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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 June 30, 2018

OR

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

For the transition period from to

Commission file number: 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)
780 Dedham Street, Suite 800 Canton, MA	**02021**
(Address of principal executive offices)	(Zip Code)

(781) 713-3699

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☐ (Do not check if a smaller reporting company)	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 July 31, 2018, there were 33,221,704 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 obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our plans to commercialize and grow sales of our products;
- our ability to effectively commercialize in-licensed products and manage our relationships with licensors, including our ability to satisfy our royalty payment obligations in connection with such products;
- the size of the markets for our products and 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 product;
- the outcome of any patent infringement or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P. and Teva Pharmaceuticals USA, Inc.;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success, cost and timing of our product development activities, studies and clinical trials;
- our ability to obtain funding for our operations;
- regulatory developments in the United States and foreign countries;
- our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products and product candidates;
- our ability to operate our business without infringing the intellectual property rights of others;
- 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 product candidates;
- our ability to comply with stringent U.S. and foreign government regulations relating to the manufacturing and marketing of pharmaceutical products, including U.S. Drug Enforcement Agency, or DEA, compliance;
- the loss of key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- 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)

	June 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 133,747	$ 118,697
Accounts receivable	68,380	9,969
Inventory	8,544	1,813
Prepaid expenses and other current assets	5,622	3,005
Total current assets	216,293	133,484
Property and equipment, net	3,203	1,826
Intangible assets, net	453,694	—
Restricted cash	—	97
Other long-term assets	139	161
Total assets	$ 673,329	$ 135,568
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 18,692	$ 5,684
Accrued expenses	23,395	8,541
Accrued rebates, returns and discounts	107,790	15,784
Current portion of asset acquisition obligations	114,825	—
Current portion of term loan payable	—	1,479
Total current liabilities	264,702	31,488
Asset acquisition obligations, long-term	314,446	—
Term loan payable, long-term	11,500	—
Total liabilities	590,648	31,488
Commitments and contingencies (see Note 12)		
Shareholders' equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at June 30, 2018 and December 31, 2017; issued and outstanding shares - none at June 30, 2018 and December 31, 2017		—
Common stock, $0.001 par value; authorized shares - 100,000,000 at June 30, 2018 and December 31, 2017; issued and outstanding shares - 33,179,860 at June 30, 2018 and 32,770,678 at December 31, 2017	33	33
Additional paid-in capital	412,409	402,096
Accumulated deficit	(329,761)	(298,049)
Total shareholders' equity	82,681	104,080
Total liabilities and shareholders' equity	$ 673,329	$ 135,568

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 June 30,		Six months ended June 30,	
	2018	**2017**	**2018**	**2017**
Product revenues, net	$ 73,061	$ 3,560	$ 136,810	$ 5,732
Costs and expenses				
Cost of product revenues	46,838	577	89,944	948
Research and development	2,237	2,179	4,505	4,309
Selling, general and administrative	31,279	22,062	62,861	44,909
Total costs and expenses	80,354	24,818	157,310	50,166
Loss from operations	(7,293)	(21,258)	(20,500)	(44,434)
Interest expense	(6,158)	—	(11,858)	—
Interest income	391	137	646	235
Net loss	$ (13,060)	$ (21,121)	$ (31,712)	$ (44,199)
Loss per share - basic and diluted	$ (0.40)	$ (0.72)	$ (0.96)	$ (1.50)
Weighted-average shares - basic and diluted	32,967,718	29,441,514	32,935,873	29,396,143

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Six months ended June 30,	
	2018	**2017**
Operating activities		
Net loss	$ (31,712)	$ (44,199)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and other amortization expense	578	332
Nucynta amortization expense	61,933	—
Lease incentive obligation	—	(17)
Stock-based compensation expense	6,254	3,767
Non-cash interest expense	11,471	—
Changes in operating assets and liabilities:		
Accounts receivable	(58,411)	(2,748)
Inventories	(508)	(204)
Prepaid expenses and other assets	(608)	(1,083)
Accounts payable	13,008	(3,494)
Accrued expenses	13,917	1,074
Accrued rebates, returns and discounts	69,346	—
Deferred revenue	—	5,417
Net cash provided by (used in) operating activities	85,268	(41,155)
Investing activities		
Cash paid for asset acquisition	(18,877)	—
Purchases of property and equipment	(987)	(478)
Net cash used in investing activities	(19,864)	(478)
Financing activities		
Cash paid for common stock offerings costs	(30)	(87)
Proceeds from issuances of common stock from employee stock purchase plans	510	673
Proceeds from term loan amendment, net of repayment of amended term loan	10,020	—
Repayment of asset acquisition obligations	(64,500)	—
Repayment of term note	—	(1,333)
Proceeds from the exercise of stock options	3,905	415
Payments made for employee restricted stock tax withholdings	(356)	(51)
Net cash used in financing activities	(50,451)	(383)
Net increase (decrease) in cash, cash equivalents and restricted cash	14,953	(42,016)
Cash, cash equivalents and restricted cash at beginning of period	118,794	153,322
Cash, and cash equivalents and restricted cash at end of period	$ 133,747	$ 111,306
Supplemental disclosure of cash flow information		
Cash paid for offering costs	$ 30	$ 87
Cash paid for interest	$ 242	$ 88
Supplemental disclosure of non-cash activities		
Offering costs in accrued expenses	$ 25	$ 25
Acquisition of property and equipment in accrued expenses	$ 1,184	$ 304
Liabilities assumed from asset acquisition in accrued rebates, returns and discounts	$ 22,660	$ —

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 Canton, Massachusetts. The Company is a specialty pharmaceutical company focused on becoming the leader in responsible pain management by developing and commercializing innovative, differentiated products for people suffering from pain and our communities. The Company's first product, Xtampza ER®, or Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. In April 2016, the U.S. Food and Drug Administration ("FDA") approved the Company's new drug application ("NDA") filing for Xtampza 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.

In December 2017, the Company and its wholly owned subsidiary, Collegium NF, LLC ("Collegium NF") entered into a Commercialization Agreement with Depomed, Inc. ("Depomed"), pursuant to which Depomed agreed to grant a sublicense of certain of its intellectual property related to Nucynta ER and IR products (the "Nucynta Products") to the Company for commercialization of the Nucynta Products in the United States. On January 9, 2018, the parties amended the Commercialization Agreement (as amended, the "Commercialization Agreement") and consummated the transactions contemplated thereby. 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 in adults. The Company began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and began commercial promotion of the Nucynta Products in February 2018. The assets and liabilities assumed by the Company in connection with the Commercialization Agreement are further described in Note 7.

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 product candidates (including development of competing products), changing regulatory environment and reimbursement landscape, litigation related to opioid marketing and distribution practices, inability or delay in completing clinical trials or obtaining regulatory approvals, inability to secure adequate supplies of active pharmaceutical ingredients for each of our products and product candidates, key personnel retention and protection of intellectual property, patent infringement litigation and the availability of additional capital financing on terms acceptable to the Company.

The Company has experienced net losses and negative cash flows from operating activities since its inception, and, as of June 30, 2018 had an accumulated deficit of $329,761. The Company expects to continue to incur net losses in the near future. A successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure.

The Company believes that its cash and cash equivalents at June 30, 2018 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 financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States

("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 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 June 30, 2018, the results of operations for the three and six months ended June 30, 2018 and 2017, and cash flows for the six months ended June 30, 2018 and 2017. The results of operations for the six months ended June 30, 2018 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 utilized in the valuation of inventory, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, 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, 2017 (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.

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").

Under the ATM Sales Agreement, Cantor Fitzgerald may sell the ATM Shares by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on The NASDAQ Global Select Market, on any other existing trading market for the ATM Shares or to or through a market maker. In addition, under the ATM Sales Agreement, Cantor Fitzgerald may sell the ATM Shares by any other method permitted by law, including in privately negotiated transactions.

The Company is not obligated to make any sales of the ATM Shares under the ATM Sales Agreement. The Company or Cantor Fitzgerald may suspend or terminate the offering of ATM Shares upon notice to the other party and subject to other conditions. The Company will pay Cantor Fitzgerald a commission of up to 3.0% of the gross proceeds from the sale of the ATM Shares pursuant to the ATM Sales Agreement and has agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights.

As of June 30, 2018, the Company had sold an aggregate of 3,126,998 shares at an average gross sales price of $11.36 per share generating net proceeds of $34,283, after deduction of underwriting discounts and commissions and expenses payable by the Company. All shares sold pursuant to the ATM Sales agreement were sold during the year ended December 31, 2017. The Company did not sell any shares pursuant to the ATM sales agreement during the six months ended June 30, 2018.

Advertising and Product Promotion Costs

Advertising and product promotion costs are included in selling, general and administrative expenses and were $5,720 and $2,567 in the three months ended June 30, 2018 and 2017, respectively. Advertising and product promotion costs were $8,282 and $6,427 in the six months ended June 30, 2018 and 2017, respectively. Advertising and product promotion costs are expensed as incurred.

Restricted Cash

Restricted cash represents cash held in a depository account at a financial institution to collateralize a conditional stand-by letter of credit related to the Company's facility lease agreements. The Company no longer has restricted cash as of June 30, 2018.

Leases

In March 2018, the Company entered into a lease for its new corporate headquarters (the "Lease") pursuant to which the Company will lease approximately 50,678 of rentable square feet of space, in Stoughton, Massachusetts. The Lease will commence when the tenant improvements in the space are substantially complete and will continue thereafter for a term of ten years. The Company has the right to extend the term of the Lease for two additional five-year terms, provided that written notice is provided to the Landlord no later than twelve months prior to the expiration of the current Lease term. The initial 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 Lease years. The Lease term will commence upon possession of the new space. The Company expects to take possession of the new space in the third quarter of 2018.

Income Taxes

For the three and six months ended June 30, 2018 and 2017, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company. The Company's losses before income taxes consist solely of losses from domestic operations. As of June 30, 2018, the Company has recorded a full valuation allowance for deferred tax assets including net operating loss ("NOL") and tax credit carryovers. The Tax Cuts and Jobs Act of 2017 ("TCJA" or "2017 Tax Act"), which was signed into law in December 2017, resulted in significant changes to the U.S. corporate income tax system. The SEC staff issued Staff Accounting Bulletin ("SAB") 118, which allows companies the ability to record provisional amounts during a measurement period not to extend more than one year beyond the Tax Act enactment date. The Company reasonably estimated the effects of the 2017 Tax Act by remeasuring its federal net deferred tax asset as of December 31, 2017. For additional information related to the TCJA and its impact on the Company, please read Note 13, Income Taxes, in the Company's Annual Report. Since the Company has recorded a full valuation allowance, this provisional estimate resulted in no impact to the financial statements. As the Company completes its analysis of the 2017 Tax Act, collects and prepares necessary data, and interprets any additional guidance issued by the U.S. Treasury Department, the IRS, and other standard-setting bodies, it may be required to make adjustments to the original provisional estimate, however the Company has not made any material changes to its provisional estimates during the three and six months ended June 30, 2018. The Company plans to finalize its review and conclusion of the impact of TCJA before year end in accordance with SAB 118 and adjust its provisional estimates as may be required by the TCJA.

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.

In May 2014, the FASB issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition*, and creates a new Topic 606, *Revenue from Contracts with Customers*. In 2015, 2016 and 2017, the FASB issued additional ASUs related to Topic 606, including ASUs 2015-14, 2016-08, 2016-10, 2016-12, 2016-20, 2017-13, 2017-14, that delayed the effective date of and clarified various aspects of the new guidance, including principal versus agent considerations, identifying performance obligations, and licensing. The Company adopted ASC Topic 606, *Revenue from Contracts with*

Customers, on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. The adoption of ASU 2014-09 did not have an impact on the Company's consolidated financial position, results of operations, equity or cash flows as of the adoption date or for the three or six months ended June 30, 2018. Refer to Note 3 "Revenue from Contracts with Customers" for the required disclosures and a discussion of the Company's policies related to revenue recognition.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, and in November 2016, the FASB issued ASU 2016-18, *Restricted Cash*. The purpose of ASU 2016-15 is to reduce the diversity in presentation and classification of the following items within the Statement of Cash Flows: debt prepayments, settlement of zero coupon debt instruments, contingent consideration payments, insurance proceeds, securitization transactions and distributions from equity method investees. The update also addresses classification of transactions that have characteristics of more than one class of cash flows. ASU 2016-18 requires the Statement of Cash Flows to explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the Statement of Cash Flows. The Company adopted these new standards on January 1, 2018 using the retrospective transition method as required with respect to each period presented. The adoption of these standards did not have an impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. ASU 2016-02 most significantly impacts lessee accounting and disclosures. First, this guidance requires lessees to identify arrangements that should be accounted for as leases. Under ASU 2016-02, for lease arrangements exceeding a 12-month term, a right-of-use asset and lease obligation is recorded by the lessee for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and amortization/interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. Leases with a term of 12 months or less will be accounted for in a manner similar to existing guidance for operating leases. This guidance is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities. The Company has not chosen early adoption for this ASU and is currently evaluating its effect on the Company's consolidated financial statements. Based on its preliminary assessment, the Company expects to recognize a right-to-use asset and corresponding lease liability on its balance sheet related to the lease agreement for its corporate headquarters upon adoption of this ASU.

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 and retailers ("customers"), which in turn sell the product to pharmacies for the treatment of patients ("end users").

Revenue Recognition

In accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 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 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 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.

Adoption of ASC Topic 606, Revenue from Contracts with Customers

The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method. Under this method, prior periods were not retrospectively adjusted and, as a result, the reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC Topic 605, *Revenue Recognition* ("legacy GAAP").

Immediately prior to the adoption date of January 1, 2018, the Company recognized revenue in accordance with legacy GAAP, or when there was persuasive evidence of an arrangement; when title and risk of loss had passed to the customer; when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns were reasonably determinable; and when collectability was reasonably assured. The satisfaction of these criteria generally occurred upon delivery of products to customers, or the sell-in method of revenue recognition under legacy GAAP. The Company began recognizing revenue on the sell-in method in the third quarter of 2017. Prior to the third quarter of 2017, the Company recognized revenue when products were dispensed to end users, or the sell-through method of revenue recognition under legacy GAAP, as the Company did not have sufficient experience with product sales to estimate returns at the time product was sold to customers.

