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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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)
100 Technology Center Drive Stoughton, MA	**02072**
(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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐ Emerging growth company ☒

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 31, 2018, there were 33,247,485 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 products;
- 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 and business development;
- regulatory developments in the United States;
- our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products and 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 government regulations relating to the manufacturing and marketing of pharmaceutical products, including U.S. Drug Enforcement Agency, or DEA, compliance;
- the loss of key commercial, 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)

	September 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 139,790	$ 118,697
Accounts receivable	66,533	9,969
Inventory	9,229	1,813
Prepaid expenses and other current assets	3,425	3,005
Total current assets	218,977	133,484
Property and equipment, net	6,039	1,826
Intangible assets, net	421,287	—
Restricted cash	—	97
Other long-term assets	205	161
Total assets	$ 646,508	$ 135,568
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 11,679	$ 5,684
Accrued expenses	20,933	8,541
Accrued rebates, returns and discounts	130,454	15,784
Current portion of asset acquisition obligations	116,334	—
Current portion of term loan payable	821	1,479
Total current liabilities	280,221	31,488
Asset acquisition obligations, long-term	284,828	—
Term loan payable, long-term	10,679	—
Total liabilities	575,728	31,488
Commitments and contingencies (see Note 12)		
Shareholders’ equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at September 30, 2018 and December 31, 2017; issued and outstanding shares - none at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at September 30, 2018 and December 31, 2017; issued and outstanding shares - 33,245,026 at September 30, 2018 and 32,770,678 at December 31, 2017	33	33
Additional paid-in capital	417,010	402,096
Accumulated deficit	(346,263)	(298,049)
Total shareholders’ equity	70,780	104,080
Total liabilities and shareholders’ equity	$ 646,508	$ 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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Product revenues, net	$ 70,176	$ 11,950	$ 206,986	$ 17,682
Costs and expenses				
Cost of product revenues	46,007	553	135,951	1,501
Research and development	1,907	2,069	6,412	6,378
Selling, general and administrative	33,448	22,758	96,309	67,667
Total costs and expenses	81,362	25,380	238,672	75,546
Loss from operations	(11,186)	(13,430)	(31,686)	(57,864)
Interest expense	(5,868)	—	(17,726)	—
Interest income	552	167	1,198	402
Net loss	$ (16,502)	$ (13,263)	$ (48,214)	$ (57,462)
Loss per share - basic and diluted	$ (0.50)	$ (0.45)	$ (1.46)	$ (1.95)
Weighted-average shares - basic and diluted	33,012,174	29,753,043	32,950,854	29,517,396

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine months ended September 30,	
	2018	**2017**
Operating activities		
Net loss	$ (48,214)	$ (57,462)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Nucynta amortization expense	94,340	—
Depreciation and other amortization expense	732	464
Lease incentive obligation	—	(26)
Stock-based compensation expense	10,180	5,867
Non-cash interest expense	17,112	—
Changes in operating assets and liabilities:		
Accounts receivable	(56,564)	(3,694)
Inventories	(1,193)	(85)
Prepaid expenses and other assets	1,523	(33)
Accounts payable	5,995	(4,124)
Accrued expenses	11,181	10,315
Accrued rebates, returns and discounts	92,010	—
Deferred revenue	—	(4,944)
Net cash provided by (used in) operating activities	127,102	(53,722)
Investing activities		
Cash paid for asset acquisition	(18,877)	—
Purchases of property and equipment	(3,704)	(818)
Net cash used in investing activities	(22,581)	(818)
Financing activities		
Cash paid for common stock offerings costs	(30)	—
Proceeds from issuances of common stock from public offerings, net of issuance costs of $0 and $507	—	9,425
Proceeds from issuances of common stock from employee stock purchase plans	1,117	1,141
Proceeds from term loan amendment, net of repayment of amended term loan	10,021	—
Repayment of asset acquisition obligations	(98,250)	—
Repayment of term loan	—	(2,000)
Proceeds from the exercise of stock options	4,087	428
Payments made for employee restricted stock tax withholdings	(470)	(68)
Net cash (used in) provided by financing activities	(83,525)	8,926
Net increase (decrease) in cash, cash equivalents and restricted cash	20,996	(45,614)
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	$ 139,790	$ 107,708
Supplemental disclosure of cash flow information		
Cash paid for offering costs	$ 30	$ 447
Cash paid for interest	$ 409	$ 121
Supplemental disclosure of non-cash activities		
Offering costs in accrued expenses	$ —	$ 60
Receivable from issuance of common stock from at-the-market offering in other current assets	$ —	2,090
Acquisition of property and equipment in accrued expenses	$ 1,456	$ 97
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 Stoughton, 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 Assertio Therapeutics, Inc. ("Assertio"), formerly known as Depomed, Inc., pursuant to which Assertio 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. Effective August 2018, the Company entered into a Second Amendment to the Commercialization Agreement to clarify the mechanism for transferring title to products to be sold by the Company pursuant to the agreement and various related matters. The Second Amendment to the Commercialization Agreement did not have an impact on the Company's financial statements. 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 September 30, 2018 had an accumulated deficit of $346,263. 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 September 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 of America ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements.

In the opinion of the Company's management, the accompanying unaudited Condensed Consolidated Financial Statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to fairly present the financial position of the Company as of September 30, 2018, the results of operations for the three and nine months ended September 30, 2018 and 2017, and cash flows for the nine months ended September 30, 2018 and 2017. The results of operations for the nine months ended September 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 September 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 nine months ended September 30, 2018.

Advertising and Product Promotion Costs

Advertising and product promotion costs are included in selling, general and administrative expenses and were $4,954 and $2,489 in the three months ended September 30, 2018 and 2017 respectively. Advertising and product promotion costs were $13,236 and $8,916 in the nine months ended September 30, 2018 and 2017 respectively. Advertising and product promotion costs are expensed as incurred.

Restricted Cash

As of December 31, 2017, the Company had restricted cash of $97, which represents cash held in a depository account at a financial institution to collateralize a conditional stand-by letter of credit for the Company's facility lease agreements. The Company had no restricted cash as of September 30, 2018

Leases

In March 2018, the Company entered into an operating lease for its new corporate headquarters (the "Lease") pursuant to which the Company leases approximately 50,678 of rentable square feet of space, in Stoughton, Massachusetts. The Lease commenced in August 2018 when the Company took possession of the space after tenant improvements were substantially complete. After the initial four-month free rent period following possession of the space, the Lease will continue for a term of 10 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 12 months prior to the expiration of the then current Lease term. The annual base rent is $1,214, or $23.95 per rentable square foot, and will increase annually by 2.5% to 3.1% over the subsequent Lease years.

Income Taxes

For the three and nine months ended September 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 September 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. Subsequently, the Company finalized its review of the impact of TCJA to the Company during the third quarter of 2018 and determined that there are some minor limitations on the Company's ability to deduct certain executive compensation associated with Internal Revenue Code Section 162(m). The Company made necessary adjustments during the quarter in order to Comply with the new Code Section 162(m) rules and regulations as required by TCJA and will monitor executive compensation going forward to make annual adjustments as required to continue to be in compliance with Section 162(m). The Company believes no other TCJA changes impact the Company at this time in any significant way that would require any further adjustments to its NOL and tax credit carryovers. In addition, the Company believes that there are no other changes as a result of TCJA that would result in a reduction in the Company's ability to utilize net operating loss and tax credit carryovers. 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.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through the date of issuance of these financial statements.

In November 2018, the Company entered into a new Loan and Security Agreement with Silicon Valley Bank ("SVB"), that supersedes the Company's original loan agreement and subsequent amendments with SVB. The new Loan and Security Agreement updated the loan documentation between the Company and SVB and modified the minimum liquidity ratio to be at least 1.5 to 1.0, along with other non-material changes. The new Loan and Security Agreement did not modify the Company's borrowings, interest rates, or repayment terms.

In October 2018, the Company amended its lease for its former corporate headquarters in Canton, Massachusetts ("Canton Facility Lease"), relinquishing 9,675 square feet office of space. In consideration, the Company was required to pay the landlord an immaterial fee. The Company continues to lease the remaining 9,660 square feet of office space under the original and amended terms of the Canton Facility Lease.

