza ER and/or deliver the dedicated facility according to the currently agreed timeline.

- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of Xtampza ER, before we may use the alternative manufacturer to produce commercial supplies.

- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturer and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.

- If our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs.

Failure to obtain the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture Xtampza ER could adversely affect our ability to commercialize the product, which could in turn adversely affect our results of operations and financial condition. Certain components of Xtampza ER are naturally derived products, for which we rely on sole suppliers. The inability of any of our raw material suppliers to provide components that meet our specifications and requirements could adversely impact our ability to manufacture our product. Furthermore, the quota procurement process limits the amount of DEA-controlled active pharmaceutical ingredient we have available for manufacture. Consequently, we are limited in our ability to execute a business strategy that builds appreciable safety stock of finished drug product.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require that Xtampza ER to be manufactured according to cGMP. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to a shortage of commercial product. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

Our commercialization partner for the Nucynta Products, Assertio, currently relies on a single supplier to manufacture each of the Nucynta Products. Any stock out, or failure to obtain sufficient supplies of each of the Nucynta Products, or the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture each of the Nucynta Products, could adversely affect our ability to commercialize the Nucynta Products, which could in turn adversely affect our results of operations and financial condition. Assertio experienced delays in the manufacture, packaging and delivery of certain dosage strengths of Nucynta ER in the third and fourth quarters of 2017 and the first quarter of 2018 following Hurricanes Irma and Maria in Puerto Rico. We and our commercialization partner may continue to experience further outages in the future.

Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredient of our products, any production problems with our supplier could have a material adverse effect on us.

We presently depend upon a single supplier for the active pharmaceutical ingredient for Xtampza ER (oxycodone base) and the Nucynta Products (tapentadol) and we contract, either directly or indirectly through Assertio, with this supplier for commercial supply of our products. Although we have identified an alternate source for oxycodone base for Xtampza ER, it would be time-consuming and costly to qualify this source. Any changes executed by our supplier to the respective drug substance raw materials, intermediates, or manufacturing processes would introduce technical and regulatory risks to our downstream drug product supply. If our supplier were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs, we might incur substantial costs and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business.

Manufacturing issues may arise that could increase product and regulatory approval costs, delay commercialization or limit commercial supply.

In our current commercial manufacturing operations, and as we scale up manufacturing of our products and conduct required stability testing, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with our planned clinical trials, obtain regulatory approval for commercial marketing and build commercial supplies. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, failure to obtain or maintain approval or limitations in our commercial supply.

We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors, that loss may materially adversely affect our financial condition and results of operations.

A significant percentage of our product shipments are to a limited number of independent wholesale pharmaceutical distributors. Three of our wholesale pharmaceutical distributors represented 33%, 31% and 30% of our product shipments for the nine months ended September 30, 2019. The loss by us of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases , could have a material adverse effect on our business, results of operations, financial condition and prospects. The significance of each wholesale pharmaceutical distributor account to our business adversely impacts our ability to negotiate favorable commercial terms with each such distributor, and as a result, we may be forced to accept terms that adversely impact our results of operations.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot guarantee that we can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our products could be subject to post-marketing requirements, which requirements may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control.

Our products are subject to a comprehensive regulatory scheme, including post-marketing requirements ("PMRs") to conduct epidemiological studies and clinical trials. We intend to fulfill our PMRs by virtue of our participation in the Opioid PMR Consortium ("OPC"). Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of OPC and engage in decision-making as a member of that organization, but do not have a majority. If the OPC fails to conduct sufficiently rigorous studies or is unable to achieve the patient enrollment or other requirements established by the FDA, we may be unable to satisfy our PMRs and the FDA may choose to withdraw or otherwise restrict its approval of our products. Such withdrawal or restriction would have an adverse impact on our business and financial condition.

In the future, we may depend on collaborations with third parties for the development and commercialization of our products. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop or commercialize our products. These collaborations, including the Nucynta Commercialization Agreement, pose the following risks to us:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of our product or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon our product, repeat or conduct new clinical trials or require a new formulation of our product for clinical testing.
- Collaborators may fail to obtain necessary regulatory approval, conduct clinical trials inappropriately, or may obtain unfavorable results in their clinical trials, which may have an adverse effect on the development or commercialization of our product.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product 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.
- A collaborator with marketing and distribution rights to our products may not commit sufficient resources to the marketing and distribution of such products.
- Collaborators may 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 proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances specified in our collaborations.

- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products.

- Collaboration agreements may not lead to development or commercialization of products in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

- Our ability to successfully commercialize products pursuant to collaboration agreements may be adversely affected by disputes or delays arising from supply and/or manufacturing agreements between such collaborators and third parties—agreements to which we may not be a party.