As a result of the considerations discussed above, the Company concluded that, as of the adoption date, it would record revenue net of a provision for estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns upon delivery of products to customers under either the sell-in method of revenue recognition under legacy GAAP or under Topic 606 as of the adoption date. Therefore, the adoption of Topic 606 did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows as of January 1, 2018, however, periods presented prior to the third quarter of 2017, when the Company recognized revenue on the sell-through method under legacy GAAP, would be impacted. For the three and six months ended June 30, 2017, the Company determined that, under Topic 606, the only significant changes to the reported results for the three and six months ended June 30, 2017 under Topic 606 would be higher product sales of $1,229 and $2,449, respectively, due to the acceleration of revenue recognition for product sales in which recognition was previously deferred due to the fees not being fixed or determinable under the sell-through method under legacy GAAP.

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 will expense 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 will estimate 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 six months ended June 30, 2018:

	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2017	$ 12,647	$ 3,137	$ 2,256
Provision related to current period sales	117,462	8,374	33,682
Changes in estimate related to prior period sales	(32)	—	—
Credits/payments made	(53,165)	(3,039)	(13,054)
Balance at June 30, 2018	$ 76,912	$ 8,472	$ 22,884

(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.

In addition to the above, the Company also recorded a liability of $22,660 related to sales of Nucynta Products that occurred prior to the closing date of January 9, 2018 which the Company is liable for under the terms of the Commercialization Agreement. This assumed liability, representing $22,406 of assumed rebates and incentives and $254 of assumed trade allowances and chargebacks, was recorded as a component of the intangible asset acquired as of the closing date of January 9, 2018.

As of June 30, 2018, 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 June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Xtampza	$ 18,116	$ 3,560	$ 33,911	$ 5,732
Nucynta	54,945	—	102,899	—
Total product revenues, net	$ 73,061	$ 3,560	$ 136,810	$ 5,732

4. Loss per Common Share

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

	Three months ended June 30,		Six months ended June 30,	
	June 30,		June 30,	
	2018	2017	2018	2017
Loss attributable to common shareholders — basic and diluted	$ (13,060)	$ (21,121)	$ (31,712)	$ (44,199)
Weighted-average number of common shares used in net loss per share - basic and diluted	32,967,718	29,441,514	32,935,873	29,396,143
Loss per share - basic and diluted	$ (0.40)	$ (0.72)	$ (0.96)	$ (1.50)

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 June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Outstanding stock options	3,665,459	3,124,039	3,665,459	3,124,039
Warrants	—	2,445	—	2,445
Unvested restricted stock (1)	12,072	57,228	12,072	57,228
Restricted stock units	522,190	223,194	522,190	223,194

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

5. Fair Value of Financial Instruments

Disclosures of fair value information about financial instruments are required, whether recognized in the Balance Sheet or not, 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

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at June 30, 2018 and December 31, 2017.

June 30, 2018	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	$ 121,877	$ 121,877	$ —	$ —
December 31, 2017				
Money market funds, included in cash equivalents	$ 81,225	$ 81,225	$ —	$ —

The Company's cash equivalents are comprised of money market funds that are measured on a recurring basis based on quoted market prices. As of June 30, 2018 and December 31, 2017, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, prepaid expenses and other current assets, intangible assets, accounts payable, accrued expenses, accrued rebates, returns and discounts, asset acquisition obligations and term loan payable approximated their estimated fair values.

In connection with the Commercialization Agreement for the Nucynta Products, the Company recorded a liability of $482,300 representing the fair value of the future minimum royalty payments owed under the terms of the Commercialization Agreement. The fair value of the minimum royalty payments was measured by calculating the present value of the minimum royalty payments using a discount rate of 5.7%. The discount rate is a Level 2 input which was based on a review of observable market data of similar liabilities. The liability associated with the future minimum royalty payments is included as a component of the intangible asset acquired and as a component of the obligations assumed in connection with the Commercialization Agreement, which is further described in Note 7.

6. Inventory

Inventory consisted of the following:

	As of June 30, 2018	As of December 31, 2017
Raw materials	$ 350	$ 616
Work in process	709	322
Finished goods	7,485	875
Total inventory	$ 8,544	$ 1,813

The aggregate charges related to excess inventory for the three and six months ended June 30, 2018 were immaterial. During the three and six months ended June 30, 2017, the aggregate charges related to excess inventory were $257 and $350, respectively. These expenses were recorded as a component of cost of product revenues.

7. Intangible Assets and Asset Acquisition Obligations

As of June 30, 2018, the Company's only intangible asset related to the Company's Commercialization Agreement with Depomed, pursuant to which Depomed agreed to grant a sublicense of certain of its intellectual property related to the Nucynta Products to the Company for commercialization of the Nucynta Products in the United States (the "Nucynta Intangible Asset"). The Company closed the transactions contemplated by the Commercialization Agreement, as amended, on January 9, 2018, and began marketing the Nucynta Products in February 2018.

Nucynta Intangible Asset

The Company determined that the Commercialization Agreement represented an asset acquisition, 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 or group. The consideration transferred in the asset acquisition was measured at cost, including transaction costs, assets transferred by the acquirer, and liabilities assumed by the acquirer.

The transaction resulted in the Company receiving the assets and assuming the liabilities noted below, which were recognized at cost as a component of intangible assets in the Condensed Consolidated Balance Sheets upon acquisition:

Cash paid for asset acquisition	$	18,877
Identifiable assets acquired and liabilities assumed:		
Intangible assets	$	515,627
Inventory		6,223
Prepaid expenses		1,987
Minimum royalty payments		(482,300)
Other liabilities		(22,660)
Total	$	18,877

The Company will amortize 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 is approximately 4.0 years from the closing date of January 9, 2018. The Company will recognize amortization expense as cost of product revenues in the Statement of Operations on a straight-line basis over its useful life as it approximates cash flows. For the three and six months ended June 30, 2018, the Company recognized amortization expense of $32,407 and $61,933, respectively. As of June 30, 2018, the remaining amortization period is approximately 3.5 years and estimated amortization for the remainder of 2018, 2019, 2020, and 2021 is expected to be $64,813, $129,627, $129,627, and $129,627, respectively.

As of June 30, 2018, the gross carrying amount and accumulated amortization of the Nucynta Intangible Asset were as follows:

		As of June 30, 2018
Gross carrying amount	$	515,627
Accumulated amortization		(61,933)
Intangible assets, net	$	453,694

Nucynta Asset Acquisition Obligations

From January 9, 2018 through December 2021, under the terms of the Commercialization Agreement, the Company will be required to pay a minimum royalty of $135,000 per year, payable in quarterly payments of $33,750, prorated in 2018 for the closing date of January 9, 2018. The total required minimum royalty payment from the closing date of January 9, 2018 through December 2021 is $537,000. Payments are swept to Depomed daily based on proceeds received for Nucynta Product sales, and minimum payments are paid in full within 45 days of the quarter end.

Due to the nature of the obligation and fact that it will be settled in cash, the Company determined that the minimum royalty payments represented a liability incurred at the closing of the transaction and that the liability should be recorded at its fair value as of the closing date on the Condensed Consolidated Balance Sheet. The Company calculated the fair value of the minimum royalty payments to be $482,300, which was the calculated present value of the minimum royalty payments using a discount rate of 5.7%. The discount rate was determined based on a review of observable market data of similar liabilities. The Company will recognize the $54,700 discount as interest expense in the Statement of Operations using the effective interest method and will recognize the interest over the repayment period from January 9, 2018 through December 2021.

For the three and six months ended June 30, 2018, the Company recognized interest expense of $5,943 and $11,471, respectively, relating to the minimum royalty payments. As of June 30, 2018, the remaining interest expense relating to the minimum royalty payments for the remainder of 2018, 2019, 2020, and 2021 is expected to be $10,912, $17,138, $10,907, and $4,272, respectively.

For the three and six months ended June 30, 2018, the Company paid Depomed minimum royalty payments of $51,455 and $64,500, respectively.

As of June 30, 2018, the remaining minimum royalty payments due under the Commercialization Agreement are as follows:

2018	$	67,500
2019		135,000
2020		135,000
2021		135,000
Total remaining minimum royalty payments due	$	472,500
Less: Unamortized discount		(43,229)
Carrying value of minimum royalty payments	$	429,271

Onsolis Intangible Asset

In May 2016, the Company entered into an agreement with BioDelivery Sciences International, Inc. ("BDSI") to license the rights to develop, manufacture, and commercialize Onsolis® (fentanyl buccal soluble film), ("Onsolis"), in the United States. Onsolis is a Transmucosal Immediate-Release Fentanyl ("TIRF") film indicated for the management of breakthrough pain in certain cancer patients.

During the year ended December 31, 2016, the Company made an upfront payment of $2,500 and recorded the payment as a component of intangible assets (the "Onsolis Intangible Asset"). On December 8, 2017, the Company, after a review of its product portfolio, provided written notice to BDSI of termination of the License and Development Agreement. The termination was effective pursuant to the terms of such agreement on March 8, 2018. Upon such termination of the License Agreement, the Company's rights to develop and commercialize Onsolis reverted to BDSI. As a result of this notice of termination, the Company determined that the carrying amount of the intangible asset was not recoverable and that the carrying amount exceeded its fair value. As such, an impairment loss of $1,845 was recognized and included as a component of sales, general and administrative expense during the year ended December 31, 2017 and the net intangible asset is zero as of June 30, 2018 and December 31, 2017.

Amortization Expense

Amortization expense relating to the Company's intangible assets for the three and six months ended June 30, 2018 and 2017 was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Nucynta amortization expense included in cost of product revenues	$ 32,407	$ —	$ 61,933	$ —
Onsolis amortization expense included in selling, general and administrative expense	—	47	—	177
Total amortization expense	$ 32,407	47	$ 61,933	177

8. Accrued Expenses

Accrued expenses consisted of the following:

	As of June 30, 2018	As of December 31, 2017
Accrued cost of product revenues	$ 14,540	$ —
Accrued bonuses	1,828	2,940
Accrued incentive compensation	1,643	1,790
Accrued other operating costs	1,433	877
Accrued payroll and related benefits	1,401	1,382
Accrued inventory	1,385	—
Accrued audit and legal	551	405
Accrued sales and marketing	259	624
Accrued development costs	202	517
Accrued interest	153	6
Total accrued expenses	$ 23,395	$ 8,541

9. Term Loan Payable

On August 28, 2012, the Company entered into a loan agreement ("Original Term Loan") with Silicon Valley Bank ("SVB") to borrow up to a maximum amount of $1,000. The Original Term Loan bore interest at a rate per annum of 2.25% above the prime rate fixed at the time of advance of the Original Term Loan (5.50%). The Original Term Loan was subsequently amended in 2014 and 2015 to provide for additional borrowings of up to $8,000, adjust the interest rate, extend the loan draw period, and modify loan covenants (as amended, the "Existing Term Loan"). As of December 31, 2017, the future payments under the Existing Term Loan were $1,479.

In connection with, and as a condition to, consummation of the transactions contemplated by the Commercialization Agreement with Depomed, 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 (the "New Term Loan"), which replaced the Existing Term Loan and the proceeds of which were used by the Company to finance certain payment obligations under the Commercialization Agreement and to repay the balance of the Existing Term Loan. The Consent and Amendment also provided SVB's consent with respect to transactions contemplated by the Commercialization Agreement, including the delivery by SVB of a standby letter of credit in an aggregate amount of $33,750.

The New Term Loan 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 New Term Loan in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in July 2019, provided that, if the Company achieves EBITDA (as defined in the Consent and Amendment) in excess of $2,500 for two (2) consecutive calendar quarters prior to June 2019, such payments will commence in January 2020. All outstanding principal and accrued and unpaid interest under the New Term Loan, and all other outstanding obligations with respect to the New Term Loan, are due and payable in full in December 2022. The Company may prepay the New Term Loan, 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. The Company is required to refinance the New Term Loan on August 31, 2018.

Under the New Term Loan, the Company will be required to maintain a liquidity ratio of at least 2.0 to 1.0. Any amounts outstanding during the continuance of any event of default under the New Term Loan will bear additional interest at the per annum rate of 5.0%.

As of June 30, 2018, scheduled principle repayments under the Company's term loan are as follows:

2018	$ —
2019	1,642
2020	3,286
2021	3,286
2022	3,286
Balance	$ 11,500

10. Equity

The changes in shareholders' equity for the six months ended June 30, 2018 were as follows:

	Common Stock		Additional Paid- In	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance, December 31, 2017	32,770,678	$ 33	$ 402,096	$ (298,049)	$ 104,080
Exercise of common stock options	321,406	—	3,905	—	3,905
Issuance for employee stock purchase plan	50,151	—	510	—	510
Vesting of restricted stock units	53,640	—	—	—	—
Shares withheld for employee taxes upon vesting of restricted stock units	(16,015)	—	(356)	—	(356)
Stock-based compensation	—	—	6,254	—	6,254
Net loss	—	—	—	(31,712)	(31,712)
Balance, June 30, 2018	33,179,860	$ 33	$ 412,409	$ (329,761)	$ 82,681

11. 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 June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Research and development expenses	$ 380	$ 242	$ 703	$ 451
Selling, general and administrative expenses	3,146	1,704	5,551	3,316
Total stock-based compensation expense	$ 3,526	$ 1,946	$ 6,254	$ 3,767

At June 30, 2018, there was approximately $34,073 of unrecognized compensation expense related to unvested options, restricted stock units and restricted stock awards, which is expected to be recognized as expense over a weighted average period of approximately 2.6 years.

Restricted Stock Awards, Restricted Stock 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 June 30, 2018, there were 1,139,189 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 and restricted stock units. The Company's equity awards 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.

In June 2018, the Company's board of directors approved a modification to the former President and Chief Executive Officer's equity-based awards to provide that all of those awards, to the extent unvested as of the Company's 2020 annual meeting of shareholders, will vest on such date, subject to his continued service on the Company's board of directors through such date. This modification was effective on June 4, 2018 and affected 116,250 shares of non-vested restricted stock units and 225,625 unvested stock options to purchase the Company's common stock. This modification did not create incremental value as the fair value of these awards was unchanged. The shorter requisite service period will result in the accelerated recognition of stock-based compensation expense through 2020.

A summary of the Company's restricted stock award activity for the six months ended June 30, 2018 and related information is as follows:

	Shares (1)	Weighted-Average Purchase Price per Share
Unvested at December 31, 2017	10,816	$ 5.73
Granted	—	—
Vested	(10,816)	5.73
Unvested at June 30, 2018	—	$ —

(1) Excludes activity from the early exercise of stock options. As of June 30, 2018, 12,072 shares of unvested restricted stock remain outstanding from the early exercise of stock options.