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

(i) 65% of annual net sales of the Nucynta Products up to $180,000, plus
(ii) 14% of annual net sales of the Nucynta Products between $180,000 and $200,000, plus
(iii) 58% of annual net sales of the Nucynta Products between $210,000 and $233,000, plus
(iv) 20% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(v) 15% of annual net sales of the Nucynta Products in excess of $258,000.

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

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 the three and nine months ended September 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, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, and in November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): 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)*, which 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 fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Target Improvements*, which clarifies certain aspects of ASU 2016-02 to correct unintended application of guidance and provide additional transition guidance.

The Company will adopt ASU 2016-02 on January 1, 2019 and is currently evaluating its effect on the consolidated financial statements. The Company anticipates adopting this standard using a modified retrospective approach by initially applying the new standard at the adoption date and recognizing a cumulative-effect adjustment to the opening balance of retained earnings. This adoption method will not impact comparative prior period disclosures presented. The Company will take advantage of the transition package of practical expedients permitted within the new standard, which, among other things, allows the Company to carryforward the historical lease classification. Based on its preliminary assessment, the Company expects to recognize a material right-to-use asset and corresponding lease liability on its balance sheet primarily related to lease agreements for its corporate headquarters and dedicated production suite at its contract manufacturing organization. In addition, the Company is in the process of implementing new accounting policies, processes and controls that will be used to account for leases going forward.

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. In the third quarter of 2017, the Company transitioned to the sell-in method of revenue recognition and the Company recorded a cumulative one-time $4,377 increase to revenues during the three months ended September 30, 2017. Therefore, the adoption of Topic 606 would not have had a material impact on the Company’s consolidated financial position, results of operations, equity or cash flows as of September 30, 2017.

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 nine months ended September 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	178,411	12,675	50,637
Liabilities assumed from asset acquisition (4)	22,406	—	254
Changes in estimate related to prior period sales	(32)	—	—
Credits/payments made	(94,587)	(4,203)	(34,220)
Balance at September 30, 2018	$ 118,845	$ 11,609	$ 18,927

(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.

(4) The Company recorded a liability of $22,660 related to sales of Nucynta Products that occurred prior to the closing date of January 9, 2018, for which the Company is liable 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 September 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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Xtampza	$ 17,034	$ 11,950	$ 50,945	$ 17,682
Nucynta	53,142	—	156,041	—
Total product revenues, net	$ 70,176	$ 11,950	$ 206,986	$ 17,682

4. Loss per Common Share

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Loss attributable to common shareholders — basic and diluted	$ (16,502)	$ (13,263)	$ (48,214)	$ (57,462)
Weighted-average number of common shares used in net loss per share - basic and diluted	33,012,174	29,753,043	32,950,854	29,517,396
Loss per share - basic and diluted	$ (0.50)	$ (0.45)	$ (1.46)	$ (1.95)

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Outstanding stock options	3,693,400	3,056,954	3,693,400	3,056,954
Warrants	—	2,445	—	2,445
Unvested restricted stock (1)	7,545	44,586	7,545	44,586
Restricted stock units	532,787	218,872	532,787	218,872

(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 September 30, 2018 and December 31, 2017.

September 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	$ 92,427	$ 92,427	$ —	$ —
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 September 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 September 30, 2018	As of December 31, 2017
Raw materials	$ 547	$ 616
Work in process	908	322
Finished goods	7,774	875
Total inventory	$ 9,229	$ 1,813

The aggregate charges related to excess inventory for the three and nine months ended September 30, 2018 and 2017 were immaterial. These expenses were recorded as a component of cost of product revenues.

7. Intangible Assets and Asset Acquisition Obligations

As of September 30, 2018, the Company's only intangible asset related to the Company's Commercialization Agreement with Assertio, pursuant to which Assertio 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 the Commercialization Agreement should be accounted for as 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 a component of cost of product revenues in the Statement of Operations on a straight-line basis over its useful life as it approximates cash inflows. For the three and nine months ended September 30, 2018, the Company recognized amortization expense of $32,407 and $94,340, respectively. As of September 30, 2018, the remaining amortization period is approximately 3.3 years and estimated amortization for the remainder of 2018, 2019, 2020, and 2021 is expected to be $32,406, $129,627, $129,627, and $129,627, respectively.

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

	As of September 30, 2018	
Gross carrying amount	$	515,627
Accumulated amortization		(94,340)
Intangible assets, net	$	421,287

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 Assertio 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 nine months ended September 30, 2018, the Company recognized interest expense of $5,641 and $17,112 relating to the minimum royalty payments. As of September 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 $5,271, $17,138, $10,907, and $4,272, respectively.

For the three and nine months ended September 30, 2018, the Company paid Assertio minimum royalty payments of $33,750 and $98,250, respectively.

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

2018	$	33,750
2019		135,000
2020		135,000
2021		135,000
Total remaining minimum royalty payments due	$	438,750
Less: Unamortized discount		(37,588)
Carrying value of minimum royalty payments	$	401,162

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 September 30, 2018 and December 31, 2017.

Amortization Expense

Amortization expense relating to the Company’s intangible assets for the three and nine months ended September 30, 2018 and 2017 was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2018	**2017**	**2018**	**2017**
Nucynta amortization expense included in cost of product revenues	$ 32,407	$ —	$ 94,340	$ —
Onsolis amortization expense included in selling, general and administrative expense	—	48	—	225
Total amortization expense	$ 32,407	$ 48	$ 94,340	$ 225

8. Accrued Expenses

Accrued expenses consisted of the following:

	As of September 30, 2018	As of December 31, 2017
Accrued cost of product revenues	$ 7,440	$ —
Accrued inventory	4,778	—
Accrued bonuses	2,721	2,940
Accrued incentive compensation	1,744	1,790
Accrued payroll and related benefits	1,600	1,382
Accrued other operating costs	1,159	877
Accrued sales and marketing	844	624
Accrued audit and legal	431	405
Accrued interest	212	6
Accrued development costs	4	517
Total accrued expenses	$ 20,933	$ 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 Assertio, the Company entered into a Consent and Amendment to Loan and Security Agreement (the “Consent and Amendment”) with SVB to amend the Existing Term Loan. The Consent and Amendment provided the Company with a new term loan facility in an original principal amount of $11,500 (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.

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 September 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 nine months ended September 30, 2018 were as follows:

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount			
Balance, December 31, 2017	32,770,678	$ 33	$ 402,096	$ (298,049)	$ 104,080
Exercise of common stock options	335,025	—	4,087	—	4,087
Issuance for employee stock purchase plan	86,929	—	1,117	—	1,117
Vesting of restricted stock units	74,585	—	—	—	—
Shares withheld for employee taxes upon vesting of restricted stock units	(22,191)	—	(470)	—	(470)
Stock-based compensation	—	—	10,180	—	10,180
Net loss	—	—	—	(48,214)	(48,214)
Balance, September 30, 2018	33,245,026	$ 33	$ 417,010	$ (346,263)	$ 70,780

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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Research and development expenses	$ 388	$ 222	$ 1,091	$ 673
Selling, general and administrative expenses	3,538	1,878	9,089	5,194
Total stock-based compensation expense	$ 3,926	$ 2,100	$ 10,180	$ 5,867

At September 30, 2018, there was approximately $31,566 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 September 30, 2018, there were 1,066,087 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 upon termination.

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. The Company accounted for this modification under ASC 718, and, per guidance, determined the 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 nine months ended September 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 September 30, 2018	—	$ —

(1) Excludes activity from the early exercise of stock options. As of September 30, 2018, 7,545 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 nine months ended September 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	403,334	23.41
Vested	(74,585)	13.67
Forfeited	(14,834)	18.91
Outstanding at September 30, 2018	532,787	$ 20.48

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	1,132,280	23.89		
Exercised	(335,025)	12.20		
Cancelled	(141,545)	16.97		
Outstanding at September 30, 2018	3,693,400	$ 16.25	8.2	$ 7,101
Exercisable at September 30, 2018	1,492,524	$ 12.71	7.4	$ 4,670
Vested and expected to vest at September 30, 2018	3,459,105	$ 15.96	8.1	$ 6,922

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

	Nine months ended September 30,	
	2018	2017
Risk-free interest rate	2.6 %	2.0 %
Volatility	65 %	71 %
Expected term (years)	6.11	6.01
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 nine months ended September 30, 2018, 86,929 shares of common stock were purchased for total proceeds of $1,117. The expense for the three months ended September 30, 2018 and 2017 was $156 and $74, respectively. The expense for the nine months ended September 30, 2018 and 2017 was $398 and $288, 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 entered an order to institute post-grant review of all claims of the ’961 patent on October 4, 2018, upon a finding that it is more likely than not that the claims of the ′961 patent are unpatentable. The PTAB has scheduled oral argument on the proceedings for July 10, 2019 and, absent special circumstances, will issue a decision on the patentability of the ′961 patent by no later than October 4, 2019.