We rely on third parties to conduct our non-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to maintain regulatory approval for our products and our business could suffer a material adverse effect.

We have relied upon and plan to continue to rely upon contract research organizations ("CROs") to monitor and manage data for our ongoing non-clinical and clinical programs. We rely on these parties for execution of our non-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are 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 and our CROs are required to comply with federal regulations and current good clinical practices ("GCP"), which are international standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, advisors and monitors, enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and foreign regulatory authorities in the form of International Conference on Harmonization guidelines for all of our products. We are also subject to GLP requirements for our non-clinical study programs. Regulatory authorities enforce GCP and GLP through periodic inspections of trial sponsors, principal investigators, trial sites and animal study sites. In addition, we and our CROs are required to comply with special regulations regarding the enrollment of recreational drug abusers in clinical trials. If we or any of our CROs fail to comply with applicable GCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our products may require us to repeat preclinical studies and clinical trials, which would have an adverse impact on our commercial efforts.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced 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 may not be able to obtain regulatory approval for our products. As a result, the commercial prospects for our products would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus, and there is a limited number of CROs that are equipped and willing to manage clinical trials that involve recreational drug abusers. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs,

there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our products through clinical trials will be compromised. 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, financial condition and prospects.

Risks Related to Our Business and Strategy

Litigation or regulatory action regarding opioid medications could negatively affect our business.

Beginning in 2018, lawsuits alleging damages related to opioids have been filed naming us as a defendant along with other manufacturers of prescription opioid medications. These lawsuits, filed in multiple jurisdictions, are brought by various local governments as well as private claimants, against various manufacturers, distributors and retail pharmacies throughout the United States. These lawsuits generally contend that we have engaged in improper marketing practices related to Xtampza ER. Plaintiffs seek a variety of remedies, including abatement, restitution, civil penalties, disgorgement of profits, treble damages, attorneys' fees and injunctive relief. In some of the lawsuits, the plaintiffs are seeking joint and several liability among the defendants. None of the complaints specify the exact amount of damages at issue. These cases are generally in early stages of litigation.

In addition, certain governmental and regulatory agencies are focused on the abuse of opioid medications, a concern we share, and we have received Civil Investigation Demands from three state attorneys general, investigating our sales and marketing of opioids and seeking documents relating to the manufacture, marketing and sale of opioid medications. We are cooperating fully in these investigations. Managing litigation and responding to governmental investigations is costly and may involve a significant diversion of management attention. Such proceedings are unpredictable and may develop over lengthy periods of time. An adverse resolution of any of these lawsuits or investigations may involve injunctive relief or substantial monetary penalties, either or both of which could have a material adverse effect on our reputation, business, results of operations and cash flows.

We face substantial competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing products more successfully than we do.

The competition in the pain and opioid market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Our products compete with oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Actavis, BioDelivery Sciences, Endo, Mallinckrodt, Pfizer, Purdue, Teva, and others. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that allow them to develop and commercialize their products before us and limit our ability to develop or commercialize our products. Our competitors may also develop drugs that are safer, more effective, more widely used and less costly than ours, and they may also be more successful than us in manufacturing and marketing their products.

Our competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our products. Our competitors may develop products that are safer, more effective or less costly than our products and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of currently available therapies with which our products compete may limit market acceptance of our products. Oral medications, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices are currently available treatments for chronic pain, are widely accepted in the medical community and have a long history of use. These treatments will compete with our products and the established use of these competitive products may limit the potential for our products to receive widespread acceptance.

Our future success depends on our ability to retain our key personnel.

We are highly dependent upon the services of our key personnel, including our President and Chief Executive Officer, Joseph Ciaffoni, our Chief Technology Officer, Alison Fleming, PhD, our Chief Financial Officer, Paul Brannelly, our Chief Commercial Officer, Scott Dreyer, our General Counsel, Shirley Kuhlmann, and our Chief Medical Officer, Dr. Richard Malamut. Each employee is employed by us at will and is permitted to terminate his or her employment with us at any time pursuant to the terms of his or her employment agreement. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of Mr. Ciaffoni, Dr. Fleming, Mr. Brannelly, Mr. Dreyer, Ms. Kuhlmann or Dr. Malamut could impede the achievement of our development and commercialization objectives.