A summary of the Company's restricted stock units activity for the six months ended June 30, 2018 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2017	218,872	$ 12.64
Granted	360,858	23.62
Vested	(53,640)	12.57
Forfeited	(3,900)	21.00
Outstanding at June 30, 2018	522,190	$ 20.17

A summary of the Company's stock option activity and related information follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	3,037,690	$ 13.00	8.4	$ 16,829
Granted	1,045,662	24.17		
Exercised	(321,406)	12.15		
Cancelled	(96,487)	16.22		
Outstanding at June 30, 2018	3,665,459	$ 16.17	8.4	$ 29,126
Exercisable at June 30, 2018	1,312,351	$ 12.73	7.5	$ 14,588
Vested and expected to vest at June 30, 2018	3,408,606	$ 15.83	8.3	$ 28,146

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

	Six months ended June 30,	
	2018	2017
Risk-free interest rate	2.6 %	2.0 %
Volatility	65 %	71 %
Expected term (years)	6.11	6.02
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 our common stock on (1) the first day of the purchase period or (2) the last day of the purchase period. During the six months ended June 30, 2018, 50,151 shares of common stock were purchased for total proceeds of $510. The expense for the three months ended June 30, 2018 and 2017 was $120 and $108, respectively. The expense for the six months ended June 30, 2018 and 2017 was $242 and $214, respectively.

12. Commitments and Contingencies

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 Litigation

The Company filed the NDA for Xtampza 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 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. 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 will make its institution decision on or before October 10, 2018.

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 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 continues to assert infringement of five patents: the '497 patent, the '933 patent, the '717 patent, the '919 patent, and the '961 patent. None of these suits are associated with any stay of FDA approval for Xtampza. Purdue has made a demand for monetary relief but has not quantified their 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.

The parties are in the early stages of fact discovery. Written discovery has commenced with depositions expected to commence during the second half of 2018. A claim construction and summary judgment 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. At this time, the Motion for Summary Judgment, which asserted that claims of the '933, '497, and '717 patents are invalid and not infringed, remains pending. The Company is not able to predict with certainty when the Court will decide the Company's motion. The Scheduling Order has been amended to stay the close of fact discovery until after the Court decides our Motion for Summary Judgment. No trial date has been scheduled.

The Company is, and plans to continue, defending 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 Collegium NF and 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. The Company filed its answer to the Complaint on April 9, 2018. Purdue filed its answer to the Company's counterclaims on April 30, 2018. The Court adopted the parties' proposed scheduling order on June 6, 2018. Fact and expert discovery will close on October 9, 2019 and March 18, 2020, respectively. The Court scheduled trial for September 28, 2020.

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 fourteen 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 (the "Orange Book Patents").

Teva Pharmaceuticals USA, Inc. ("Teva") filed a Notice Letter of Patent Certification against twelve of the fourteen listed Orange Book Patents (the '598 and '729 patents were listed among the Orange Book Patents after receipt of Teva's Notice Letter), 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 have proposed a schedule and the court will hold a case management conference on July 23, 2018. According to the proposed schedule, fact discovery will close on July 30, 2019 and expert discovery will close on January 31, 2020.

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. The action alleges a variety of claims related to opioid marketing and distribution practices, including false advertising, deceptive trade practices, public nuisance, unjust enrichment, violations of state narcotics statutes and civil conspiracy. The suit seeks monetary penalties. The Company was served with the lawsuit on April 30, 2018.

On March 21, 2018, the Company and 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 relating to opioid marketing and distribution practices. On April 2, 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 and 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. The lawsuits allege violations of the RICO Act, fraud, public nuisance, negligence, and violations of state consumer protections laws. The lawsuits all seek, generally, penalties and/or injunctive relief. The MDL lawsuits in which the Company has been named are not designated 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. On June 12, 2018, a lawsuit was filed by Clinton County, Pennsylvania, against the Company and other pharmaceutical manufacturers and distributors. Both lawsuits allege claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws. The Company has not been served with either lawsuit.

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 the 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 focused on becoming the leader in responsible pain management by developing and commercializing innovative, differentiated products for people suffering from pain and our communities. Our first product, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. In April 2016, the U.S. Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, filing for Xtampza 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. Certain human abuse potential studies are included in the approved label, as well as data supporting the administration of the product as a sprinkle or administered through feeding tubes. In June 2016, we announced the commercial launch of Xtampza.

Xtampza has the same active ingredient as OxyContin OP, which is the largest selling abuse-deterrent, extended-release opioid in the United States by dollars, with $1.7 billion in U.S. sales in 2017. We conducted a comprehensive preclinical and clinical program for Xtampza consistent with FDA guidance on abuse-deterrence. These studies and clinical trials demonstrated, among other things, that chewing, and crushing Xtampza, 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 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 to include comparative oral pharmacokinetic data from the clinical study evaluating the effect of physical manipulation by crushing Xtampza 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.

In December 2017, we entered into a Commercialization Agreement with Depomed, Inc., or Depomed, pursuant to which Depomed agreed to grant us a sublicense of certain of its intellectual property related to Nucynta ER and Nucynta IR, or the Nucynta Products, for commercialization of such 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 in adults.

We closed the transactions contemplated by the Commercialization Agreement, as amended, on January 9, 2018, and we began marketing and commercially selling the Nucynta Products in February 2018.

Outlook

We expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities. We are promoting Xtampza to approximately 10,700 physicians who write approximately 60% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 150 sales representatives and sales managers. In addition, we deploy a separate, hospital focused sales team.

We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018, and we began commercial promotion of the Nucynta Products in February 2018. We are detailing the Nucynta Products to the same physicians to whom we detail Xtampza, leveraging our existing sales organization. We will pay a royalty to Depomed on all revenues from the sale of Nucynta Products based on certain net sales thresholds, with a minimum royalty of $135.0 million per year during the first four years of the Commercialization Agreement, with 2018 prorated for the closing of the transactions on January 9, 2018, subject to certain conditions. If Depomed or its contract manufacturers are unable to deliver a certain percentage of ordered quantities of the Nucynta Products for a period of two months or longer in calendar year 2018, then Depomed may be required to make a payment (or offset the minimum royalties) to ensure that we receive a minimum level of gross profit for 2018.

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $31.7 million and $44.2 million for the six months ended June 30, 2018 and 2017 respectively. As of June 30, 2018, we had an accumulated deficit of $329.8 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 Xtampza and the Nucynta Products. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase in connection with our ongoing activities as we:

- expand our promotional efforts for Xtampza and the Nucynta Products, including hiring additional personnel to expand our commercial organization;
- expand our regulatory and compliance functions;
- continue scale-up and improvement of our manufacturing processes;
- continue our research and development efforts;
- maintain, expand and protect our intellectual property portfolio;
- hire additional scientific and clinical personnel to support our product development efforts;
- implement operational, financial and management systems; and
- hire additional selling, general and administrative personnel to operate as a commercial stage public company.

We believe that our cash and cash equivalents at June 30, 2018 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, 2017, or Annual Report, relate to revenue recognition, inventory, impairment of long-lived assets, stock-based compensation and income taxes. We have also identified the accounting policy related to intangible assets as a critical accounting policy in the interim periods ended June 30, 2018. 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 have also identified the estimate of useful lives with respect to intangible assets as a significant estimate in the interim periods ended June 30, 2018. 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.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers,* or ASC 606 using the modified retrospective method. Under this method, prior periods were not retrospectively adjusted. As a result, the reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC Topic 605, *Revenue Recognition* ("legacy GAAP").

Immediately prior to the adoption date of January 1, 2018, we recognized revenue in accordance with legacy GAAP, or when there was persuasive evidence of an arrangement; when title and risk of loss had passed to the customer; when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns were reasonably determinable; and when collectability was reasonably assured. The satisfaction of these criteria generally occurred upon delivery of products to customers, or the sell-in method of revenue recognition under legacy GAAP. We began recognizing revenue on the sell-in method in the third quarter of 2017. Prior to the third quarter of 2017, we recognized revenue when products were dispensed to end users, or the sell-through method of revenue recognition under

legacy GAAP, as we did not have sufficient experience with product sales to estimate returns at the time product was sold to customers.

We concluded that, as of January 1, 2018, we would record revenue net of a provision for estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns upon delivery of products to customers, as we have been under legacy GAAP since the third quarter of 2018, under either the sell-in method of revenue recognition under legacy GAAP or under ASC 606 as of the adoption date. Therefore, the adoption of ASC 606 did not have a material impact on our consolidated financial position, results of operations, equity or cash flows as of January 1, 2018.

RESULTS OF OPERATIONS
(in thousands)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Product revenues, net	$ 73,061	$ 3,560	$ 136,810	$ 5,732
Cost of product revenues	46,838	577	89,944	948
Research and development	2,237	2,179	4,505	4,309
Selling, general and administrative	31,279	22,062	62,861	44,909
Interest expense	(6,158)	—	(11,858)	—
Interest income	391	137	646	235
Net loss	$ (13,060)	$ (21,121)	$ (31,712)	$ (44,199)

Comparison of the three months ended June 30, 2018 and June 30, 2017

Product revenues, net were $73.1 million for the three months ended June 30, 2018, or the 2018 Quarter, compared to $3.6 million for the three months ended June 30, 2017, or the 2017 Quarter. The $69.5 million increase was primarily related to the Commercialization Agreement with Depomed consummated in January 2018 to sublicense the Nucynta Products. In the 2018 Quarter, Nucynta IR and ER product revenues, net were $34.2 million and $20.8 million, respectively. In addition, Xtampza product revenues, net were $18.1 million in the 2018 Quarter, which represents a $14.5 million increase compared to the 2017 Quarter. The increase in Xtampza product revenues, net was primarily due to an increase in sales volume due to increasing demand.

Cost of product revenues was $46.8 million for the 2018 Quarter, compared to $577,000 for the 2017 Quarter. The $46.2 million increase was primarily related to $32.4 million of amortization expense associated with the intangible asset related to the Commercialization Agreement for the Nucynta Products. The remaining increase was primarily related to increased product revenues in the 2018 Quarter.

Research and development expenses were $2.2 million for the 2018 Quarter, compared to $2.2 million for the 2017 Quarter. In the 2018 Quarter, salaries, wages and benefits increased $178,000, primarily due to increases in employee headcount, including an increase in stock-based compensation expense, offset by a $202,000 decrease in manufacturing costs relating to Onsolis.

Selling, general and administrative expenses were $31.3 million for the 2018 Quarter, compared to $22.1 million for the 2017 Quarter. The $9.2 million increase was primarily related to:

- an increase in salaries, wages and benefits of $3.1 million, primarily due to an increase in employee headcount, including an increase in stock-based compensation expense, of $1.4 million, and incentive compensation;
- an increase in commercialization costs, including consulting and marketing expenses, of $3.1 million primarily related to the Nucynta Products and continued support of Xtampza;
- an increase in audit, legal, and other professional fees of $1.2 million;
- an increase in regulatory costs, including consulting and subscriptions, of $753,000 primarily due to the acquisition of the Nucynta Products; and
- an increase in PDUFA related expenses of $733,000, primarily due to the acquisition of the Nucynta Products.

Interest expense was $6.2 million for the 2018 Quarter, compared to none in the 2017 Quarter. The increase was primarily due to an increase of $5.9 million in interest expense associated with the minimum royalty payments related to the Commercialization Agreement for Nucynta, which was entered into in the 2018 Quarter, and interest expense on our term loan of $215,000.

Interest income was $391,000 for the 2018 Quarter, compared to $137,000 in the 2017 Quarter. The increase was primarily due to higher interest rates on money market funds.

Comparison of the six months ended months June 30, 2018 and June 30, 2017

Product revenues, net were $136.8 million for the six months ended June 30, 2018, or the 2018 Period, compared to $5.7 million for the six months ended June 30, 2017, or the 2017 Period. The $131.1 million increase was primarily related to the Commercialization Agreement with Depomed consummated in January 2018 to sublicense the Nucynta Products. In the 2018 Period, Nucynta IR and ER product revenues, net were $61.4 million and $41.5 million, respectively. In addition, Xtampza product revenues, net were $33.9 million in the 2018 Period, which represents a $28.2 million increase compared to the 2017 Period. The increase in Xtampza product revenues, net was primarily due to an increase in sales volume due to increasing demand.

Cost of product revenues were $89.9 million for the 2018 Period, compared to $948,000 for the 2017 Period. The $89.0 million increase was primarily related to $61.9 million of amortization expense associated with the intangible asset related to the Commercialization Agreement for the Nucynta Products. The remaining increase was primarily related to increased product revenues in the 2018 Period.

Research and development expenses were $4.5 million for the 2018 Period, compared to $4.3 million for the 2017 Period. The $200,000 increase was primarily due to increases in employee headcount, including an increase in stock-based compensation expense.

Selling, general and administrative expenses were $62.9 million for the 2018 Period, compared to $44.9 million for the 2017 Period. The $18.0 million increase was primarily related to:

- an increase in salaries, wages and benefits of $6.9 million, primarily due to increases in employee headcount, including an increase in incentive compensation and stock-based compensation expense;
- an increase in sales and marketing costs of $3.5 million, primarily related to the Nucynta Products and continued support of Xtampza;
- an increase in audit, legal, and other professional fees of $1.8 million;
- an increase in PDUFA related expenses of $1.6 million, primarily due to the acquisition of the Nucynta Products;
- an increase in regulatory costs, including consulting and subscriptions, of $1.5 million, primarily due to the acquisition of the Nucynta Products; and
- an increase in insurance expense of $1.0 million, primarily due to an increase in product liability insurance.

Interest expense was $11.9 million for the 2018 Period, compared to none in the 2017 Period. The increase was primarily due to an increase of $11.5 million in interest expense associated with the minimum royalty payments related to the Commercialization Agreement for Nucynta, which was entered into in the 2018 Period, and interest expense on our term loan of $393,000.

Interest income was $646,000 for the 2018 Period, compared to $235,000 in the 2017 Period. The increase was primarily due to higher interest rates on money market funds.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We have incurred net losses and negative cash flows 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 June 30, 2018, we had $133.7 million in cash and cash equivalents.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents at June 30, 2018 together with expected cash inflows from the commercialization of our products, will enable the us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

Equity Financing

In March 2017, we commenced an "at-the-market" offering of our common stock and entered into a Controlled Equity Offering Sales Agreement (the "ATM Sales Agreement") with Cantor Fitzgerald, as agent, pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $60.0 million. As of June 30, 2018, we sold an aggregate of 3,126,998 shares of common stock under the ATM Sales Agreement at an average gross sales price of $11.36 per share generating net proceeds of $34.3 million, after deduction of underwriting discounts and commissions and expenses payable by us, all of which were sold during the year ended December 31, 2017. We did not sell any shares pursuant to the ATM Sales Agreement during the three and six months ended June 30, 2018.