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 asserted infringement of five patents: the ′497 patent, the ′933 patent, the ′717 patent, the ′919 patent, and the ′961 patent. The Court issued an order on September 28, 2018 in which it granted in part a motion for summary judgment filed by the Company, and in which the Court ruled that the ′497 and ′717 patents are not infringed by the Company. As a result, only the ′933, the ′919, and the ′961 patents remain in dispute. On October 16, 2018, the Company filed a motion to stay proceedings in the district court on the ‘961 patent pending the PGR. None of these suits are associated with any stay of FDA approval for Xtampza. Purdue has made a demand for monetary relief but has not quantified its alleged damages. Purdue has also requested a judgment of infringement, an adjustment of the effective date of FDA approval, and an injunction on the sale of the Company's products accused of infringement. The Company has denied all claims and seeks a judgment that the patents are invalid and/or not infringed by the Company; the Company is also seeking a judgment that the case is exceptional, with an award to the Company of its fees for defending the case.

The parties are in the early stages of fact discovery. Written discovery has commenced with depositions expected to commence during the first half of 2019. A claim construction hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the ′933, ′497, and ′717 patents. No trial date has been scheduled.

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. According to the Scheduling Order, 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 and other pharmaceutical manufacturers and distributors filed motions to dismiss the case and the Plaintiffs filed oppositions to these motions to dismiss. These motions are currently pending before the Court.

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 14, 2018, the lawsuit was conditionally transferred by the Judicial Panel on Multi-District Litigation to the federal Prescription Opiate Multi District Litigation (the "MDL") in the Southern District of Ohio. On April 10, 2018, the conditional transfer was finalized and the lawsuit was docketed in the MDL on April 11, 2018. On May 4, 2018, the Company 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. On September 26, 2018, the Company was named in two lawsuits filed in the MDL by the Fiscal Court of Lee County, Kentucky and the Fiscal Court of Wolfe County, Kentucky. 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. On June 6, 2018, a lawsuit was filed by Mercer County, Pennsylvania, against the Company and other pharmaceutical manufacturers and distributors. These lawsuits allege claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws. These cases have been consolidated for discovery purposes in the Delaware County Court of Common Pleas as part of a consolidated proceeding of similar lawsuits brought by numerous Pennsylvania counties against other pharmaceutical manufacturers and distributors.

On July 30, 2018, a lawsuit was filed by the City of Worcester, Massachusetts against the Company and other pharmaceutical manufacturers and distributors. The action alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, violations of Mass Gen. Laws ch. 93A, *Section 11*, unjust enrichment and civil conspiracy. On September 26, 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. Plaintiffs have opposed the Conditional Transfer

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 Assertio Therapeutics, Inc. (formerly known as Depomed, Inc.), or Assertio, pursuant to which Assertio 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 managers.

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 Assertio 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 Assertio 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 Assertio 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 $48.2 million and $57.5 million for the nine months ended September 30, 2018 and 2017 respectively. As of September 30, 2018, we had an accumulated deficit of $346.3 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We expect to continue to incur net losses in the near future as we continue to commercialize our products. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase in connection with our ongoing activities as we:

- expand our promotional efforts for our 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 September 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 September 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 September 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, 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 2017, 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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(in thousands)			
Product revenues, net	$ 70,176	$ 11,950	$ 206,986	$ 17,682
Cost of product revenues	46,007	553	135,951	1,501
Research and development	1,907	2,069	6,412	6,378
Selling, general and administrative	33,448	22,758	96,309	67,667
Interest expense	(5,868)	—	(17,726)	—
Interest income	552	167	1,198	402
Net loss	$ (16,502)	$ (13,263)	$ (48,214)	$ (57,462)

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

Product revenues, net were $70.2 million for the three months ended September 30, 2018, or the 2018 Quarter, compared to $12.0 million for the three months ended September 30, 2017, or the 2017 Quarter. The $58.2 million increase was primarily related to the Commercialization Agreement with Assertio consummated in January 2018 to sublicense the Nucynta Products. In the 2018 Quarter, Nucynta IR and ER product revenues, net were $34.3 million and $18.9 million, respectively. In addition, Xtampza product revenues, net were $17.0 million in the 2018 Quarter, which represents a $5.0 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 $46.0 million for the 2018 Quarter, compared to $553,000 for the 2017 Quarter. The $45.4 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 $1.9 million for the 2018 Quarter, compared to $2.1 million for the 2017 Quarter. In the 2018 Quarter, development manufacturing expenses decreased by $509,000 following the termination of the Onsolis License and Development Agreement in 2017, offset by a $268,000 increase in employee headcount, including an increase in stock-based compensation expense.

Selling, general and administrative expenses were $33.4 million for the 2018 Quarter, compared to $22.8 million for the 2017 Quarter. The $10.6 million increase was primarily related to:

- an increase in commercialization costs, including consulting and marketing expenses, of $4.1 million primarily related to the Nucynta Products and continued support of Xtampza;
- an increase in salaries, wages and benefits of $3.2 million, primarily due to an increase in employee headcount, including an increase in stock-based compensation expense, of $1.7 million, and incentive compensation;
- an increase in management consulting costs of $1.2 million;
- an increase in PDUFA related expenses of $756,000, primarily due to the acquisition of the Nucynta Products; and
- an increase in audit, legal, and other professional fees of $631,000.

Interest expense was $5.9 million for the 2018 Quarter, compared to none in the 2017 Quarter. The increase was primarily due to an increase of $5.6 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 $197,000.

Interest income was $552,000 for the 2018 Quarter, compared to $167,000 in the 2017 Quarter. The increase was primarily due to higher interest rates on money market funds.

Comparison of the nine months ended months September 30, 2018 and September 30, 2017

Product revenues, net were $207.0 million for the nine months ended September 30, 2018, or the 2018 Period, compared to $17.7 million for the nine months ended September 30, 2017, or the 2017 Period. The $189.3 million increase was primarily related to the Commercialization Agreement with Assertio consummated in January 2018 to sublicense the Nucynta Products. In the 2018 Period, Nucynta IR and ER product revenues, net were $95.7 million and $60.3 million, respectively. In addition, Xtampza product revenues, net were $51.0 million in the 2018 Period, which represents a $33.3 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 $136.0 million for the 2018 Period, compared to $1.5 million for the 2017 Period. The $134.5 million increase was primarily related to $94.3 million of amortization expenses 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 $6.4 million for the 2018 Period, compared to $6.4 million for the 2017 Period. In the 2018 Period, salaries, wages and benefits increased $503,000, primarily due to increases in employee headcount and stock-based compensation expense, offset by a $553,000 decrease in development manufacturing expenses following the termination of the Onsolis License and Development Agreement in 2017.

Selling, general and administrative expenses were $96.3 million for the 2018 Period, compared to $67.7 million for the 2017 Period. The $28.6 million increase was primarily related to:

- an increase in salaries, wages and benefits of $10.4 million, primarily due to increases in employee headcount, including an increase in incentive compensation and stock-based compensation expense, of $3.9 million, and incentive compensation;
- an increase in sales and marketing costs of $9.1 million, primarily related to the Nucynta Products and continued support of Xtampza;
- an increase in PDUFA related expenses of $2.3 million, primarily due to the acquisition of the Nucynta Products;
- an increase in audit, legal, and other professional fees of $2.0 million;
- an increase in regulatory costs, including consulting and subscriptions, of $2.0 million, primarily due to the acquisition of the Nucynta Products;

- an increase in management consulting fees costs of $1.6 million; and
- an increase in insurance expense of $1.4 million, primarily due to an increase in product liability insurance.