If we are unable to attract and retain highly qualified employees, we may not be able to achieve future success.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our scientific, clinical, manufacturing and commercial employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized nature of our business, we rely heavily on our ability to attract and retain qualified personnel. The competition for qualified personnel in the pharmaceutical field is intense, and as a result, we may be unable to continue to attract and retain qualified personnel necessary to execute business or to recruit suitable replacement personnel.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, which could have a material adverse effect on our operating results, dilute our shareholders’ ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or businesses, in-licensing or out-licensing of products or technologies, or other strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We have limited experience with acquiring other companies, products or product candidates, and limited experience with licensing and forming strategic alliances and collaborations. We may not find suitable acquisition candidates, and if we make an acquisition, we may not integrate the acquisition successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to

find suitable strategic alliances or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions, licenses or collaborations, we may incur significant transaction expenses and we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common stock is low or volatile, we may not be able to acquire, license, or otherwise obtain rights to other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Commercial sales of our products and clinical trials of our products and any future product candidates may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all.

We currently carry product liability insurance. Product liability claims may be brought against us by patients, healthcare providers, others using, administering or selling our products or patients enrolled in our clinical trials. If we cannot successfully defend ourselves against claims that our products caused injuries, we could incur substantial liabilities. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any products;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- termination of clinical trial sites or entire trial programs;
- withdrawal of clinical trial participants;
- regulatory or legislative actions that significantly impact the opioid market;
- the inability to commercialize our products; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

Our inability to maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our products. Any agreements we may enter into in the future with collaborators in connection with the development or commercialization of our products may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, many of our agreements require us to indemnify third parties and these indemnification obligations may exceed the coverage under our product liability insurance policy.

Our products may be associated with undesirable adverse reactions or have other properties that could result in significant negative consequences.

Undesirable adverse reactions associated with our products could cause us, institutional review boards, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in a restrictive product label or the delay, denial or withdrawal of regulatory approval by the FDA. For example, even though Xtampza ER was generally well tolerated by patients in our clinical trials, in some cases there were adverse reactions, one of which was a serious adverse event, moderate in severity, of gastroesophageal reflux.

If we or others identify undesirable adverse events associated with our products, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of the product;
- regulatory authorities may withdraw their approvals of the product or impose restrictions on its distribution;
- regulatory authorities may require additional warnings or contradictions in the product label that could diminish the usage or otherwise limit the commercial success of the product;
- we may be required to conduct additional post-marketing studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our products.

Our employees, independent contractors, principal investigators, CROs, CMOs, wholesalers, distributors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, CMOs, wholesalers, distributors, consultants and vendors may engage in fraudulent conduct 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:

- FDA, DEA or similar regulations of foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by foreign regulatory authorities; or
- laws that require the reporting of financial information or data accurately.

In particular, 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. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Ethics, but it is not always possible to identify and deter misconduct by

employees and other third parties, and the precautions we take to detect and prevent this activity may 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 comply 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 material adverse effect on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

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

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of our products. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products and any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal False Claims Act, which imposes criminal and 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 or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute to defraud any healthcare benefit program or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal laws requiring drug manufacturers to report annually information related to certain payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership or investment interests held by physicians and their immediate family members, including under the federal Open Payments program, commonly known as the

Sunshine Act, as well as other state laws regulating marketing activities and requiring manufacturers to report marketing expenditures, payments and other transfers of value to physicians and other healthcare providers;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, potential liability for the failure to report such prices in an accurate and timely manner, and potentially limit our ability to offer certain marketplace discounts; and

- state equivalents of each of the above laws, including 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 payors, including private insurers; state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; and state laws governing the privacy and security of health 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.

While we do not submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support regarding our products to our customers and patients. If a government authority were to conclude that we provided improper advice to our customers and/or encouraged the submission of false claims for reimbursement, we could face action by government authorities. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

In connection with our research and development activities and our manufacture of materials and products, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development involves the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. We cannot eliminate the risk of contamination or injury from these materials. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We maintain insurance for environmental liability or toxic tort claims, but we may not continue to maintain such insurance in the future, and such insurance, to the extent maintained, may not be adequate to cover liabilities that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Our business and operations would suffer in the event of computer system failures, accidents or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our CROs, contract manufacturing organization and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks and other malfeasance, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercial and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our commercialization and drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization of our products could be delayed.

Changes in data privacy and protection laws and regulations, or any failure to comply with such laws and regulations, could adversely affect our business and financial results.

Legislators and regulators in the U.S. are proposing new and more robust cybersecurity rules in light of the recent broad-based cyberattacks at a number of companies. These initiatives could increase the cost of developing, implementing or securing our servers and require us to allocate more resources to improved technologies, adding to our information technology and compliance costs. In addition, enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. The enactment of more restrictive laws, rules, regulations, or future enforcement actions or investigations could impact us through increased costs or restrictions on our business, and noncompliance could result in regulatory penalties and significant legal liability.