Silicon Valley Bank Term Loan Facility

Since August 2012, we have maintained a term loan facility with Silicon Valley Bank ("SVB"), which was amended in connection with, and as a condition to, consummation of the transactions contemplated by the Commercialization Agreement. Under the amended term loan, we now have a term loan facility in an amount of $11.5 million, or the New Term Loan, which replaces our previously existing term loan facility. The proceeds of the New Term Loan were used to finance certain payment obligations under the Commercialization Agreement and to repay the balance of the previously existing term loan. The New Term Loan also provided SVB's consent with respect to transactions contemplated by the Commercialization Agreement, including the delivery by SVB of a standby letter of credit in an aggregate amount of $33.8 million.

The New Term Loan bears interest at a rate per annum of 0.75% above the prime rate (as defined in the agreement governing the New Term Loan). We will repay the New Term Loan in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in July 2019, provided that, if we achieve EBITDA (as defined in the agreement governing the New Term Loan) in excess of $2.5 million for two consecutive calendar quarters prior to June 2019, such payments will commence in January 2020. All outstanding principal and accrued and unpaid interest under the New Term Loan, and all other outstanding obligations with respect to the New Term Loan, are due and payable in full in December 2022. We may prepay the New Term Loan, in full but not in part, with a prepayment fee of (i) 3.0% of the outstanding principal balance prior to January 2019, (ii) 2.0% of the outstanding principal balance following January 2019 and prior to January 2020 and (iii) 1.0% of the outstanding principal balance following January 2020, plus, in each case, a final payment fee of $719.

Under the New Term Loan, we will be required to maintain a liquidity ratio of at least 2.0 to 1.0. Any amounts outstanding during the continuance of any event of default under the New Term Loan will bear additional interest at the per annum rate of 5.0%.

Cash Flows

	Six months ended June 30, 2018	2017
Net cash provided by (used in) operating activities	$ 85,268	$ (41,155)
Net cash used in investing activities	(19,864)	(478)
Net cash used in financing activities	(50,451)	(383)

Operating activities. Cash provided by operating activities was $85.3 million in the 2018 Period, compared to cash used by operating activities of $41.2 million in the 2017 Period. The increase in cash provided by operating activities was primarily due to (i) the non-cash impact of the Commercialization Agreement with Depomed in the 2018 Period, including $61.9 million of amortization expense from the intangible asset and non-cash interest expense associated with the minimum royalty payments of $11.5 million; and (ii) a benefit from changes in the working capital accounts. We expect cash provided by operating activities to increase for the foreseeable future as we continue to commercialize our products and fund research, development and clinical activities for additional product candidates.

Investing activities. Cash used in investing activities was $19.9 million in the 2018 Period, compared to $478,000 used in the 2017 Period. The increase in cash used in investing activities was primarily due to $18.9 million paid to Depomed for the Nucynta asset acquisition.

Financing activities. Cash used in financing activities was $50.5 million for the 2018 Period, compared to $383,000 used in the 2017 Period. The increase in cash used by financing activities was primarily due to an increase in cash used in the repayment of minimum royalty payments associated with the Commercialization Agreement for the Nucynta Products of $64.5 million, offset by an increase in proceeds received from our term loan, which was amended in the 2018 Period, of $10.0 million, and an increase in proceeds received from the exercise of stock options of $3.9 million. The remaining change is primarily due to higher payments made for employee restricted stock tax withholdings.

Funding Requirements

We believe that our cash and cash equivalents at June 30, 2018 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 Management 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 or product candidates. 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 the sale of Xtampza and Nucynta Products;
- the cost of growing and maintaining sales, marketing and distribution capabilities for Xtampza, the Nucynta Products and any other products we may acquire or develop;

- the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities 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) Xtampza and the Nucynta Products, for commercial sale and clinical trials, and (2) our product candidates for preclinical studies, clinical trials and, if approved, for commercial sale;
- the cost of patent infringement litigation, including our litigation with each of Purdue and Teva, relating to Xtampza, the Nucynta Products or our product candidates, which may be expensive to defend;
- the cost of litigation related to opioid marketing and distribution practices;
- the cost of implementing additional infrastructure and internal systems and hiring additional employees to operate as a commercial stage public company;
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

If we cannot expand our operations or otherwise 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 U.S. generally accepted accounting principles, or GAAP, basis, we have included information about non-GAAP adjusted loss. We internally use non-GAAP adjusted loss to understand, manage and evaluate the Company as we believe it represents the performance of our core business. Because this non-GAAP 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 measure in order to portray the results of our major operations – developing and 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. Non-GAAP adjusted loss is not based on any standardized methodology prescribed by GAAP and represents GAAP net 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 to Depomed in connection with the 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
GAAP net loss	$ (13,060)	$ (21,121)	$ (31,712)	$ (44,199)
Non-GAAP adjustments:				
Stock-based compensation expense	3,526	1,946	6,254	3,767
Nucynta related amortization expense (1)	32,407	-	61,933	-
Nucynta non-cash interest expense (2)	5,943	-	11,471	-
Nucynta minimum royalty payment due (3)	(33,750)	-	(64,500)	-
Total non-GAAP adjustments	$ 8,126	$ 1,946	$ 15,158	$ 3,767
Non-GAAP adjusted loss	$ (4,934)	$ (19,175)	$ (16,554)	$ (40,432)

	First Quarter 2018	Second Quarter 2018
GAAP net loss	$ (18,652)	$ (13,060)
Non-GAAP adjustments:		
Stock-based compensation expense	2,728	3,526
Nucynta related amortization expense (1)	29,526	32,407
Nucynta non-cash interest expense (2)	5,528	5,943
Nucynta minimum royalty payment due (3)	(30,750)	(33,750)
Total non-GAAP adjustments	$ 7,032	$ 8,126
Non-GAAP adjusted loss	$ (11,620)	$ (4,934)

(1) Represents amortization expense of the Nucynta intangible asset.

(2) Represents non-cash interest expense recognized related to the Nucynta minimum royalty payments.

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

CONTRACTUAL OBLIGATIONS

In March 2018, we entered into an Office Lease (the "Lease") with Campanelli-Trigate 100TCD Stoughton, LLC (the "Landlord"), pursuant to which we will lease approximately 50,678 of rentable square feet of space, in Stoughton, Massachusetts. The Lease will commence when the tenant improvements in the space are substantially complete and will continue thereafter for a term of ten years. We have the right to extend the term of the Lease for two additional five- year terms, provided that written notice is provided to the Landlord no later than twelve months prior to the expiration of the initial term of the Lease. The initial 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 Lease years. The Lease term will commence upon possession of the new space. We expect to take possession of the new space in the third quarter of 2018.

There have been no other material changes to the contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our last Quarterly 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, 2017.

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 June 30, 2018. 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 June 30, 2018, 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 12 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

We currently generate limited revenue from the sale of products and may never become profitable. Our ability to generate additional revenue and become profitable is dependent upon our ability to develop, license or acquire, and commercialize Xtampza, the Nucynta Products and any other products and product candidates on a timely basis, and to address all regulatory requirements applicable to the development and commercialization of our products and 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, in June 2016 and assumed responsibility for the sales and marketing of the Nucynta Products in January 2018, and in each case have generated limited revenue from product sales. Our ability to generate additional revenue and become profitable depends upon our ability to successfully commercialize Xtampza, the Nucynta 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 and product candidates depends on a number of factors, including our ability to:

- successfully commercialize Xtampza and the Nucynta Products;
- successfully satisfy FDA post-marketing requirements for Xtampza and the Nucynta 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 Xtampza and the Nucynta Products;
- set a commercially viable price for Xtampza and the Nucynta 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 ourselves in the markets in which we have retained or acquired commercialization rights;
- find suitable distribution collaborators to help us market, sell and distribute our products, if approved, in markets outside the United States;
- obtain coverage and adequate reimbursement from third parties, including government payors;
- successfully complete development activities, including the necessary clinical trials, with respect to our product candidates;

- complete and submit regulatory submissions to the FDA and obtain regulatory approval for our product candidates; 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, including that we may not successfully commercialize our products or that our product candidates may not advance through development or achieve the safety and efficacy endpoints of applicable clinical trials, 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. Furthermore, we anticipate incurring significant costs associated with commercializing our products and, if regulatory approval is obtained, our product candidates.

Even though we are generating revenues from the sale of our products currently, 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 product candidates.

Our operations have consumed substantial amounts of cash. We believe that our cash and cash equivalents at June 30, 2018 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 Management 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 or the commercialization of Xtampza, our product candidates or one or more of our other research and development initiatives;

- delay, scale back or discontinue the commercialization of the Nucynta Products;

- seek collaborators for Xtampza and/or one or more of our 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 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 reasonable levels of revenue from the sale of Xtampza and the Nucynta Products;

- the cost of growing and maintaining sales, marketing and distribution capabilities for Xtampza, the Nucynta Products and any other products we may acquire or develop;

- the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities 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) Xtampza and the Nucynta Products, for commercial sale and clinical trials, and (2) our product candidates for preclinical studies, clinical trials and, if approved, for commercial sale;
- the cost of patent infringement litigation, including our litigation with each of Purdue and Teva, relating to Xtampza, the Nucynta Products or our product candidates, which may be expensive to defend;
- the cost of litigation related to opioid marketing and distribution practices;
- the cost of implementing additional infrastructure and internal systems and hiring additional employees to operate as a commercial stage public company;
- 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 Xtampza, the Nucynta Products, our technologies or product candidates.

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 Xtampza, the Nucynta Products, or our product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing 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. 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. We are currently in the early years of operating as a commercial stage company, and although we have expanded our product portfolio to include Xtampza and the Nucynta Products, 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.

The Commercialization Agreement with Depomed, pursuant to which we assumed responsibility for the sales and marketing of the Nucynta Products, requires us to pay significant royalties, some of which are payable whether or not our commercialization efforts are successful. Such licensing fees may adversely affect our cash flow and our ability to operate our business and our prospects for future growth.

In December 2017, we entered into the Commercialization Agreement, pursuant to which we assumed responsibility for the sales and marketing of the Nucynta Products. We closed the transactions contemplated by the Commercialization Agreement, as amended, on January 9, 2018, and we began marketing the Nucynta Products in February 2018. During the term of the Commercialization Agreement and through December 31, 2021, we are required to pay to Depomed a minimum annual royalty of $135.0 million paid quarterly in arrears, plus double-digit royalties on net sales of Nucynta Products in excess of $233.0 million per year. Beginning January 1, 2022 and for each year of the Commercialization Agreement term thereafter, we are required to pay double-digit royalties on all net sales of Nucynta Products. If our commercialization efforts of the Nucynta Products are unsuccessful, there can be no assurance that we will have sufficient cash flow to pay such licensing fees.

Our obligation to Depomed to pay such licensing fees could:

- make it more difficult for us to satisfy obligations with respect to our indebtedness, and any failure to comply with the obligations of any of our debt instruments, including financial and other restrictive covenants, could result in an event of default under the agreements governing such indebtedness;
- require us to dedicate a substantial portion of available cash flow to pay licensing fees, which will reduce the funds available for working capital, capital expenditures, acquisitions and other general corporate purposes;
- limit flexibility in planning for and reacting to changes in our business and in the industry in which we operate;
- limit our ability to engage in strategic transactions or implement our business strategies;
- limit our ability to borrow additional funds; and
- place us at a disadvantage compared to our competitors.

Any of the factors listed above could materially and adversely affect our business and our results of operations. If we do not have sufficient cash flow to pay the licensing fees under the Commercialization Agreement, we may be required to terminate the Commercialization Agreement, sell assets, borrow money or sell securities, none of which we can guarantee we will be able to do on favorable terms, if at all.

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

As of December 31, 2017, we had a federal net operating loss, or NOL, carryforward of approximately $249.5 million and state NOL carryovers of approximately $205.1 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 $3.4 million, and state tax credits of approximately $589,000. 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 (Code), or Section 382.

The 2017 Tax Cuts and Jobs Act, or TCJA, generally will allow losses incurred after 2017 to be carried over indefinitely, but limits the NOL deduction to the lesser of the NOL carryover or 80% of a corporation's taxable income (subject to Sections 382 and 383 of the Code and other conditions). Also, there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 will generally be deductible to the extent of the lesser of a corporation's NOL carryover or 100% of a corporation's taxable income and be available for twenty years from the period the loss was generated. We have not finalized our review of the impact of TCJA on the NOL rules, and the impact, if any, to our ability to utilize and carryover net operating losses.

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, 2017 and 2016, we have provided a full valuation allowance for deferred tax assets including NOL and tax credit carryovers.

We have been and may be the subject of litigation matters, including government investigations, for which we may be unable to obtain or maintain insurance adequate to cover potential liabilities.

Our business exposes us to significant potential risk from litigation matters, including government investigations and lawsuits alleging violations of various federal and state laws in connection with the marketing and sale of opioids. For example, we, along with other manufacturers of prescription opioid medications, are the subject of lawsuits brought by counties and localities in Arkansas, Pennsylvania and Kentucky, in addition to a health system and various member hospitals, regarding the sales and marketing of opioid medications. In addition to direct expenditures for defense, settlement and damages, there is a possibility of adverse publicity, loss of revenues and disruption of business as a result of such litigation matters. The resolution of these lawsuits may require lengthy and costly negotiations, and we may incur substantial defense costs in addition to any settlement or other liabilities or restrictions that we may accept in order to resolve such matters. Further, we may be unable to obtain or maintain insurance in the future on acceptable terms or with adequate coverage against potential liabilities or other losses incurred in connection with certain litigation matters. The cost, effort and management attention required to resolve these lawsuits may adversely affect our financial condition and ability to conduct our business.

Risks Related to our Products and Product Candidates

Our success depends in large part on the commercial success of Xtampza, our lead product, and the Nucynta Products, which we will commercialize pursuant to a Commercialization Agreement with Depomed.

To date, we have invested substantial resources in the development of our lead product, Xtampza, which has been approved by the FDA. Our business and future success are substantially dependent on our ability to successfully and timely commercialize this product. We currently generate limited revenues from product sales and we may never be able to commercialize Xtampza, the Nucynta Products, or any product candidates that are approved by the FDA, successfully.

Our ability to successfully commercialize Xtampza 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 and its components;
- our ability to manufacture commercial quantities of Xtampza 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;
- our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of Xtampza;
- the perceived availability and advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments for chronic pain and chronic pain with dysphagia;
- our ability to successfully defend any challenges to our intellectual property relating to Xtampza;
- the availability of coverage and adequate reimbursement for Xtampza;
- a continued acceptable safety profile of Xtampza following approval; and
- our ability to comply with applicable legal and regulatory requirements.