Interest expense was $17.7 million for the 2018 Period, compared to none in the 2017 Period. The increase was primarily due to an increase of $17.1 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 $614,000.

Interest income was $1.2 million for the 2018 Period, compared to $402,000 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 September 30, 2018, we had $139.8 million in cash and cash equivalents.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents at September 30, 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 September 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 nine months ended September 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%.

In November 2018, we entered into a new Loan and Security Agreement with Silicon Valley Bank ("SVB"), that supersedes our original loan agreement and subsequent amendments with SVB. The new Loan and Security Agreement updated the loan documentation between us and SVB and modified the minimum liquidity ratio to be at least 1.5 to 1.0, along with other non-material changes. The new Loan and Security Agreement did not modify our borrowings, interest rates, or repayment terms.

Cash Flows

	Nine months ended September 30,	
	2018	2017
Net cash provided by (used in) operating activities	$ 127,102	$ (53,722)
Net cash used in investing activities	(22,581)	(818)
Net cash used in financing activities	(83,525)	8,926

Operating activities. Cash provided by operating activities was $127.1 million in the 2018 Period, compared to cash used by operating activities of $53.7 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 Assertio in the 2018 Period, including $94.3 million of amortization expense from the intangible asset and non-cash interest expense associated with the minimum royalty payments of $17.1 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 $22.6 million in the 2018 Period, compared to $818,000 used in the 2017 Period. The increase in cash used in investing activities was primarily due to $18.9 million paid to Assertio for the Nucynta asset acquisition and $3.7 million paid for purchases of property, plant, and equipment for the corporate headquarters and dedicated production suite at its contract manufacturing organization.

Financing activities. Cash used in financing activities was $83.5 million for the 2018 Period, compared to $8.9 million provided 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 $98.3 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 $3.7 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 September 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 us to seek additional cash through private or public debt or equity offerings. Such funds may not be available when needed, or, we may not be able to obtain funding on favorable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products 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 our products;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products;
- the outcome, timing and cost of regulatory approvals by the FDA, including the potential for the FDA to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;
- the timing and costs associated with manufacturing (1) our products, for commercial sale and clinical trials, and (2) our 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;
- 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 Assertio 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
GAAP net loss	$ (16,502)	$ (13,263)	$ (48,214)	$ (57,462)
Non-GAAP adjustments:				
Stock-based compensation expense	3,926	2,100	10,180	5,867
Nucynta related amortization expense (1)	32,407	-	94,340	-
Nucynta non-cash interest expense (2)	5,641	-	17,112	-
Nucynta minimum royalty payment due (3)	(33,750)	-	(98,250)	-
Total non-GAAP adjustments	$ 8,224	$ 2,100	$ 23,382	$ 5,867
Non-GAAP adjusted loss	$ (8,278)	$ (11,163)	$ (24,832)	$ (51,595)

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

(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 Assertio in connection with the Commercialization Agreement.

CONTRACTUAL OBLIGATIONS

In August 2018, we took possession of our new corporate headquarters, , which we lease approximately 50,678 of rentable square feet of space, in Stoughton, Massachusetts (the “Lease”) with Campanelli-Trigate 100TCD Stoughton, LLC (the “Landlord”),. After the initial four-month free rent period following possession of the space, the Lease will continue for a term of 10 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 12 months prior to the expiration of the initial term of the Lease. The annual base rent is $1,214, or $23.95 per rentable square foot, and will increase annually by 2.5% to 3.1% over the subsequent Lease years.

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 September 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 September 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

Although we currently generate revenue from the sale of products, we may never become profitable. Our ability to generate sufficient revenue to become profitable is dependent upon our ability to develop, license or acquire, and commercialize our 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. Our ability to generate sufficient revenue to become profitable depends upon our ability to successfully commercialize our products and any other products and product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from our current or future products and product candidates depends on a number of factors, including our ability to:

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

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

Even though we are generating revenues from the sale of our products 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 September 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 us to seek additional cash through private or public debt or equity offerings.

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

- significantly delay, scale back or discontinue the development and/or the commercialization of our products or our product candidates or one or more of our other research and development initiatives;
- seek collaborators for our products 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 sufficient levels of revenue from the sale of our products;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products and any other products we may acquire or develop;
- the outcome, timing and cost of regulatory approvals by the FDA, including the potential for the FDA to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;
- the timing and costs associated with manufacturing (1) our products, for commercial sale and clinical trials, and (2) our 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;
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our products, 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 our 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, 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 Assertio, 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 Assertio 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 of the Nucynta Products is unsuccessful, there can be no assurance that we will have sufficient cash flow to pay such licensing fees.

Our obligation to Assertio 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 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, Massachusetts, 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 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 our products.

To date, we have invested substantial resources in the development of Xtampza, which has been approved by the FDA. In February 2018, we began marketing the Nucynta Products Our business and future success are substantially dependent on our ability to successfully and timely commercialize these products. We may never be able to commercialize our 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 with similar indications;
- our ability to successfully defend any challenges to our intellectual property or suits asserting patent infringement relating to Xtampza;
- the availability of coverage and adequate reimbursement for Xtampza;
- a continued acceptable safety profile of Xtampza; 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 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 or suits asserting patent infringement relating to the Nucynta Products;
- obtain adequate supply of Nucynta ER and Nucynta IR; and
- comply with applicable legal and regulatory requirements.

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 Assertio 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 our products. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

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

The FDA can change the product labeling for Xtampza 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.

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 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 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 and the Nucynta Products, 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. 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 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 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 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 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 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 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.

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.

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 Assertio 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, Assertio 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, Assertio 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 Assertio will have the right to terminate the Commercialization Agreement without penalty. Assertio 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.

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 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, in the United States. 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 our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies.

In the United States, engaging in off-label promotion of our products 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 our 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.

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

Our products and our product candidates contain, and our future product candidates will likely contain, controlled substances that are subject to state and federal 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 and federal law enforcement and regulatory agencies and comply with state and federal laws and regulations regarding the manufacture, use, sale, importation,

exportation and distribution of controlled substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. 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. For 2019, the DEA has proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas. 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 our 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 our 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 our products and product candidates and any commercial sales of our 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 our products and our product candidates. Any agreements we may enter into in the future with collaborators in connection with the development or commercialization of our products 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.

Our 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 our 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. 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 our 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 our 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, 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, and hydrocodone 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 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 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 in the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking.

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

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

With respect to patent rights, our patent applications may not issue into patents, and any issued patents may not provide protection against competitive technologies, may be held invalid or unenforceable if challenged or may be interpreted in a manner that does not adequately protect our technology, 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 is highly uncertain, and changes in U.S. patent law have increased that uncertainty and could diminish the value of patents in general, thereby impairing our ability to protect our 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 may diminish the value of our patents or narrow the scope of our patent protection.

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

Patent reform legislation could increase the uncertainties and costs associated with the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, 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. 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 in the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor, or those to whom they communicate with, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed, our competitive position would be harmed.

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

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

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

The USPTO requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO in several stages over the lifetime of the patents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our 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 our 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 our 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 our products;
- 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 our products or our product candidates. To the extent we commercialize our products 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 our 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 our products or any of our product candidates (if regulatory approval is obtained), for which we receive final regulatory approval. Acceptance and use of our 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 our 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 our products and our product candidates relative to competing products;
- the potential and perceived advantages of our products and our product candidates over alternative treatments;
- the convenience and ease of administration to patients of our products and our product candidates;
- actual and perceived availability of coverage and reimbursement for our 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 our 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 our 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 sufficient revenue to 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 our products and our product candidates and may reduce the prices we are able to obtain for our products.

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

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.

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.

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

In addition, state pharmacy laws may permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents, or may permit pharmacists and pharmacy benefit managers to seek prescriber authorization to substitute generics in place of our products 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 can vary widely. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Pricing limitations may hinder our ability to recoup our investment in our products 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 our 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. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for our products 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 our 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 our 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 our 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 SUPPORT Act, described above, also addresses opioid-related abuse by, among other things, seeking to increase access to and reimbursement for addiction treatment, advancing new initiatives to promote education and awareness of appropriate pain treatment among health care providers and improving coordination among federal agencies in relation to border checks.