Risks Related to Our Common Stock

The price of our common stock may be volatile and you may lose all or part of your investment.

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors, some of which are beyond our control. In addition to the factors discussed in these Risk Factors, these factors include:

- 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;
- the outcome of any patent infringement or other litigation that may be brought by or against us, including the ongoing Purdue and Teva litigation matters;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our products or those of our competitors;

- regulatory or legal developments in the United States;
- 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 our products or clinical development programs;
- actual or anticipated variations in our quarterly operating results;
- the number and characteristics of our efforts to in-license or acquire additional products;
- introduction of new products or services by us or our competitors;
- failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other shareholders;
- changes in accounting practices;
- significant lawsuits, including patent or shareholder litigation;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- publication of research reports about us, our competitors or our industry, or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and pharmaceutical and 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 our 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 stated above could have a material adverse effect on the market price of our common stock.

As we operate in the pharmaceutical and biotechnology industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Actual or potential sales of our common stock by our directors or employees, including our executive officers, pursuant to pre-arranged stock trading plans or otherwise could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by investors.

In accordance with the guidelines specified under Rule 10b5-1 of the Exchange Act and our policies regarding stock transactions, our directors and employees, including our executive officers, could adopt stock trading plans pursuant to which they may sell shares of our common stock from time to time in the future. Generally, sales under such plans by our executive officers and directors require public filings. Actual or potential sales of our common stock by such persons could cause our common stock to fall or prevent it from increasing for numerous reasons. For example, a substantial number of shares of our common stock becoming available (or being perceived to become available) for sale in the public market could cause the market price of our common stock to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by investors.

Future issuances 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 shareholders and could cause our stock price to fall.

Significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Our principal shareholders and management own a significant portion of our stock and have the ability to exert significant control over matters subject to shareholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant portion of our voting stock, including shares subject to outstanding options. As a result, if these shareholders were to choose to act together, they would be able to significantly influence the outcome of all matters requiring shareholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest. The interests of this group of shareholders may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. Such concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and/or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other shareholders may desire.

We are subject to anti-takeover provisions in our amended and restated articles of incorporation and amended and restated bylaws and under Virginia law that could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our shareholders.

Certain provisions of Virginia law, the state in which we are incorporated, and our amended and restated articles of incorporation and amended and restated bylaws could hamper a third party's acquisition of us, or discourage a third party from attempting to acquire control of us. These provisions include:

- a provision allowing our board of directors to set the terms of and issue preferred stock with rights senior to those of the common stock without any vote or action by the holders of our common stock. The issuance of preferred stock could adversely affect the rights and powers, including voting rights, of the holders of common stock;
- advance written notice procedures and notice requirements with respect to shareholder proposals and shareholder nomination of candidates for election as directors;
- a provision that only the board of directors, the chairman of the board of directors or the president may call a special meeting of the shareholders;
- the application of Virginia law prohibiting us from entering into certain transactions with the beneficial owner of more than 10 percent of our outstanding voting stock for a period of three years after such person first reached that level of stock ownership, unless certain conditions are met;
- a provision dividing our board of directors into three classes, each serving three-year terms;
- the requirement that the authorized number of our directors be changed only by resolution of our board of directors;
- a provision that our board of directors shall fill any vacancies on our board of directors, including vacancies resulting from a board of directors' resolution to increase the number of directors;
- limitations on the manner in which shareholders can remove directors from the board of directors;
- the lack of cumulative voting in the election of directors; and
- the prohibition on shareholders acting by less-than-unanimous written consent.

These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, these provisions make it more difficult for our shareholders to remove our board of directors or management or elect new directors to our board of directors.

We may fail to qualify for continued listing on The NASDAQ Global Select Market which could make it more difficult for investors to sell their shares.

Our common stock is listed on The NASDAQ Global Select Market ("NASDAQ"). As a NASDAQ listed company, we are required to satisfy the continued listing requirements of NASDAQ for inclusion in the Global Select Market to maintain such listing, including, among other things, the maintenance of a minimum closing bid price of $1.00 per share and shareholders' equity of at least $10.0 million. There can be no assurance that we will be able to maintain compliance with the continued listing requirements or that our common stock will not be delisted from NASDAQ in the future. If our common stock is delisted by NASDAQ, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;

- a determination that our shares are a "penny stock," which will require brokers trading in our shares to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares;

- a limited amount of news and analyst coverage for our company; and

- a decreased ability to issue additional securities or obtain additional financing in the future.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

As of December 31, 2018, we are no longer an "emerging growth company" and, as a result, are required to comply with increased disclosure and governance requirements.