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;
- achieve, maintain and grow market acceptance of, and demand 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 relating to Nucynta Products;
- obtain adequate supply of Nucynta ER and Nucynta IR; and

- comply with applicable legal and regulatory requirements.

The success of our efforts to commercialize the Nucynta Products may also depend on additional factors, including the outcome of a pending appellate decision in litigation between Depomed and ANDA filers who are seeking to market a generic version of the Nucynta Products in the U.S.

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 Xtampza, and/or the Nucynta 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 and our ability to successfully market Xtampza may be adversely affected.

It is estimated that the U.S. market includes approximately 11 million patients with chronic pain with dysphagia. Our Xtampza microspheres are designed to be removed from the capsule and sprinkled on food or into a cup, and then directly into the mouth, or in feeding tubes, without compromising their extended-release properties. On April 26, 2016, the FDA granted approval for the Xtampza NDA, including an approved product label.

The FDA could change the product labeling at any time. If the product label for Xtampza is modified in the future so as to exclude the flexible dose administration options, or the FDA requires us to have a boxed warning 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," it will limit our ability to differentiate Xtampza from other abuse-deterrent opioid formulations on the basis of flexible dosing options, and we may not be able to market Xtampza for use by patients with chronic pain with dysphagia. As a result, this may have an adverse effect on our business and our prospects for future growth.

In November 2017, the FDA approved an sNDA for Xtampza to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza 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. Data that emerges from post-marketing studies or other sources could prompt the FDA to withdraw or amend its approval of the product labeling approved in connection with the sNDA, which withdrawal or amendment could adversely impact our ability to successfully commercialize Xtampza.

If the FDA does not conclude that our product candidates in development are sufficiently bioequivalent, or demonstrate comparable bioavailability to their respective listed drugs, or if the FDA otherwise does not conclude that our product candidates satisfy the requirements for the Section 505(b)(2) approval pathway, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not approve those product candidates.

A key element of our strategy is to seek FDA approval for our product candidates through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FD&C Act, permits the filing of an NDA that contains full safety and efficacy reports but where at least some of the information required for approval comes from studies not conducted by or for the applicant, such as the FDA's findings of safety and efficacy in the approval of a similar drug, and for which the applicant has not obtained a right of reference and/or published literature. Such reliance is typically predicated on a showing of bioequivalence or comparable bioavailability to an approved drug.

If the FDA does not allow us to pursue the Section 505(b)(2) approval pathway for our product candidates, or if we cannot demonstrate bioequivalence or comparable bioavailability of our product candidates to approved products, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates would increase. Moreover, our inability to pursue the Section 505(b)(2) approval pathway could result in new competitive products reaching the market sooner than our product candidates, which could have a material adverse effect on our competitive position and our business prospects. Even if we are allowed to pursue the Section

505(b)(2) approval pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization on a timely basis, if at all.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its policies and practices with respect to Section 505(b)(2) regulatory approvals, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Even if our product candidates are approved under Section 505(b)(2), the approval will likely be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products, including additional preclinical studies and clinical trials.

Our decision to seek approval of our product candidates under Section 505(b)(2) increases the risk that a patent infringement suit may be filed against us, which would delay the FDA's final regulatory approval of such product candidates and subject us to expensive and time consuming litigation.

In connection with any NDA that we file under Section 505(b)(2), we are required to notify the patent holders of the reference listed drug that we have certified to the FDA that any patents listed for the reference 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, expiration of the patents, settlement of the lawsuit or 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 product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product candidates may be commercialized.

Even if we are found not to infringe any potential plaintiff's patent claims or the claims are found invalid or unenforceable, defending any such infringement claim could be expensive and time-consuming, and could delay the launch of our product candidates and distract management from their normal responsibilities. The Court could decline to hear our summary judgment motion, could decline to act expeditiously to issue a decision or hold a trial, or could decline to find that all of the listed patents are invalid or non-infringed. If we are unsuccessful in our defense of non-infringement and unable to prove invalidity of the listed patents, the court could issue an injunction prohibiting the launch of our product candidates. If we were to receive final regulatory approval by the FDA and launch any of our product candidates, prior to a full and final determination that the patents are invalid or non-infringed, we could be subject to substantial liability for damages if we do not ultimately prevail on our defenses to a claim of patent infringement.

For example, Xtampza was approved under Section 505(b)(2) and we are currently involved in patent infringement litigation with Purdue regarding alleged infringement of the Purdue patents. The continued litigation is expensive and time consuming, and, while we are vigorously defending the infringement claims, we could be subject to substantial damages if unsuccessful.

The regulatory approval processes of the FDA and foreign regulatory authorities are lengthy, time-consuming and unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval varies among jurisdictions and may change during the course of a product candidate's clinical development. Although the FDA has approved Xtampza, it is possible that none of our product candidates or any future product candidates that we may in-license, acquire or develop will ever obtain final regulatory approval from the FDA or any foreign regulatory authority. Moreover, even after any product candidate

receives final regulatory approval, the FDA may impose, as it has for Xtampza and the Nucynta Products, costly post-marketing requirements. Successful and timely satisfaction of these post-marketing requirements will be necessary for us to maintain regulatory approval.

Our product candidates, including product candidates that we may in-license or acquire in the future, could fail to receive regulatory approval from the FDA or a foreign regulatory authority, or we may be required to conduct more extensive studies and clinical trials in order to receive such approval, for many reasons, including, but not limited to:

- the FDA and/or foreign regulatory authorities may disagree with or disapprove of the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure to demonstrate that a product candidate is bioequivalent to its listed drug;
- failure of clinical trials to meet criteria required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- deficiencies in the manufacturing processes or failure of third-party manufacturing facilities with whom we contract for clinical and commercial supplies to pass inspection;
- the FDA or foreign regulatory authorities may not approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; or
- insufficient data collected from clinical trials of our product candidates or changes in the approval policies or regulations that render our preclinical and clinical data insufficient to support the submission and filing of an NDA or to obtain regulatory approval.

The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve, with respect to certain foreign regulatory authorities, the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing requirements, or may approve a product label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. Any of the foregoing scenarios could have a material adverse effect on our business.

The FDA or a foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or cause us to abandon the development program. Even if we obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, such approval may be contingent on the performance of costly post-marketing requirements, or we may not be allowed to include the labeling claims necessary or desirable for the successful commercialization of such product candidate.

In order to market and sell our products outside the United States, we will need to obtain separate marketing approvals and comply with numerous and varied regulatory requirements and regimes, which can involve additional testing, may take substantially longer than the FDA approval process, and still generally includes all of the risks associated with

obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. FDA approval does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by the FDA or regulatory authorities in other countries or jurisdictions. We may not obtain any regulatory approvals for our current product candidates on a timely basis, if at all. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in countries outside the United States, the commercial prospects of that product candidate may be diminished, and our business prospects could decline.

Development of our product candidates is not complete, and we cannot be certain that our product candidates will be commercialized.

To commercialize our product candidates, we must successfully research, develop, obtain regulatory approval for, manufacture, launch, market and distribute product candidates under development. For each product candidate that we intend to develop and commercialize, we must successfully meet a number of critical developmental milestones, including:

- selecting and developing a drug delivery technology to deliver the proper dose of drug over the desired period of time;
- determining the appropriate drug dosage that will be tolerated, safe and effective;
- demonstrating the drug formulation will be stable for commercially reasonable time periods;
- demonstrating that the drug is safe and effective in patients for the intended indication; and
- completing the manufacturing development and scale-up to permit manufacture of our product candidates in commercial quantities and at acceptable prices.

The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for any of our product candidates in development. We may not be able to finalize the design or formulation of any product candidate. In addition, we may select components, solvents, excipients or other ingredients to include in our product candidates that have not been previously approved for use in pharmaceutical products, which may require us to perform additional studies and may delay clinical testing and regulatory approval of our product candidates. Even after we complete the design of a product candidate, the product candidate must still be shown to be bioequivalent to an approved drug or safe and effective in required clinical trials before approval for commercialization.

We are continuing to test and develop our product candidates and may explore possible design or formulation changes to address bioavailability, safety, efficacy, manufacturing efficiency and performance issues. If we are unable to complete development of our product candidates, we will not be able to earn revenue from them.

Xtampza 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. We anticipate that our product candidates, if approved, will also be subject to mandatory REMS programs.

The FDA has approved a Risk Evaluation and Mitigation Strategy ("REMS") for extended release, or ER, and long acting, or LA, opioid drugs formulated with the active 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 2017, the FDA announced that immediate-release, or IR, opioid drugs will be subject to the same REMS as ER/LA opioids. 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 Blueprint for Prescriber Education for Extended Release and Long Acting Opioid Analgesics. 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.

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 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 agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with Depomed or other licensors, we could lose license rights that are important to our business.

We are, or may become, a party to certain intellectual property license agreements, including the Commercialization Agreement, that are important to our business and may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone, royalty and other obligations on us. If we fail to comply with the obligations under the Commercialization Agreement or other such agreements, Depomed or another such licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

In addition, Depomed may terminate the 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 $180,000,000 through January 1, 2022, or if they are less than $140,000,000 per year in any 12-month period commencing on January 1, 2022, then Depomed will have the right to terminate the Commercialization Agreement without penalty. Depomed may also terminate the Commercialization Agreement for convenience at any time prior to December 31, 2018, provided it will be required to pay a termination fee to us.

In some cases, patent prosecution of our licenses is controlled solely by the licensor, like in certain circumstances under the 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 have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products or product candidates.

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

Xtampza 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 from other opioid products containing the same active 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, 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. 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

Even if our product candidates receive regulatory approval, they will be subject to ongoing regulatory requirements, and we may face regulatory enforcement action if we do not comply with the requirements.

Even after a product candidate is approved, we remain subject to ongoing FDA and other regulatory requirements governing the product labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. If we experience delays in obtaining FDA approval of our advertising and promotional materials for any product candidate that receives marketing approval, or if FDA approval of such materials is contingent upon substantial modifications, our promotional efforts relating to any approved product candidate may be impaired, and sales of such products may suffer.

The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and other regulations. If we or a regulatory agency discover problems with a product which were previously unknown, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing, among other things. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;

- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

- require us to enter into a consent decree, which can include the imposition of various fines, reimbursements for inspection costs and penalties for noncompliance, and require due dates for specific actions;

- seek an injunction or impose civil, criminal and/or administrative penalties, damages, monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- refuse to allow us to enter into government contracts.

Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue and may cause a material adverse impact on our financial condition and cash flows.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Failure to comply with ongoing governmental regulations for marketing any product, including Xtampza 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 and the Nucynta Products, is heavily scrutinized by, among others, the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress and the public. Violations, including promotion of Xtampza or the Nucynta Products, and any product for which we receive final regulatory approval, 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. Additionally, advertising and promotion of any product that obtains approval outside the United States will be heavily scrutinized by foreign regulatory authorities.

In the United States, engaging in off-label promotion of Xtampza or the Nucynta Products, or any other 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. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing the full commercial potential of Xtampza, the Nucynta Products and our product candidates:

- failure to obtain or maintain requisite governmental approvals;
- failure to obtain approvals of product labeling with abuse-deterrent claims; or
- FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our product candidates.

Xtampza, the Nucynta Products and our product candidates contain controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.

Xtampza, the Nucynta Products and our product candidates contain, and our future product candidates will likely contain, controlled substances that are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza's active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as controlled substances under the Controlled Substances Act of 1970, or CSA, and regulations of the U.S. Drug Enforcement Administration, or DEA. A number of states also independently regulate these drugs, including oxycodone and tapentadol, as controlled substances.

Controlled substances are classified by the DEA as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Oxycodone and tapentadol are both listed by the DEA as Schedule II controlled substances under the CSA. For our products and product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign 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. The DEA continues to increase its efforts to hold manufacturers, distributors, prescribers and pharmacies accountable through various enforcement actions as well as the implementation of compliance practices for controlled substances. In April 2018, the DEA proposed new guidelines aimed at strengthening the process for setting controls over diversion of controlled substances and making other improvements in the quota managements regulatory system for the production, manufacturing and procurement of controlled substances. Following a public comment period, the DEA published the final guidelines, which were substantially similar to the proposed guidelines, in July 2018. 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, 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 ingredient (in the case of Xtampza, 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 Xtampza, the Nucynta Products, and product candidates 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 Xtampza, the Nucynta Products, and product candidates 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.

Because the results of preclinical studies and early-stage clinical trials are not necessarily predictive of future results, any product candidate we advance into additional clinical trials may not continue to have favorable results or receive regulatory approval.

All of our product candidates are in preclinical or early-stage clinical development. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Many companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after positive results in earlier clinical trials. Despite preliminary preclinical studies for our other extended-release, abuse deterrent product candidates, including hydrocodone and oxymorphone for pain, and methylphenidate for the treatment of ADHD, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety or otherwise provide adequate information to result in regulatory approval to market any of our product candidates in any particular jurisdiction. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be compromised.

Conducting clinical trials of Xtampza and our product candidates and any commercial sales of Xtampza, the Nucynta Products, and/or 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 or product candidates 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 product or product candidates that we may develop;
- 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;

- the inability to commercialize our products or product candidates that we may develop; 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 Xtampza, the Nucynta Products, and our product candidates. Any agreements we may enter into in the future with collaborators in connection with the development or commercialization of Xtampza and our product candidates 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 indemnifications obligations may exceed the coverage under our product liability insurance policy.

Xtampza, the Nucynta Products, and our product candidates may be associated with undesirable adverse reactions or have other properties that could result in significant negative consequences.

Undesirable adverse reactions associated with Xtampza, the Nucynta Products, and our product candidates could cause us, our IRBs, 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 or foreign regulatory authorities. For example, even though Xtampza 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 Xtampza, the Nucynta Products, or any product candidate for which we receive final regulatory approval, 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 Xtampza or the Nucynta Products or any of our product candidates, if approved.

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 develop product candidates and commercialize products without infringing the intellectual property rights of others. Our current or future product candidates or 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 elsewhere in the world 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, oxymorphone, hydrocodone, morphine, and methylphenidate drugs and 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 Xtampza or our product candidates, 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 Xtampza or our product candidates or force us to cease some of our business operations.

In connection with any NDA that we file under Section 505(b)(2), including the NDA for Xtampza, 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 product candidates only to be subject to significant delay and patent litigation before our product candidates 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 approval or commercialization of our product candidates 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 in countries outside 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 technology, products and product candidates, we may lose valuable assets or experience reduced market share.