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

Recently, CVS Pharmacy announced it would only fill first-time opioid prescriptions for acute pain for a seven day supply. In July 2017, the Pharmaceutical Care Management Association, a trade association representing pharmacy benefit managers, wrote a letter to the commissioner of the FDA in which it expressed support for, among other things, the CDC guidelines and a seven-day limit on the supply of opioids for acute pain. In addition, states, including the Commonwealths of Massachusetts and Virginia and the States of New York, Ohio, Arizona, Maine, New Hampshire, Vermont, Rhode Island, Colorado, Wisconsin, Alabama, South Carolina, Washington and New Jersey, have either recently enacted, intend to enact, or have pending legislation or regulations designed to, among other things, limit the

duration and quantity of initial prescriptions of immediate release forms of opiates and mandate the use by prescribers of prescription drug databases and mandate prescriber education. 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 our 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 our 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. In July 2018, the FDA posted three revised product-specific guidances related to generic abuse-deterrent
opioid formulations, which recommend specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of FDA's wider focus on assisting developers of generic abuse-deterrent formulations navigate the regulatory path to market more quickly. Earlier market entry of generic abuse-deterrent formulations could have a material adverse effect on our business.

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

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

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

We presently depend upon a single supplier for the active ingredient for Xtampza (oxycodone base) and the Nucynta Products (tapentadol) and we contract, either directly or indirectly, through Assertio 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, Assertio, currently obtain active ingredients from this manufacturer on a purchase-order basis, either we, Assertio, 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.

Our products 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.

Our products are and any product candidate for which we obtain marketing approval could be subject to a comprehensive regulatory scheme, including post-marketing requirements (“PMRs”)to conduct epidemiological studies and clinical trials. We intend to fulfill our PMRs by virtue of our participation in the Opioid PMR Consortium (“OPC”). Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of OPC and engage in decision-making as a member of that organization, but do not have a majority. If the OPC fails to conduct sufficiently rigorous studies or is unable to achieve the patient enrollment or other requirements established by the FDA, we may be unable to satisfy our PMRs and the FDA may choose to withdraw or otherwise restrict its approval of our products 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 our 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 our 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 our 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 35%, 31% and 28% of our product shipments for nine months ended September 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. Our 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, BioDelivery Sciences, 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

- 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, which could have a material adverse effect on our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or 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 our 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 our products and any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including:

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

- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, 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 laws regulating marketing activities and requiring manufacturers to report marketing expenditures, payments and other transfers of value to physicians and other healthcare providers;

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

- state equivalents of each of the above laws, including state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers; state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

In connection with our research and development activities and our manufacture of materials and products 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;
- 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 September 30, 2018, holders of an aggregate of approximately 1.5 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, a person associated with Skyline Venture Partners V, L.P. currently serves on our board of directors. The interests of Skyline Venture Partners V, L.P. may not always coincide with the interests of the other shareholders, and the concentration of control in 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 September 30, 2018, there were outstanding options to purchase an aggregate of 3,693,400 shares of our common stock at a weighted average exercise price of $16.25 per share, of which options to purchase 1,492,524 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 September 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
July 1, 2018 through July 31, 2018	1,275	$ 20.15	-	-
August 1, 2018 through August 31, 2018	4,901	$ 18.03	-	-
September 1, 2018 through September 30, 2018	-	-	-	-
Total	**6,176**	**$ 18.47**	-	-

(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+	Employment Agreement dated July 10, 2018, by and between Collegium Pharmaceutical, Inc. and Scott Dreyer [(1)].
10.2	Second Amendment, dated August 29, 2018, to Commercialization Agreement by and among Assertio Therapeutics, Inc. and Collegium Pharmaceutical, Inc. and Collegium NF, LLC (filed herewith).
10.3	Second Amendment, dated October 19, 2018, to Lease by and between Park at 95, LLC and Collegium Pharmaceutical, Inc. (filed herewith).
10.4	Amended and Restated Loan and Security Agreement, dated November 1, 2018, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc. (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 Quarter Report on Form 10-Q filed with the Commission on August 8, 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: November 8, 2018

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

Date: November 8, 2018

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

AMENDMENT NO. 2 TO COMMERCIALIZATION AGREEMENT

THIS AMENDMENT NO. 2 TO COMMERCIALIZATION AGREEMENT (this "Amendment No. 2") is entered into as of August 29, 2018, by and among Assertio Therapeutics, Inc. (f/k/a Depomed, Inc.), a Delaware corporation ("Assertio"), Collegium Pharmaceutical, Inc., a Virginia corporation ("Collegium"), and Collegium NF, LLC, a Delaware limited liability company and wholly owned subsidiary of Collegium ("Newco") and amends that certain Commercialization Agreement, dated as of December 4, 2017, as amended January 9, 2018 (the "Commercialization Agreement"), by and among Assertio, Collegium, and Newco. Each of Assertio, Collegium and Newco is referred to herein individually as a "party" and collectively as the "parties." Defined terms used herein but not otherwise defined herein shall have the meaning ascribed to such terms in the Commercialization Agreement.

WHEREAS, the parties entered into that certain Commercialization Agreement and wish to further amend certain terms of the Commercialization Agreement; and

WHEREAS, Section 17.4 of the Commercialization Agreement provides that the Commercialization Agreement may be amended by written agreement of the parties thereto.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants herein contained, the parties, intending to be legally bound, hereby agree as follows:

1. Section 3.2(c)(viii) of the Commercialization Agreement is hereby amended and restated as follows:

"(viii) To the extent permitted under the applicable CMO Supply Agreement, title to the Supplied Products ordered hereunder by or on behalf of Collegium shall transfer as follows:

(A) Title shall transfer from the applicable CMO to Depomed at such time as the Supplied Products are loaded onto a carrier vehicle arranged for and managed by Depomed for shipment at the shipping point; and

(B) Title shall transfer from Depomed to Collegium upon delivery of the Supplied Products to the loading dock of Collegium's third-party logistics provider.

Notwithstanding the terms set forth in subsection (B), above, in the event of a supply shortage with respect to the Supplied Products, Depomed and Collegium may modify the foregoing as the parties may mutually agree is necessary or advisable to facilitate the delivery and availability of such Supplied Products.

The time during which Depomed retains title to the Supplied Products shall be referred to as the "Depomed Supplied Product Title Period." Collegium shall cover all costs incurred by, and insurance requirements of, Depomed during the Depomed Supplied Product Title Period pursuant to this Section 3.2(c)(viii) in accordance with the applicable provisions of Section 3.2(c)."

2. Section 8.2 of the Commercialization Agreement is hereby amended and restated as follows:

Following the Closing, and in any event not later than October 31, 2018, Collegium shall obtain or reserve its own NDC Numbers for the Products and shall use commercially reasonable efforts to have in place as soon as reasonably practicable all

authorizations from Governmental Authorities necessary for Collegium to use such NDC Numbers for the Products. Additionally, following the completion of the product serialization process, Assertio shall use its best efforts to complete the labelling changes required to reflect both the new NDC Numbers and the involvement of Collegium as soon as reasonably practical. Following such time, Collegium shall use its new NDC numbers on all invoices, order and other communications with customers and Governmental Authorities.

3. Except as herein expressly amended, the Commercialization Agreement is ratified and confirmed in all respects by each of the parties hereto and shall remain in full force and effect and enforceable against them in accordance with its terms. Unless the context otherwise requires, the term "Agreement" as used in the Commercialization Agreement shall be deemed to refer to the Commercialization Agreement as amended hereby.

4. This Amendment No. 2 may be executed in one or more counterparts, each of which shall be deemed an original, and together shall constitute one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party, it being understood that the parties need not sign the same counterpart. This Amendment No. 2, following its execution, may be delivered via telecopier machine or other form of electronic delivery, which shall constitute delivery of an execution original for all purposes.

5. This Amendment No. 2 shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law, principles or rules of such state, to the extent such principles or rules are not mandatorily applicable by statute and would permit or require the application of the laws of another jurisdiction.

(The remainder of this page is intentionally left blank. The signature page follows.)

IN WITNESS WHEREOF, the parties have caused this Amendment No. 2 to be executed on the date first above written.

ASSERTIO THERAPEUTICS, INC.

By: _____

Name: _____

Title: _____

COLLEGIUM PHARMACEUTICAL, INC.