As the market value of our common stock held by non-affiliates was greater than $700 million as of the last business day of the second quarter of 2018, we ceased to be an "emerging growth company" as defined in the JOBS Act as of December 31, 2018. As a large accelerated filer, we are subject to certain requirements that apply to other public companies but did not previously apply to us. These requirements include:

- the provisions of Section 404(b) of the 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 requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act; and
- the "say on pay" provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding stockholder 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.

Therefore, our Annual Reports are subject to Section 404(b) of the Sarbanes-Oxley Act, which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting. Compliance with Section 404 is expensive and time consuming for management and could result in the detection of internal control deficiencies of which we are currently unaware. The loss of "emerging growth company" status and compliance with the additional requirements substantially increases our legal and financial compliance costs and make some activities more time consuming and costly.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. We are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an

attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, 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, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations reflect the reality that judgments 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.

The exercise of options and warrants and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute your ownership interests and may adversely affect the future market price of our common stock.

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by those of our current shareholders may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

As of September 30, 2019, there were outstanding options to purchase an aggregate of 4,140,629 shares of our common stock at a weighted average exercise price of $15.81 per share, of which options to purchase - shares of our common stock were then exercisable. In addition, as of September 30, 2019, the Company had an outstanding warrant with Assertio to purchase 1,041,667 shares of our common stock at an exercise price of $19.20 per share. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

Any issuance of our common stock that is not made solely to then-existing shareholders proportionate to their interests, such as in the case of a stock dividend or stock split, will result in dilution to each shareholder by reducing his, her or its percentage ownership of the total outstanding shares. Moreover, if we issue options or warrants to purchase our common stock in the future and those options or warrants are exercised you may experience further dilution. Holders of shares of our common stock have no preemptive rights that entitle them to purchase their pro rata share of any offering of shares of any class or series.

We have broad discretion in the use of our cash and cash equivalents, and, despite our efforts, we may use them in a manner that does not increase the value of our shareholders' investment.

We have broad discretion in the use of our cash and cash equivalents, and investors must rely on the judgment of our management regarding the use of our cash and cash equivalents. Our management may not use cash and cash equivalents in ways that ultimately increase the value of our common stock. Our failure to use our cash and cash equivalents effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the commercialization of our products. We may invest our cash and cash equivalents in short-term or long-term, investment-grade, interest-bearing securities. These investments may not yield favorable returns. If we do not invest or apply our cash and cash equivalents in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our common stock to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our shareholders' sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our capital stock will be our shareholders' sole source of gain for the foreseeable future.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

RECENT SALES OF UNREGISTERED SECURITIES

There were no unregistered sales of equity securities during the period covered by this Quarterly Report on Form 10-Q.

PURCHASE OF EQUITY SECURITIES

The following table sets forth purchases of our common stock for the three months ended September 30, 2019:

Period	(a) Total number of shares purchased [1]	(b) Average Price Paid per Share	(c) Total number of shares purchased as part of publicly announced plans or programs	(d) Maximum number of shares that may yet be purchased under the plans or programs
July 1, 2019 through July 31, 2019	4,067	$ 12.26	-	-
August 1, 2019 through August 31, 2019	12,297	$ 11.27	-	-
September 1, 2019 through September 30, 2019	736	$ 12.44	-	-
Total	17,100	$ 11.56	-	-

(1) All of the shares were transferred to us from employees in satisfaction of minimum tax withholding obligations associated with the vesting of restricted stock units during the period.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Exhibit Description
31.1	Certification of Chief Executive Officer pursuant to Rules 13a- 14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer pursuant to Rules 13a- 14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from Collegium Pharmaceutical's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in Inline XBRL

SIGNATURES

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

COLLEGIUM PHARMACEUTICAL, INC.

Date: November 6, 2019

By: /s/ JOSEPH CIAFFONI
Joseph Ciaffoni
Chief Executive Officer
(Principal executive officer)

Date: November 6, 2019

By: /s/ PAUL BRANNELLY
Paul Brannelly
Chief Financial Officer
(Principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Ciaffoni, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Collegium Pharmaceutical, 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.

/s/ JOSEPH CIAFFONI

Joseph Ciaffoni
President and Chief Executive Officer

Date: November 6, 2019

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul Brannelly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Collegium Pharmaceutical, 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.

/s/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: November 6, 2019

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joseph Ciaffoni, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

/s/ JOSEPH CIAFFONI

Joseph Ciaffoni
President and Chief Executive Officer

Date: November 6, 2019

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Brannelly, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

/s/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: November 6, 2019