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 and other countries with respect to our proprietary technology, products and product candidates.

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, both inside and outside 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, product candidates 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 and in foreign jurisdictions is highly uncertain, and changes in U.S. and foreign patent law have increased that uncertainty and could diminish the value of patents in general, thereby impairing our ability to protect our product candidates and any future products.

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 and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions 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, both in the United States and abroad, 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, or 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, or 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 and abroad. 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 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, products and product candidates, 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 both within and outside 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 not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and sell their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents or our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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 and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO and foreign patent agencies 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 product candidates, our competitive position would be adversely affected.

Risks Related to the Commercialization of Our Products and Product Candidates

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 Xtampza, the Nucynta Products and, if approved, our product candidates and may be unable to generate sufficient product revenue.

Our commercial organization continues to grow and evolve, and in light of its short history and limited track record, we cannot guarantee that we will be successful in marketing Xtampza, the Nucynta Products or any of our product candidates 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 and product candidates 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 Xtampza, the Nucynta Products and our product candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; 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 building a sales and marketing infrastructure or if we do not successfully enter into appropriate strategic alliances with marketing collaborators, agreements with contract sales organizations or collaboration arrangements, we will have difficulty commercializing Xtampza, the Nucynta Products or our product candidates. To the extent we commercialize Xtampza or our product candidates by entering into agreements with third-party collaborators, we may have limited or no control over the sales, marketing and distribution activities of these third parties, in which case our future revenues would depend heavily on the success of the efforts of these third parties.

If physicians, patients, healthcare payors and the medical community do not accept and use Xtampza, the Nucynta Products or our product candidates, if approved, 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 Xtampza, the Nucynta Products or any of our product candidates (if regulatory approval is obtained), for which we receive final regulatory approval. Acceptance and use of Xtampza, the Nucynta Products and any product candidates for which we receive final regulatory approval will depend on a number of factors including:

- the timing of market introduction of our products and product candidates 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 Xtampza, the Nucynta Products and our product candidates;
- perceptions by members of the healthcare community, including physicians, about the relevance and efficacy of our abuse deterrent technology in reducing potential risks of unintended use;
- the pricing and cost-effectiveness of Xtampza, the Nucynta Products and our product candidates relative to competing products;
- the potential and perceived advantages of Xtampza, the Nucynta Products and our product candidates over alternative treatments;
- the convenience and ease of administration to patients of Xtampza, the Nucynta Products and our product candidates;
- actual and perceived availability of coverage and reimbursement for Xtampza, the Nucynta Products and our product candidates from government or other third-party payors;
- any negative publicity related to our or our competitors' products that include the same active ingredient as Xtampza, the Nucynta Products and our product candidates;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA approved product labeling;
- our ability to implement a REMS; and
- effectiveness of marketing and distribution efforts by us and any licensees and distributors.

If Xtampza, the Nucynta Products, or our product candidates for which we receive final regulatory approval, fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients or the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable. Since we expect to rely on sales generated by Xtampza and the Nucynta Products for substantially all of our revenues for the foreseeable future, the failure of Xtampza or the Nucynta Products to find market acceptance would harm our business prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize Xtampza, the Nucynta Products, and our product candidates and may reduce the prices we are able to obtain for our products.

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

Cost reduction legislation could decrease the coverage and price that we receive for any approved products, including for reimbursement through Medicare and private payors.

The pricing of pharmaceutical products, in general, and specialty drugs, in particular, has also been a topic of concern in the U.S. government. There can be no assurance as to how this scrutiny on pricing of pharmaceutical products will impact future pricing of our products or pharmaceutical products generally. The current administration has indicated that reducing the price of prescription drugs will be a priority of the administration. The implementation of any price controls on prescription drugs, whether at the federal or state level, may adversely affect our business, operating results and financial condition.

In April 2018, New York enacted a statute called the Opioid Stewardship Act (the "Stewardship Act") that, among other things, requires certain sellers and distributors of certain opioids in the state of New York to make annual payments of $100 million, in the aggregate, to a newly created fund, with each party's share determined in proportion to its share of opioid sales in New York (based on morphine milligram equivalents). While the effect of this legislation remains uncertain, and it has already been challenged as an unconstitutional law, we may be required to make payments to the fund and take additional actions to comply with the Stewardship Act. Compliance with the Stewardship Act, or similar requirements that could be enacted by other jurisdictions, could have an adverse effect on our business, results of operations, financial condition and cash flows.

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. The Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products. At the same time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act. For example, the TCJA, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years and is likely to lead to increases in insurance premiums. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future.

Newly enacted FDA regulations may require us to expend additional resources to obtain or maintain regulatory approval. For example, in August 2017 President Trump signed into law the Food & Drug Administration Reauthorization Act (the "FDARA"). This legislation imposes significant new requirements for clinical trial sponsors which will affect, among other things, the development of drugs and biological products for pediatric use. This legislation may result in new regulations, which may affect future options or timelines for regulatory approval.

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 approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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 3 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 Xtampza, the Nucynta Products, and our product candidates if approved. In addition, in 2017 several states, including Indiana, Louisiana, and Utah, enacted laws that further limit or restrict opioid prescriptions.

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 Xtampza, the Nucynta Products or our product candidates (that receive regulatory approval), which could significantly diminish demand for them and significantly impact our ability to successfully commercialize our products and generate revenues.

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

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 Xtampza, the Nucynta Products and our product candidates, if approved. 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. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or foreign regulatory authorities. 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 Xtampza, the Nucynta Products or any product candidates approved 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 Xtampza, the Nucynta Products, and our product candidates.

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 Xtampza, the Nucynta Products, and our product candidates.

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 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 Xtampza, the Nucynta Products, and our product candidates and decrease the revenues we are able to generate from their sale. 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 are considering various bills intended to reduce opioid abuse, for example by establishing prescription drug monitoring programs and mandating prescriber education. Further, the FDA is requiring “black-box” warnings on immediate release opioids highlighting the risk of misuse, abuse, addiction, overdose and death. In March 2017, President Trump announced the creation of a commission, through ONDCP, to make recommendations to the president on how to best combat opioid addiction and abuse. In August 2017, the commission issued a preliminary report calling on President Trump to officially declare the crisis of opioid abuse a national emergency. On October 26, 2017, President Trump declared the opioid crisis a “national public health emergency.” The commission’s final report was released in early November 2017. Efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for our product and product candidates. 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. 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 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. 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. We are currently subject to such lawsuits and investigations, as discussed under the heading "Legal Proceedings" in this Quarterly Report on Form 10-Q. 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. Many of these changes and others could cause us to expend additional resources in developing and commercializing Xtampza, the Nucynta Products, and our product candidates 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 product candidates and cause our product candidates to be less commercially successful.

If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with Xtampza, the Nucynta Products, or any of our product candidates, it could reduce our sales.

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 abbreviated NDA, or ANDA. The FD&C 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 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 and product candidates. 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.

Guidelines and recommendations published by various organizations can reduce the use of our products and product candidates, if approved.

Government agencies promulgate regulations and guidelines directly applicable to us and to Xtampza, the Nucynta Products, and our product candidates. 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 fails to devote sufficient time and resources to Xtampza, 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 a sole supplier to manufacture Nucynta ER, 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 and our product candidates. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturers for our products and each product candidate, as well as other vendors to formulate, test, supply, store and distribute our products and our product candidates for our clinical trials and FDA registration, and we control only certain aspects of their activities. In 2018, we began the buildout of a dedicated facility, at which only Xtampza will be manufactured, at a site operated by our contract manufacturing organization, Patheon N.V. 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 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 N.V., as our single manufacturer for Xtampza, exposes us to the following risks, any of which could delay FDA approval of our product candidates and 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 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 or any product candidate for which we receive regulatory approval, 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.

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 and our product candidates that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. 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 or a delay in, or failure to obtain, regulatory approval of any of our product candidates. 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, Depomed, 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. Depomed 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 Xtampza and Nucynta 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 ingredient for Xtampza (oxycodone base) and the Nucynta Products (tapentadol) and we contract, either directly or indirectly, through Depomed with this supplier, as necessary, for commercial supply of our products. Although we have identified an alternate source for oxycodone base for Xtampza, it would be time-consuming and costly to qualify this source. Since we and, in the case of tapentadol, Depomed, currently obtain active ingredients from this manufacturer on a purchase-order basis, either we, Depomed, and/or our supplier may terminate the arrangements, without cause, at any time without notice. If our supplier were to terminate an arrangement for an active 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.

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 obtain regulatory approval for or commercialize our product candidates and our business could suffer a material adverse effect.

We have relied upon and plan to continue to rely upon contract research organizations, or 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, or 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, or EEA, and foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our product candidates in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial 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 product candidates may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

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 or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates 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 product candidates 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.

Xtampza and the Nucynta Products are, and product candidates for which we obtain marketing approval 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.

Xtampza and the Nucynta Products are, and any product candidate for which we obtain marketing approval could be, subject to a comprehensive regulatory scheme, including post-marketing requirements to conduct 10 observational epidemiological studies and 1 clinical trial that we intend to fulfil by virtue of our participation in the Opioid PMR Consortium ("OPC"). The 10 observational epidemiological studies are designed to assess the serious risk of misuse, abuse, addition, opioid overdose and death, and doctor and/or pharmacy shopping behaviors in patients with chronic pain prescribed ER/LA opioid analgesics. The clinical trial is designed to estimate the serious risk for the development of hyperalgesia following long-term use of high dose ER/LA opioid analgesics for at least 1 year to treat chronic pain and assess this risk relative to efficacy. 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 we have a minority vote (1 of 13) and limited control over the manner in which OPC conducts studies on our behalf in order to satisfy our PMRs. 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 Xtampza, the Nucynta Products, and any product candidate for which we obtain marketing approval and which may become subject to such post-marketing requirements. 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 Xtampza, the Nucynta Products and our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products and product candidates.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop or commercialize Xtampza, the Nucynta Products and our product candidates. These collaborations, including the Commercialization Agreement for Nucynta ER and Nucynta IR, 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 product candidates 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 or product candidate, repeat or conduct new clinical trials or require a new formulation of our product or product candidate 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 or product candidates.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- A collaborator with marketing and distribution rights to one or more or product candidates may not commit sufficient resources to the marketing and distribution of such products or product candidates.

- 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 and product candidates 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 or product candidates.

- Collaboration agreements may not lead to development or commercialization of products or product candidates 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 or product candidates 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 may rely on collaborators to market and commercialize our products, and, if approved, our product candidates, who may fail to effectively commercialize our products.

We may utilize strategic collaborators or contract sales forces, where appropriate, to assist in the commercialization of Xtampza, the Nucynta Products and our product candidates, if approved by the FDA. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. If we enter into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Our collaborators, if any, may fail to develop or effectively commercialize our products and product candidates because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure of our third-party collaborators to successfully market and commercialize our products and product candidates would diminish our revenues.

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

As we scale up manufacturing of our products and product candidates 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 37%, 32% and 25% of our product shipments for the six months ended June 30, 2018. 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.

Risks Related to Our Business and Strategy

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

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. In addition, 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.

We face and will continue to face competition from other companies in the pharmaceutical and medical device industries. Xtampza, the Nucynta Products, and our product candidates, if approved, will compete with currently marketed 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, Depomed, Egalet, Endo, Mallinckrodt, Pernix, 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.

As a result of these factors, 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 and product candidates. 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.

Furthermore, if the FDA approves a competitor's 505(b)(2) application for a drug candidate before our application for a similar drug candidate and grants the competitor a period of exclusivity, the FDA may take the position that it cannot approve our NDA for a similar drug candidate. For example, several competitors have developed extended-release hydrocodone products, and if the FDA grants exclusivity, we could be subject to a delay that would dramatically reduce the expected market penetration for our hydrocodone product candidate.

In addition, 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 product candidates. Our competitors may develop products that are safer, more effective or less costly than our product candidates and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of currently available therapies with which our products and product candidates, if approved, compete may limit market acceptance of our product and product candidates even if commercialized. 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 product candidates, if approved, and the established use of these competitive products may limit the potential for our products and product candidates to receive widespread acceptance if commercialized.

The use of legal and regulatory strategies by competitors with innovator products may delay or prevent the introduction or approval of our product candidates, increase our costs associated with the introduction or marketing of our products, or significantly reduce the profit potential of our products or product candidates.

Companies with innovator drugs often pursue strategies that may serve to prevent or delay competition from alternatives to their innovator products. These strategies include, but are not limited to

- filing "citizen petitions" with the FDA that may delay competition by causing delays of our product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a product's bioequivalence or "sameness" to the related innovator product;
- filing suits for patent infringement that automatically delay FDA approval of products seeking approval based on the Section 505(b)(2) pathway;
- obtaining extensions of market exclusivity by conducting clinical trials of innovator drugs in pediatric populations or by other methods;
- persuading the FDA to withdraw the approval of innovator drugs for which the patents are about to expire, thus allowing the innovator company to develop and launch new patented products serving as substitutes for the withdrawn products;
- seeking to obtain new patents on drugs for which patent protection is about to expire; and
- initiating legislative and administrative efforts in various states to limit the substitution of innovator products by pharmacies.

These strategies could delay, reduce or eliminate our entry into the market and our ability to generate revenues from our products and product candidates.

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 Dryer, and our General Counsel, Shirley Kuhlmann. 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. Dryer or Ms. Kuhlmann could impede the achievement of our development and commercialization objectives.

If we are unable to attract and retain highly qualified scientific and technical employees, we may not be able to grow effectively.

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 scientific 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 for the development of our business or to recruit suitable replacement personnel.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

We have experienced a period of rapid growth. Our management, personnel and systems may not be adequate to support this and future growth. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of any FDA-approved products;
- overseeing clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any sales and marketing personnel engaged in connection with the commercialization of any approved product;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and financial systems and procedures; and
- developing our compliance infrastructure and processes to ensure compliance with regulations applicable to public companies.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our products and product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, that 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 product candidates, or businesses, in-licensing or out-licensing of products, product candidates 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.

Our employees, independent contractors, principal investigators, CROs, 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, 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 Xtampza, the Nucynta Products, and any product candidates for which we may obtain marketing approval. 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 Xtampza, the Nucynta 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, state and foreign 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, or 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 and foreign 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 and foreign 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 and foreign 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 and product candidates, 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 and development of our product candidates could be delayed.

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 and product candidates or our competitors' products or product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- 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 and product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our products and product candidates 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 product candidates or 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of June 30, 2018, holders of an aggregate of approximately 3.1 million shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. Once we register these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates.