By: _____

Name: _____

Title: _____

COLLEGIUM NF, LLC

By: _____

Name: _____

Title: _____

Exhibit 10.3

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE (this "Second Amendment") is made this 19th day of October, 2018, by and between **Park at 95, LLC** ("Landlord") and **Collegium Pharmaceutical, Inc.** ("Tenant").

R E C I T A L S:

A. Reference is made to that certain Office Lease Agreement dated August 28, 2012 by and between 780 Dedham Street Holdings, LLC, the predecessor in title to Landlord, and Tenant, demising approximately 9,675 square feet of rentable square feet of space on the first floor of the building known as Suite 800, located at 780 Dedham Street, Canton, Massachusetts (the "Original Premises"). Said lease, as amended by that certain First Amendment to Lease dated March 24, 2015 (the "First Amendment") is hereinafter referred to as the "Lease."

B. Landlord and Tenant are the current holders, respectively, of the landlord's and tenant's interests in the Lease.

C. Pursuant to the First Amendment, Tenant increased its rentable square footage by adding to the Original Premises approximately 9,660 rentable square feet of space on the first floor of the Building known as Suite 700 (the "Additional Space"), for a total of 19,335 rentable square feet (the "Existing Space").

D. Tenant desires to reduce the Existing Space by surrendering to Landlord the Original Premises.

E. Landlord and Tenant now desire to amend the Lease as set forth herein.

F. Capitalized terms not defined herein shall have the meanings set forth in the Lease.

A G R E E M E N T S:

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree to amend the Lease as follows:

1. Surrendered Space. Effective as of the Delivery Date, Tenant's rights and obligations under the Lease with respect to the Original Premises shall be, and hereby are, terminated. Tenant shall surrender to Landlord the Original Premises on or before October 31, 2018 (the "Delivery Date"). Effective as of the Delivery Date, and throughout the remaining Term of the Lease (as amended hereby), all references to the Premises in the Lease (as amended hereby) shall be deemed to mean the Additional Space, as identified on the plan attached hereto as Exhibit A (the "Remaining Space"). All of Tenant's and Landlord's rights and obligations under the Lease (as amended hereby) regarding the Remaining Space shall survive and continue to be in full force and effect.

2. Surrendered Personal Property. Tenant hereby agrees that any furniture remaining in the Original Premises on the day following the Delivery Date shall thereafter become the property of Landlord or, at Landlord's option, the succeeding tenant, without any warranty by Tenant whatsoever, and Tenant's rights, interest in, and ownership of said furniture shall thereupon be terminated.

3. Termination Payment. In consideration for Landlord's execution and delivery of this Second Amendment and Landlord's releasing Tenant from its future obligations under the Lease regarding the Original Premises, Tenant shall pay to Landlord the amount of $66,642.50 (the "Termination Payment") together with Tenant's execution and delivery of this Second Amendment.

4. Tenant's Pro Rata Share. Effective on the Delivery Date, Tenant's Pro Rata Share as set forth in Article I, Section E shall be 11.8%.

5. Base Rent. Effective on the Delivery Date, Base Rent for the Remaining Space for the remaining Term of the Lease (as amended hereby) shall be as follows:

Period	Annual Rent	Monthly Rent	Rent Per Square Foot
10/31/18 – 8/31/19	$119,397.60*	$9,949.80	$12.36*
9/1/19 – 8/31/20	$122,971.80	$10,247.65	$12.73

*Annualized amount.

6. Parking. The first sentence of the first paragraph of Exhibit E, Section 3, Parking, is hereby deleted in its entirety and replaced with the following:

> "Tenant shall have the right to use, on a non-reserved, non-exclusive basis, parking in the parking lot adjacent to the Building at a ratio of four (4) vehicle spaces per each one thousand (1,000) rentable square feet of the Premises (i.e. non-reserved parking for thirty-nine (39) motor vehicles based upon Tenant's occupancy of 9,660 rentable square feet; the foregoing referred to herein as "Tenant's Parking Rights").

7. Brokers. Landlord and Tenant each warrant and represent to the other that they have dealt with no brokers in connection with the negotiation or consummation of this Second Amendment other than CBRE, and in the event of any brokerage claim against either party by any person claiming to have dealt with either Landlord or Tenant in connection with this Second Amendment, the party with whom such person claims to have dealt shall defend and indemnify the other party against such claim. Landlord shall be responsible for any commission due CBRE with respect to this Second Amendment per separate agreement.

8. Ratification. In all other respects the Lease shall remain unmodified and shall continue in full force and effect, as amended hereby. The parties hereby ratify, confirm, and reaffirm all of the terms and conditions of the Lease, as amended hereby. In the event of any conflict or inconsistency between this Second Amendment and the Lease, this Second Amendment shall control.

9. Miscellaneous. Each of Landlord and Tenant represents to the other that its signatory hereto has the authority to execute and deliver the same on its behalf. This Second Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of such counterparts together will constitute one and the same instrument. Images of the handwritten signature and acknowledgement (if any) pages of each signatory on this Second Amendment may be executed via an inked or "wet" signature and the executed pages may be delivered using portable document format (i.e., PDF) or similar file type and transmitted via electronic mail and, upon receipt, shall be deemed originals and binding upon the signatories hereto.

[Signatures appear on next page]

IN WITNESS WHEREOF the parties hereto have executed this Second Amendment to Lease on the date first written above in multiple copies, each to be considered an original hereof, as a sealed instrument.

TENANT:	LANDLORD:
Collegium Pharmaceutical, Inc., a Virginia corporation	**Park at 95, LLC,** a Massachusetts limited liability company
By: _____ Name: _____ Title: _____	By: _____ Name: _____ Title: _____

AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

THIS AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT (this "**Agreement**") dated as of November 1, 2018 (the "**Effective Date**") between **SILICON VALLEY BANK**, a California corporation with a loan production office located at 275 Grove Street, Suite 2-200, Newton, Massachusetts 02466 ("**Bank**"), and **COLLEGIUM PHARMACEUTICAL, INC.**, a Virginia corporation ("**Borrower**"), provides the terms on which Bank shall lend to Borrower and Borrower shall repay Bank. This Agreement amends and restates in its entirety, and replaces, the terms of (and obligations outstanding under) that certain Loan and Security Agreement between Borrower and Bank dated as of August 28, 2012, as amended by that certain First Amendment to Loan and Security Agreement dated as of January 31, 2014, by and between Borrower and Bank, as further amended by that certain Assumption and Second Amendment to Loan and Security Agreement dated as of August 12, 2014, by and between Borrower and Bank, as further amended by that certain Third Amendment to Loan and Security Agreement dated as of September 25, 2014, by and between Borrower and Bank, as further amended by that certain Fourth Amendment to Loan and Security Agreement dated as of October 31, 2014, by and between Borrower and Bank, as further amended by that certain Consent and Fifth Amendment to Loan and Security Agreement dated as of December 31, 2015, by and between Borrower and Bank, and further amended by that certain Consent and Sixth Amendment to Loan and Security Agreement dated as of January 9, 2018, and as further amended by that certain Seventh Amendment to Loan and Security Agreement dated as of March 30, 2018, by and between Borrower and Bank (as the same may from time to time be further amended, modified, supplemented or restated "**Prior Loan Agreement**"). The parties agree as follows:

1. ACCOUNTING AND OTHER TERMS

Accounting terms not defined in this Agreement shall be construed following GAAP and calculations and determinations must be made following GAAP, provided that if at any time any change in GAAP would affect the computation of any financial ratio or requirement set forth in any Loan Document, and either Borrower or Bank shall so request, Borrower and Bank shall negotiate in good faith to amend such ratio or requirement to preserve the original intent thereof in light of such change in GAAP; provided, further, that, until so amended, (a) such ratio or requirement shall continue to be computed in accordance with GAAP prior to such change therein and (b) Borrower shall provide Bank financial statements and other documents required under this Agreement or as reasonably requested hereunder setting forth a reconciliation between calculations of such ratio or requirement made before and after giving effect to such change in GAAP. Calculations and determinations must be made following GAAP. Notwithstanding the foregoing, all financial covenant calculations (if any) shall be computed with respect to Borrower only, and not on a consolidated basis. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein.