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.

In addition, persons associated with Longitude Capital Partners, LLC and Skyline Venture Partners V, L.P. currently serve on our board of directors. The interests of Longitude Capital Partners, LLC and Skyline Venture Partners V, L.P. may not always coincide with the interests of the other shareholders, and the concentration of control in Longitude Capital Partners, LLC and Skyline Venture Partners V, L.P. limits other shareholders' ability to influence corporate matters. We may also take actions that our other shareholders do not view as beneficial, which may adversely affect our results of operations and financial condition and cause a decline in our stock price.

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 will no longer be an "emerging growth company" and, as a result, we will have 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 most recent second quarter, we will cease to be an "emerging growth company" as defined in the JOBS Act as of December 31, 2018. We will be, as of December 31, 2018, a large accelerated filer and, as such, will be subject to certain requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. 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.

Beginning with our Annual Report on Form 10-K for the year ending December 31, 2018, we will be 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 will

be expensive and time consuming for management and could result in the detection of internal control deficiencies of which we are currently unaware. We expect that the loss of "emerging growth company" status and compliance with the additional requirements will substantially increase 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.

In addition, as of June 30, 2018, there were outstanding options to purchase an aggregate of 3,665,459 shares of our common stock at a weighted average exercise price of $16.17 per share, of which options to purchase 1,312,351 shares of our common stock were then exercisable. The exercise of options 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 or development of our products and product candidates. 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 June 30, 2018:

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
April 1, 2018 through April 30, 2018	-	-	-	-
May 1, 2018 through May 31, 2018	6,205	$ 22.62	-	-
June 1, 2018 through June 30, 2018	-	-	-	-
Total	**6,205**	**$ 22.62**	**-**	**-**

(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
10.1+	Amendment to Employment Agreement, dated June 4, 2018, by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni.(1)
10.2+	Letter Agreement dated June 4, 2018, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan.(1)
10.3+	Employment Agreement, dated July 10, 2018, by and between Collegium Pharmaceutical, Inc. and Scott Dreyer (filed herewith).
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+Indicates management contract or compensatory plan.

(1) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on June 4, 2018.

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: August 8, 2018

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

Date: August 8, 2018

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

Exhibit 10.3

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is made by and between COLLEGIUM PHARMACEUTICAL, INC. (the "Company") and SCOTT DREYER (the "Executive").

WHEREAS, the Company desires to employ Executive on an at-will basis, and the Executives wishes to continue to be employed by the Company on at-will basis, on the terms and conditions set forth herein; and

WHEREAS, the parties wish to enter into this Agreement to memorialize the terms of Executive's continued employment by the Company.

NOW, THEREFORE, in consideration of the foregoing and intending to be bound hereby, the parties agree as follows:

1. Duration of Agreement. This Agreement shall be effective on July 10, 2018 (the "Effective Date"), and has no specific expiration date. Unless terminated by agreement of the parties, this Agreement will govern Executive's continued employment by the Company until that employment ceases.

2. Title; Duties. Executive will be employed as the Company's Executive Vice President and Chief Commercial Officer, reporting directly to the Company's Chief Executive Officer. Executive will devote his best efforts and substantially all of his business time and services to the Company and its affiliates to perform such duties as may be customarily incident to his position and as may reasonably be assigned to him from time to time. Executive will not, in any capacity, engage in other business activities or perform services for any other individual, firm or corporation without the prior written consent of the Company; *provided, however*, that without such consent, Executive may engage in charitable, non-profit and public service activities, so long as such activities do not in any respect interfere or conflict with Executive's performance of his duties and obligations to the Company.

3. Place of Performance. Executive will perform his services hereunder at the principal executive offices of the Company in Massachusetts; *provided, however,* that Executive may be required to travel from time to time for business purposes.

4. Compensation and Indemnification.

4.1. Base Salary. Executive's annual salary will be $375,000 (the "Base Salary"), paid in accordance with the Company's payroll practices as in effect from time to time. The Base Salary will be reviewed annually by the Compensation Committee of the Company's Board of Directors (the "Committee").

4.2. Annual Bonuses.

4.2.1. For each fiscal year ending during his employment, Executive will be eligible to earn an annual bonus. For the Company's 2018 fiscal year, the aggregate annual bonus shall be determinable based on a target amount of 40% of Executive's Base Salary earned during the period January 1, 2018 through July 9, 2018 and 50% of Executive's Base Salary earned during the period July 10, 2018 through December 31, 2018. For each fiscal year beginning with the Company's 2019 fiscal year, the target amount of the annual bonus will be 50% of Executive's Base Salary for the applicable fiscal year. The actual bonus payable with respect to a particular year will be determined by the Committee, based on the achievement of corporate and /or individual performance objectives established by the Committee. Any bonus payable under this paragraph will be paid during the calendar year immediately following the fiscal year in respect of which the bonus is payable and, except as otherwise provided in Section 5.1.1, will only

be paid if Executive remains continuously employed by the Company through the actual bonus payment date.

4.2.2. For purposes of determining any bonus payable to Executive, the measurement of corporate and individual performance will be performed by the Committee in good faith. From time to time, the Committee may, in its sole discretion, make adjustments to corporate or individual performance goals, so that required departures from the Company's operating budget, changes in accounting principles, acquisitions, dispositions, mergers, consolidations and other corporate transactions, and other factors influencing the achievement or calculation of such goals do not affect the operation of this provision in a manner inconsistent with its intended purposes.

4.3. Equity Incentive Award. As soon as practicable following the Effective Date and subject to the approval of the Committee, Executive will be granted a restricted stock unit award (the "RSU Award") for a number of restricted stock units, rounded down to the nearest whole number, equal to (i) 400,000, divided by (ii) the average closing price of the Corporation's common stock for the 50-day period ending on July 9, 2018, under and subject to the Company's Amended and Restated 2014 Stock Incentive Plan (the "Plan"). Subject to Executive's continued employment with the Company, the RSU Award will vest 25% on the first anniversary of the RSU Award grant date and the remainder will vest in substantially equal installments every six months during the three-year period commencing on the first anniversary of the grant date. The RSU Award will be subject to the terms and conditions of the Plan and the award agreement evidencing such grant.

4.4. Employee Benefits. During Executive's employment, Executive will be eligible to participate in all employee benefit plans and programs made available by the Company from time to time to employees generally, subject to applicable plan terms and policies. The Company periodically reviews its benefits, policies, benefits providers and practices and may terminate, alter or change them at its discretion from time to time.

4.5. Reimbursement of Expenses. The Executive will be reimbursed by the Company for all reasonable business expenses incurred by Executive in accordance with the Company's customary expense reimbursement policies as in effect from time to time. Notwithstanding anything herein to the contrary, to the extent any expense, reimbursement or in-kind benefit provided to the Executive constitutes a "deferral of compensation" within the meaning of Section 409A of the Internal Revenue Code (the "Code") (i) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive must be incurred during the Executive's term of employment; (ii) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive in any other calendar year, (iii) the reimbursements for expenses for which the Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (iv) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.

5. Termination. Executive's employment with the Company may be terminated by the Company or Executive at any time and for any reason. Upon any cessation of his employment with the Company, Executive will be entitled only to such compensation and benefits as described in this Section 5. Upon any cessation of his employment for any reason, unless otherwise requested by the Company,

Executive agrees to resign immediately from all officer and director positions he then holds with the Company and its affiliates.

5.1. Termination without Cause or for Good Reason. If Executive's employment by the Company ceases due to a termination by the Company without Cause (as defined below) or a resignation by Executive for Good Reason (as defined below), Executive will be entitled to:

5.1.1. payment of any annual bonus otherwise payable (but for the cessation of Executive's employment) with respect to a year ended prior to the cessation of Executive's employment;

5.1.2. continuation of Executive's Base Salary for a period equal to 9 months, payable in accordance with the Company's standard payroll practices; and

5.1.3. waiver of the applicable premium otherwise payable for COBRA continuation coverage for Executive (and, to the extent covered immediately prior to the date of such cessation, his eligible dependents) for a period equal to 9 months.

Except as otherwise provided in this Section 5.1, and except for payment of all (i) accrued and unpaid Base Salary through the date of such cessation, (ii) any expense reimbursements to be paid in accordance with Company policy and (iii) payments for any accrued but unused paid time off in accordance with the Company's policies and applicable law, all compensation and benefits will cease at the time of such cessation and the Company will have no further liability or obligation by reason of such cessation. The payments and benefits described in this Section 5.1 are in lieu of, and not in addition to, any other severance arrangement maintained by the Company. Notwithstanding any provision of this Agreement, the payments and benefits described in Section 5.1 are conditioned on: (a) the Executive's execution and delivery to the Company and the expiration of all applicable statutory revocation periods, by the 45th day following the effective date of his cessation of employment, of a general release of claims against the Company and its affiliates in a form reasonably prescribed by the Company (the "Release"); and (b) the Executive's continued compliance with the Restrictive Covenants (as defined below). Subject to Section 5.4, below, the benefits described in Section 5.1 will be paid or provided (or begin to be paid or provided) as soon as administratively practicable (or determinable in the case of the benefits described in Section 5.1.1) after the Release becomes irrevocable, provided that if the 45 day period described above begins in one taxable year and ends in a second taxable year such payments or benefits shall not commence until the second taxable year.

5.2. Termination Following a Change in Control. For cessations of employment described in Section 5.1 that occur during the twelve (12) month period immediately following the occurrence of a Change in Control (as defined below), the Executive will receive the payments and benefits described in Section 5.1 above, subject to the following modifications:

5.2.1. the references in Sections 5.1.2 and 5.1.3 to "9 months" will each be replaced with a reference to "12 months"; and

5.2.2. all unvested restricted stock, stock options and other equity incentives awarded to Executive by the Company will become immediately and automatically fully vested and exercisable (as applicable).

5.3. Other Terminations. If Executive's employment with the Company ceases for any reason other than as described in Section 5.1 above, including, but not limited to, termination (i) by the Company for Cause, (ii) as a result of Executive's death, (iii) as a result of Executive's Disability or (iv) by Executive without Good Reason, then the Company's obligation to Executive will be limited solely to (a) accrued and unpaid Base Salary through the date of such cessation, (b) any expense reimbursements to be

paid in accordance with Company policy and (c) payments for any accrued but unused paid time off in accordance with the Company's policies and applicable law. All compensation and benefits will cease at the time of such cessation and, except as otherwise provided by COBRA or this Section 5.3, the Company will have no further liability or obligation by reason of such termination. The foregoing will not be construed to limit Executive's right to payment or reimbursement for claims incurred prior to the date of such termination under any insurance contract funding an employee benefit plan, policy or arrangement of the Company in accordance with the terms of such insurance contract.

5.4. Compliance with Section 409A. If the termination giving rise to the payments described in Section 5.1 is not a "Separation from Service" within the meaning of Treas. Reg. § 1.409A-1(h)(1) (or any successor provision), then the amounts otherwise payable pursuant to that section will instead be deferred without interest and will not be paid until Executive experiences a Separation from Service. To the maximum extent permitted under Section 409A of the Code and its corresponding regulations, the cash severance benefits payable under this Agreement are intended to meet the requirements of the short-term deferral exemption under Section 409A of the Code and the "separation pay exception" under Treas. Reg. §1.409A-1(b)(9)(iii). To the extent compliance with the requirements of Treas. Reg. § 1.409A-3(i)(2) (or any successor provision) is necessary to avoid the application of an additional tax under Section 409A of the Internal Revenue Code to payments due to Executive upon or following his Separation from Service, then notwithstanding any other provision of this Agreement (or any otherwise applicable plan, policy, agreement or arrangement), any such payments that are otherwise due within six months following Executive's Separation from Service (taking into account the preceding sentence of this paragraph) will be deferred without interest and paid to Executive in a lump sum immediately following that six month period. For purposes of the application of Treas. Reg. § 1.409A-1(b)(4)(or any successor provision), each payment in a series of payments will be deemed a separate payment.

5.5. PPACA. Notwithstanding anything in this Agreement to the contrary, the waiver in respect of COBRA premiums pursuant to Section 5.1.3 shall cease to the extent required to avoid adverse consequences to the Company under the Patient Protection and Affordable Care Act of 2010 and regulations thereunder.

5.6. Section 280G. If any payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise pursuant to or by reason of any other agreement, policy, plan, program or arrangement or the lapse or termination of any restriction on or the vesting or exercisability of any payment or benefit (each a "Payment"), would be subject to the excise tax imposed by Section 4999 of the Code (or any successor provision thereto) or to any similar tax imposed by state or local law (such tax or taxes are hereafter collectively referred to as the "Excise Tax"), then the aggregate amount of Payments payable to Executive shall be reduced to the aggregate amount of Payments that may be made to the Executive without incurring an excise tax in accordance with the immediately following sentence; *provided that* such reduction shall only be imposed if the aggregate after-tax value of the Payments retained by Executive (after giving effect to such reduction) is equal to or greater than the aggregate after-tax value (after giving effect to the Excise Tax) of the Payments to Executive without any such reduction. Any such reduction shall be made in the following order: (i) first, any future cash payments (if any) shall be reduced (if necessary, to zero); (ii) second, any current cash payments shall be reduced (if necessary, to zero); (iii) third, all non-cash payments (other than equity or equity derivative related payments) shall be reduced (if necessary, to zero); and (iv) fourth, all equity or equity derivative payments shall be reduced.

5.7. Definitions. For purposes of this Agreement:

5.7.1. "Cause" means (a) commission or conviction of any felony or any crime involving dishonesty; (b) commission of any fraud against the Company; (c) intentional and material

damage to any material property of the Company; (d) Executive's material breach of any agreement with or duty owed to the Company or any of its affiliates (including, without limitation, Executive's material breach of any of the Restrictive Covenants, as defined below); or (e) refusal to perform the lawful, reasonable and material directives of the Company's Board of Directors (the "Board") or the Company's Chief Executive Officer. Before "Cause" under clause (c), (d) or (e) has been deemed to have occurred, the Board must provide the Executive with written notice detailing why the Board has determined that Cause has occurred and the actions required to cure the same, to the extent reasonably subject to cure. The Executive shall then, where the grounds for Cause are reasonably subject to cure within such time, have thirty (30) days after the Executive's receipt of written notice to cure the item cited in the written notice so that "Cause" will have not formally occurred with respect to the event in question until such period, where applicable, shall have expired.

5.7.2. "Change in Control" means the first to occur of any of the events described in Section 1(g) of the Plan (or any successor provision).

5.7.3. "Disability" means a condition entitling the Executive to benefits under the Company's long term disability plan, policy or arrangement; *provided, however*, that if no such plan, policy or arrangement is then maintained by the Company and applicable to the Executive, "Disability" will mean the Executive's inability to perform his duties under this Agreement due to a mental or physical condition that can be expected to result in death or that can be expected to last (or has already lasted) for a continuous period of 90 days or more, or for 120 days in any 180 consecutive day period. Termination as a result of a Disability will not be construed as a termination by the Company "without Cause."

5.7.4. "Good Reason" means any of the following, without the Executive's prior consent: (a) a material diminution of the Executive's duties or authority with the Company, reporting relationships or the assignment of duties and responsibilities inconsistent with Executive's status at the Company; (b) a reduction in Base Salary; or (c) the relocation of the Executive's primary place of employment to a location that is (i) more than 50 miles from the location of the Executive's permanent primary place of employment prior to such relocation and (ii) more than 50 miles from the location of the Executive's residence. However, none of the foregoing events or conditions will constitute Good Reason unless the Executive provides the Company with written objection to the event or condition within 30 days following the occurrence thereof, the Company does not reverse or otherwise cure the event or condition within 30 days of receiving that written objection, and the Executive resigns Executive's employment within 30 days following the expiration of that cure period.

6 . Restrictive Covenants. To induce the Company to enter into this Agreement and in recognition of the compensation to be paid to the Executive pursuant to Sections 4 and 5 of this Agreement, the Executive agrees to be bound by the provisions of this Section 6 (the "Restrictive Covenants"). These Restrictive Covenants will apply without regard to whether any termination or cessation of the Executive's employment is initiated by the Company or the Executive, and without regard to the reason for that termination or cessation.

6.1. Covenant Not To Compete. The Executive covenants that, during his employment by the Company and for a period of 9 months following immediately thereafter (the "Restricted Period"),

the Executive will not (except in his capacity as an employee or director of the Company) do any of the following, directly or indirectly:

6.1.1. engage or participate in any Competing Business (as defined below) wherever the Company or its affiliates do business, do or plan to do business or sell or market their products or services;

6.1.2. become interested in (as owner, stockholder, lender, partner, co-venturer, director, officer, employee, agent or consultant) any person, firm, corporation, association or other entity engaged in a Competing Business. Notwithstanding the foregoing, the Executive may hold up to 1% of the outstanding securities of any class of any publicly-traded securities of any company;

6.1.3. influence or attempt to influence any employee, consultant, supplier, licensor, licensee, contractor, agent, strategic partner, distributor, customer or other person to terminate or modify any written or oral agreement, arrangement or course of dealing with the Company or any of its affiliates; or

6.1.4. solicit for employment or retention as an independent contractor (or arrange to have any other person or entity solicit for employment or retention) any person employed or retained by the Company or any of its affiliates.

6.2. Confidentiality. The Executive recognizes and acknowledges that the Proprietary Information (as defined in below) is a valuable, special and unique asset of the business of the Company and its affiliates. As a result, both during the term of this Agreement and thereafter, the Executive will not, without the prior written consent of the Company, for any reason divulge to any third-party or use for his own benefit, or for any purpose other than the exclusive benefit of the Company and its affiliates, any Proprietary Information. Notwithstanding the foregoing, nothing in this Agreement prohibits the Executive from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General (collectively, the "Regulators"), or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. In connection with any such activity, the Executive must identify any information that is confidential and ask the Regulator for confidential treatment of such information. Despite the foregoing, Executive is not permitted to reveal to any third party, including any governmental, law enforcement, or regulatory authority, information employee came to learn during the course of Executive's employment with the Company that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege, attorney work product doctrine and/or other applicable legal privileges. The Company does not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information. Notwithstanding any other provisions of this Agreement, pursuant to 18 USC Section 1833(b), Executive shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made: (a) confidentially to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (b) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. If Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose a trade secret of the Company to Executive's attorney and use the trade secret

information in related court proceedings, provided that Executive files any document containing the trade secret information under seal and does not disclose the trade secret, except pursuant to court order.

6.3. Property of the Company.

6.3.1. Proprietary Information. All right, title and interest in and to Proprietary Information will be and remain the sole and exclusive property of the Company and its affiliates. The Executive will not remove from the Company's or its affiliates' offices or premises any documents, records, notebooks, files, correspondence, reports, memoranda or similar materials of or containing Proprietary Information, or other materials or property of any kind belonging to the Company or its affiliates unless necessary or appropriate in the performance of his duties to the Company and its affiliates. If the Executive removes such materials or property in the performance of his duties, he will return such materials or property promptly after the removal has served its purpose. The Executive will not make, retain, remove and/or distribute any copies of any such materials or property, or divulge to any third person the nature of and/or contents of such materials or property, except to the extent necessary to satisfy contractual obligations of the Company or its affiliates or to perform his duties on behalf of the Company and its affiliates. Upon termination of the Executive's employment with the Company, he will leave with the Company and its affiliates or promptly return to the Company and its affiliates all originals and copies of such materials or property then in his possession.

6.3.2. Intellectual Property. The Executive agrees that all the Intellectual Property (as defined below) will be considered "works made for hire" as that term is defined in Section 101 of the Copyright Act (17 U.S.C. § 101) and that all right, title and interest in such Intellectual Property will be the sole and exclusive property of the Company and its affiliates. To the extent that any of the Intellectual Property may not by law be considered a work made for hire, or to the extent that, notwithstanding the foregoing, the Executive retains any interest in the Intellectual Property, the Executive hereby irrevocably assigns and transfers to the Company and its affiliates any and all right, title, or interest that the Executive may now or in the future have in the Intellectual Property under patent, copyright, trade secret, trademark or other law, in perpetuity or for the longest period otherwise permitted by law, without the necessity of further consideration. The Company and its affiliates will be entitled to obtain and hold in its own name all copyrights, patents, trade secrets, trademarks and other similar registrations with respect to such Intellectual Property. The Executive further agrees to execute any and all documents and provide any further cooperation or assistance reasonably required by the Company, at the Company's expense, to perfect, maintain or otherwise protect its rights in the Intellectual Property. If the Company or its affiliates, as applicable, are unable after reasonable efforts to secure the Executive's signature, cooperation or assistance in accordance with the preceding sentence, whether because of the Executive's incapacity or any other reason whatsoever, the Executive hereby designates and appoints the Company, the appropriate affiliate, or their respective designee as the Executive's agent and attorney-in-fact, to act on his behalf, to execute and file documents and to do all other lawfully permitted acts necessary or desirable to perfect, maintain or otherwise protect the Company's or its affiliates' rights in the Intellectual Property. The Executive acknowledges and agrees that such appointment is coupled with an interest and is therefore irrevocable.

6.4. Definitions. For purposes of this Agreement:

6.4.1. "Competing Business" means any person, firm, corporation, partnership, association or other entity engaged in developing, manufacturing, marketing, distributing or selling, directly or indirectly, pharmaceutical abuse-deterrent products or any other product for pain indications that directly competes with a product developed, manufactured, marketed, distributed or sold by the Company. A division, subsidiary or similar business unit of an entity that does not engage in the business activities

described in this definition will not be considered a Competing Business even if another separate division, subsidiary or similar business unit does engage in such activities.

6.4.2. "Intellectual Property" means (a) all inventions (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents and patent applications claiming such inventions, (b) all trademarks, service marks, trade dress, logos, trade names, fictitious names, brand names, brand marks and corporate names, together with all translations, adaptations, derivations, and combinations thereof and including all goodwill associated therewith, and all applications, registrations, and renewals in connection therewith, (c) all copyrightable works, all copyrights, and all applications, registrations, and renewals in connection therewith, (d) all mask works and all applications, registrations, and renewals in connection therewith, (e) all trade secrets (including research and development, know-how, formulas, compositions, manufacturing and production processes and techniques, methodologies, technical data, designs, drawings and specifications), (f) all computer software (including data, source and object codes and related documentation), (g) all other proprietary rights, (h) all copies and tangible embodiments thereof (in whatever form or medium), or (i) similar intangible personal property which have been or are developed or created in whole or in part by the Executive (1) at any time and at any place while the Executive is employed by Company and which, in the case of any or all of the foregoing, are related to and used in connection with the business of the Company or its affiliates, or (2) as a result of tasks assigned to the Executive by the Company or its affiliates.

6.4.3. "Proprietary Information" means any and all proprietary information developed or acquired by the Company or any of its subsidiaries or affiliates that has not been specifically authorized to be disclosed. Such Proprietary Information shall include, but shall not be limited to, the following items and information relating to the following items: (a) all intellectual property and proprietary rights of the Company (including, without limitation, the Intellectual Property), (b) computer codes and instructions, processing systems and techniques, inputs and outputs (regardless of the media on which stored or located) and hardware and software configurations, designs, architecture and interfaces, (c) business research, studies, procedures and costs, (d) financial data, (e) distribution methods, (f) marketing data, methods, plans and efforts, (g) the identities of actual and prospective suppliers, (h) the terms of contracts and agreements with, the needs and requirements of, and the Company's or its affiliates' course of dealing with, actual or prospective suppliers, (i) personnel information, (j) customer and vendor credit information, and (k) information received from third parties subject to obligations of non-disclosure or non-use. Failure by the Company or its affiliates to mark any of the Proprietary Information as confidential or proprietary shall not affect its status as Proprietary Information.

6.5. Acknowledgements. The Executive acknowledges that the Restrictive Covenants are reasonable and necessary to protect the legitimate interests of the Company and its affiliates, that the duration and geographic scope of the Restrictive Covenants are reasonable given the nature of this Agreement and the position the Executive holds within the Company, and that the Company would not enter into this Agreement or otherwise employ or continue to employ the Executive unless the Executive agrees to be bound by the Restrictive Covenants set forth in this Section 6.

6.6. Remedies and Enforcement Upon Breach.

6.6.1. Specific Enforcement. The Executive acknowledges that any breach by him, willfully or otherwise, of the Restrictive Covenants will cause continuing and irreparable injury to the Company or its affiliates for which monetary damages would not be an adequate remedy. The Executive shall not, in any action or proceeding to enforce any of the provisions of this Agreement, assert the claim or defense that such an adequate remedy at law exists. In the event of any such breach or threatened breach by the Executive of any of the Restrictive Covenants, the Company or its affiliates, as applicable, shall be entitled to injunctive or other similar equitable relief in any court, without any requirement that a bond or

other security be posted, and this Agreement shall not in any way limit remedies of law or in equity otherwise available to the Company and its affiliates.

6.6.2. Judicial Modification. If any court determines that any of the Restrictive Covenants, or any part thereof, is unenforceable because of the duration or geographical scope of such provision, such court shall have the power to modify such provision and, in its modified form, such provision shall then be enforceable.

6.6.3. Enforceability. If any court holds the Restrictive Covenants unenforceable by reason of their breadth or scope or otherwise, it is the intention of the parties hereto that such determination not bar or in any way affect the right of the Company and its affiliates to the relief provided above in the courts of any other jurisdiction within the geographic scope of such Restrictive Covenants.

6.6.4. Disclosure of Restrictive Covenants. The Executive agrees to disclose the existence and terms of the Restrictive Covenants to any employer that the Executive may work for during the Restricted Period.

6.6.5. Extension of Restricted Period. If the Executive breaches Section 6.1 in any respect, the restrictions contained in that section will be extended for a period equal to the period that the Executive was in breach.

7. Miscellaneous.

7.1. Other Agreements. Executive represents and warrants to the Company that there are no restrictions, agreements or understandings whatsoever to which he is a party that would prevent or make unlawful his execution of this Agreement, that would be inconsistent or in conflict with this Agreement or Executive's obligations hereunder, or that would otherwise prevent, limit or impair the performance by Executive of his duties under this Agreement.

7.2. Successors and Assigns. The Company may assign this Agreement to any successor to its assets and business by means of liquidation, dissolution, sale of assets or otherwise. The duties of Executive hereunder are personal to Executive and may not be assigned by him.

7.3. Governing Law and Enforcement. This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the principles of conflicts of laws. Any legal proceeding arising out of or relating to this Agreement will be instituted in a state or federal court in the Commonwealth of Massachusetts, and Executive and the Company hereby consent to the personal and exclusive jurisdiction of such court(s) and hereby waive any objection(s) that they may have to personal jurisdiction, the laying of venue of any such proceeding and any claim or defense of inconvenient forum.

7.4. Waivers. The waiver by either party of any right hereunder or of any breach by the other party will not be deemed a waiver of any other right hereunder or of any other breach by the other party. No waiver will be deemed to have occurred unless set forth in a writing. No waiver will constitute a continuing waiver unless specifically stated, and any waiver will operate only as to the specific term or condition waived.

7.5. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law. However, if any provision of this Agreement is held to be invalid, illegal or

unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision, and this Agreement will be reformed, construed and enforced as though the invalid, illegal or unenforceable provision had never been herein contained.

7.6. Survival. This Agreement will survive the cessation of Executive's employment to the extent necessary to fulfill the purposes and intent the Agreement.

7.7. Notices. Any notice or communication required or permitted under this Agreement will be made in writing and (a) sent by overnight courier, (b) mailed by overnight U.S. express mail, return receipt requested or (c) sent by telecopier. Any notice or communication to Executive will be sent to the address contained in his personnel file. Any notice or communication to the Company will be sent to the Company's principal executive offices, to the attention of its Chief Executive Officer. Notwithstanding the foregoing, either party may change the address for notices or communications hereunder by providing written notice to the other in the manner specified in this paragraph.

7.8. Entire Agreement; Amendments. This Agreement contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to that subject matter (including, without limitation, the employment offer letter dated February 12, 2018). This Agreement may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.

7.9. Withholding. All payments (or transfers of property) to Executive will be subject to tax withholding to the extent required by applicable law.

7.10. Section Headings. The headings of sections and paragraphs of this Agreement are inserted for convenience only and will not in any way affect the meaning or construction of any provision of this Agreement.

7.11. Counterparts; Facsimile. This Agreement may be executed in multiple counterparts (including by facsimile signature), each of which will be deemed to be an original, but all of which together will constitute but one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

<remainder of page intentionally left blank; signature page follows>

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer, and Executive has executed this Agreement, on the date(s) indicated below.

COLLEGIUM PHARMACEUTICAL, INC.

By: _____

Name: _____

Title: _____

Date: _____

SCOTT DREYER

_____

Date: _____

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: August 8, 2018

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: August 8, 2018

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 June 30, 2018 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: August 8, 2018

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 June 30, 2018 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: August 8, 2018