2. LOAN AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay Bank the outstanding principal amount of all Credit Extensions and accrued and unpaid interest thereon as and when due in accordance with this Agreement.

2.1.1 Term Loan Advance.

(a) Availability. Subject to the terms and conditions of this Agreement, on or about January 9, 2018, Bank made one (1) Term Loan Advance in an original principal amount of Eleven Million Five Hundred Thousand Dollars ($11,500,000.00) (the "**Term Loan Advance**"), whereby all or a portion of the Term Loan Advance was used to repay in full Borrower's outstanding obligations and liabilities to Bank. After repayment, the Term Loan Advance (or any portion thereof) may not be reborrowed.

(b) Interest Period. Commencing on February 1, 2018, and continuing on each Payment Date thereafter, Borrower shall make monthly payments of interest on the principal amount of the Term Loan Advance at the rate set forth in Section 2.2(a).

(c) Repayment. Commencing on the Term Loan Amortization Date and continuing on each Payment Date thereafter, Borrower shall repay the Term Loan Advance in (i) consecutive equal monthly installments of principal based on the Repayment Schedule, plus (ii) monthly payments of accrued interest at the rate set forth in Section 2.2(a). All outstanding principal and accrued and unpaid interest with respect to the Term Loan Advance, and all other outstanding Obligations with respect to the Term Loan Advance, are due and payable in full on the Term Loan Maturity Date.

(d) Mandatory Prepayment Upon an Acceleration. If the Term Loan Advance is accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Bank an amount equal to the sum of: (i) all outstanding principal plus accrued and unpaid interest, plus (ii) the Prepayment Fee, (iii) the Final Payment, and (iv) all other sums, if any, that shall have become due and payable, including interest at the Default Rate with respect to any past due amounts.

(e) Permitted Prepayment of Term Loan Advance. Borrower shall have the option to prepay all, but not less than all, the Term Loan Advance advanced by Bank under this Agreement, provided Borrower (i) provides written notice to Bank of its election to prepay the Term Loan Advance at least five (5) Business Days prior to such prepayment, and (ii) pays, on the date of such prepayment (A) all outstanding principal plus accrued and unpaid interest, (B) the Prepayment Fee, (C) the Final Payment, and (D) all other sums, if any, that shall have become due and payable, including interest at the Default Rate with respect to any past due amounts.

2.2 Payment of Interest on the Credit Extensions.

(a) Interest Rate. Subject to Section 2.2(b), the principal amount outstanding for the Term Loan Advance shall accrue interest at a floating per annum rate equal to three-quarters of one percent (0.75%) above the Prime Rate, which interest shall be payable monthly in accordance with Section 2.2(d) below.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall bear interest at a rate per annum which is five percent (5.0%) above the rate that is otherwise applicable thereto (the "**Default Rate**"). Fees and expenses which are required to be paid by Borrower pursuant to the Loan Documents (including, without limitation, Bank Expenses) but are not paid when due shall bear interest until paid at a rate equal to the highest rate applicable to the Obligations. Payment or acceptance of the increased interest rate provided in this Section 2.2(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Bank.

(c) Adjustment to Interest Rate. Changes to the interest rate of any Credit Extension based on changes to the Prime Rate shall be effective on the effective date of any change to the Prime Rate and to the extent of any such change.

(d) Payment; Interest Computation. Interest is payable monthly on the Payment Date and shall be computed on the basis of a 360-day year for the actual number of days elapsed. In computing interest, (i) all payments received after 12:00 p.m. Eastern time on any day shall be deemed received at the opening of business on the next Business Day, and (ii) the date of the making of any Credit Extension shall be included and the date of payment shall be excluded; provided, however, that if any Credit Extension is repaid on the same day on which it is made, such day shall be included in computing interest on such Credit Extension.

2.3 Fees. Borrower shall pay to Bank:

(a) Prepayment Fee. The Prepayment Fee, when due hereunder;

(b) Final Payment. The Final Payment, when due hereunder; and

(c) Bank Expenses. All Bank Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement, but excluding Taxes, which are addressed in Section 2.5) incurred through and after the Effective Date, when due (or, if no stated due date, upon demand by Bank).

Unless otherwise provided in this Agreement or in a separate writing by Bank, Borrower shall not be entitled to any credit, rebate, or repayment of any fees earned by Bank pursuant to this Agreement notwithstanding any termination of this Agreement or the suspension or termination of Bank's obligation to make loans and advances hereunder. Bank may deduct amounts owing by Borrower under the clauses of this Section 2.3 pursuant to the terms of Section 2.4(c). Bank shall provide Borrower written notice of deductions made from the Designated Deposit Account pursuant to the terms of the clauses of this Section 2.3.

2.4 Payments; Application of Payments; Debit of Accounts.

(a) All payments to be made by Borrower under any Loan Document shall be made in immediately available funds in Dollars, without setoff or counterclaim, before 12:00 p.m. Eastern time on the date when due. Payments of principal and/or interest received after 12:00 p.m. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment shall be due the next Business Day, and additional fees or interest, as applicable, shall continue to accrue until paid.

(b) Bank has the exclusive right to determine the order and manner in which all payments with respect to the Obligations may be applied. Borrower shall have no right to specify the order or the accounts to which Bank shall allocate or apply any payments required to be made by Borrower to Bank or otherwise received by Bank under this Agreement when any such allocation or application is not specified elsewhere in this Agreement.

(c) Bank may debit any of Borrower's deposit accounts, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes Bank when due. These debits shall not constitute a set-off.

2.5 Withholding.

(a) Defined Terms. For purposes of this Section 2.5, the term "applicable law" includes FATCA.

(b) Payments Free of Taxes. Any and all payments by or on account of any obligation of Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law (as determined in the good faith discretion of Borrower or the applicable withholding agent) requires the deduction or withholding of any Tax from any such payment, then Borrower (or applicable withholding agent) shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable law and, if such Tax is an Indemnified Tax, then the sum payable by Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 2.5(b)), Bank receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(c) Payment of Other Taxes by Borrower. Borrower shall timely pay to the relevant Governmental Authority in accordance with applicable law, or at the option of Bank timely reimburse it for the payment of, any Other Taxes.

(d) Indemnification by Borrower. Borrower shall indemnify Bank within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 2.5(d)) payable or paid by Bank or required to be withheld or deducted from a payment to Bank and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to Borrower by Bank, shall be conclusive absent manifest error.

(e) Evidence of Payments. As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to this Section 2.5, Borrower shall deliver to Bank the original or a certified copy

of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to Bank.

(f) Status of Lenders.

(i) Bank, and any other Person holding a beneficial interest in the Term Loan Advance (including for avoidance of doubt, any successor or assign), if entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document, shall deliver to Borrower, at the time or times reasonably requested by Borrower, such properly completed and executed documentation reasonably requested by Borrower as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, Bank and any other Person holding a beneficial interest in the Term Loan Advance, if reasonably requested by Borrower, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower as will enable Borrower to determine whether or not Bank or such other Person is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth below in subparagraphs (ii)(A), (ii)(B) and (ii)(D) of this Section 2.5(f)) shall not be required if in the reasonable judgment of Bank or any other Person holding a beneficial interest in the Term Loan Advance such completion, execution or submission would subject Bank or such other Person to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of Bank or of such other Person.

(ii) Without limiting the generality of the foregoing,

(A) if requested by Borrower, Bank, or any such other Person holding a beneficial interest in the Term Loan Advance, that is a US Person shall deliver to Borrower on or prior to the date on which such other Person acquires a beneficial interest in the Term Loan Advance (and from time to time thereafter upon the reasonable request of Borrower), executed copies of IRS Form W-9 certifying that Bank or such other Person is exempt from U.S. federal backup withholding tax;

(B) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower (in such number of copies as shall be requested by Borrower) on or prior to the date on which such Foreign Lender acquires a beneficial interest in the Term Loan Advance (and from time to time thereafter upon the reasonable request of Borrower), executed copies of the applicable IRS Form W-8, duly completed, together with such supplementary documentation as may be prescribed by applicable law (or reasonably requested by Borrower, including a customary “non-bank” certificate) to permit Borrower to determine the withholding or deduction required to be made;

(C) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender acquires a beneficial interest in the Term Loan Advance (and from time to time thereafter upon the reasonable request of Borrower), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower to determine the withholding or deduction required to be made; and

(D) if a payment made to Bank or any other Person holding a beneficial interest in the Term Loan Advance would be subject to U.S. federal withholding Tax imposed by FATCA if Bank or such other Person were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Internal Revenue Code, as applicable), Bank or such other Person shall deliver to Borrower at the time or times prescribed by law and at such time or times

reasonably requested by Borrower such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Internal Revenue Code) and such additional documentation reasonably requested by Borrower as may be necessary for Borrower to comply with its obligations under FATCA and to determine that Bank or such other Person has complied with the obligations imposed by FATCA on Bank or such other Person or to determine the amount to deduct and withhold from such payment. Solely for purposes of this clause (D), "FATCA" shall include any amendments made to FATCA after the Effective Date.

Bank and any such other Person holding a beneficial interest in the Term Loan Advance agree that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify Borrower in writing of its legal inability to do so.

(g) Refunds. If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this Section 2.5 (including by the payment of additional amounts pursuant to this Section 2.5), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under this Section 2.5 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this paragraph (g) (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this paragraph (g), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this paragraph (g) the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This paragraph shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

(h) Survival. Each party's obligations under this Section 2.5 shall survive the termination of this Agreement and the Loan Documents.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Credit Extension. Bank's obligation to make the initial Credit Extension is subject to the condition precedent that Bank shall have received, in form and substance satisfactory to Bank, such documents, and completion of such other matters, as Bank may reasonably deem necessary or appropriate, including, without limitation:

(a) duly executed signatures to the Loan Agreement;

(b) the Operating Documents of Borrower's jurisdiction of organization, if amended;

(c) duly executed signatures to the completed Borrowing Resolutions for Borrower;

(d) the Perfection Certificate of Borrower, together with the duly executed signature thereto;

(e) a bailee's waiver in favor of Bank for each Borrower's bailee locations located at (i) Integrated Commercialization Solutions, 420 International Blvd, Brooks, KY 40109, and (ii) Patheon Pharmaceuticals, 2110 E Galbraith Rd., Cincinnati, OH 45237 by each such third party, together with the duly executed signatures thereto; and

(f) payment of the fees and Bank Expenses then due as specified in Section 2.3 hereof.

3.2 Conditions Precedent to all Credit Extensions. Bank's obligations to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) except as otherwise provided in Section 3.4, timely receipt of an executed Payment/Advance Form;

(b) the representations and warranties in this Agreement shall be true, accurate, and complete in all material respects on the date of the Payment/Advance Form and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in this Agreement remain true, accurate, and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date; and

(c) Bank determines to its reasonable satisfaction that there has not been any material impairment in the general affairs, management, results of operation, financial condition or the prospect of repayment of the Obligations, nor any material adverse deviation by Borrower from the most recent business plan of Borrower presented to and accepted by Bank.

3.3 Covenant to Deliver. Borrower agrees to deliver to Bank each item required to be delivered to Bank under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Bank of any such item shall not constitute a waiver by Bank of Borrower's obligation to deliver such item, and the making of any Credit Extension in the absence of a required item shall be in Bank's sole discretion.

3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Credit Extension set forth in this Agreement, to obtain a Credit Extension, Borrower shall notify Bank (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 p.m. Eastern time at least two (2) Business Days prior to the proposed Funding Date of the Credit Extension. Together with any such electronic or facsimile notification, Borrower shall deliver to Bank by electronic mail or facsimile a completed Payment/Advance Form executed by an Authorized Signer. Bank may rely on any telephone notice given by a person whom Bank reasonably believes is an Authorized Signer. Bank shall credit the Credit Extensions to the Designated Deposit Account. Bank may make Credit Extensions under this Agreement based on instructions from an Authorized Signer or without instructions if the Credit Extensions are necessary to meet Obligations which have become due.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Bank, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Bank, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof.

Borrower acknowledges that it previously has entered, and/or may in the future enter, into Bank Services Agreements with Bank. Regardless of the terms of any Bank Services Agreement, Borrower agrees that any amounts Borrower owes Bank thereunder shall be deemed to be Obligations hereunder and that it is the intent of Borrower and Bank to have all such Obligations secured by the first priority perfected security interest in the Collateral granted herein (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Bank's Lien in this Agreement).

If this Agreement is terminated, Bank's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as Bank's obligation to make Credit Extensions has terminated, Bank

shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower. In the event (x) all Obligations (other than inchoate indemnity obligations), except for Bank Services, are satisfied in full, and (y) this Agreement is terminated, Bank shall terminate the security interest granted herein upon Borrower providing cash collateral acceptable to Bank in its good faith business judgment for Bank Services, if any. In the event such Bank Services consist of outstanding Letters of Credit, Borrower shall provide to Bank cash collateral in an amount equal to (x) if such Letters of Credit are denominated in Dollars, then at least one hundred five percent (105.0%); and (y) if such Letters of Credit are denominated in a Foreign Currency, then at least one hundred ten percent (110.0%), of the Dollar Equivalent of the face amount of all such Letters of Credit plus, in each case, all interest, fees, and costs due or to become due in connection therewith (as estimated by Bank in its business judgment), to secure all of the Obligations relating to such Letters of Credit.

4.2 Priority of Security Interest. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Bank's Lien under this Agreement). If Borrower shall acquire a commercial tort claim, Borrower shall promptly notify Bank in a writing signed by Borrower of the general details thereof and grant to Bank in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Bank.

4.3 Authorization to File Financing Statements. Borrower hereby authorizes Bank to file financing statements, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Bank's interest or rights hereunder, including a notice that any disposition of the Collateral, by either Borrower or any other Person, shall be deemed to violate the rights of Bank under the Code. Such financing statements may indicate the Collateral as "all assets of the Debtor" or words of similar effect, or as being of an equal or lesser scope, or with greater detail, all in Bank's discretion.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants as follows:

5.1 Due Organization, Authorization; Power and Authority. Borrower is duly existing and in good standing as a Registered Organization in its jurisdiction of formation and is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its business or its ownership of property requires that it be qualified except where the failure to do so would not reasonably be expected to have a material adverse effect on Borrower's business. In connection with this Agreement, Borrower has delivered to Bank a completed certificate signed by Borrower, entitled "Perfection Certificate". Borrower represents and warrants to Bank that (a) Borrower's exact legal name is that indicated on the Perfection Certificate and on the signature page hereof; (b) Borrower is an organization of the type and is organized in the jurisdiction set forth in the Perfection Certificate; (c) the Perfection Certificate accurately sets forth Borrower's organizational identification number or accurately states that Borrower has none; (d) the Perfection Certificate accurately sets forth Borrower's place of business, or, if more than one, its chief executive office as well as Borrower's mailing address (if different than its chief executive office); (e) except as set forth in the Perfection Certificate, Borrower (and each of its predecessors) has not, in the past five (5) years, changed its jurisdiction of formation, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificate pertaining to Borrower and each of its Subsidiaries is accurate and complete (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificate after the Effective Date to the extent permitted by one or more specific provisions in this Agreement). If Borrower is not now a Registered Organization but later becomes one, Borrower shall promptly notify Bank of such occurrence and provide Bank with Borrower's organizational identification number.

The execution, delivery and performance by Borrower of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's organizational documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or any of its Subsidiaries or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except

such Governmental Approvals which have already been obtained and are in full force and effect (or are being obtained pursuant to Section 6.1(b))) or (v) conflict with, contravene, constitute a default or breach under, or result in or permit the termination or acceleration of, any material agreement by which Borrower is bound. Borrower is not in default under any agreement to which it is a party or by which it is bound in which the default could reasonably be expected to have a material adverse effect on Borrower's business.

5.2 Collateral. Borrower has good title to, rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien hereunder, free and clear of any and all Liens except Permitted Liens. Borrower has no Collateral Accounts at or with any bank or financial institution other than Bank or Bank's Affiliates except for the Collateral Accounts described in the Perfection Certificate delivered to Bank in connection herewith and which Borrower has taken such actions as are necessary to give Bank a perfected security interest therein, pursuant to the terms of Section 6.6(b). The Accounts are bona fide, existing obligations of the Account Debtors.

The Collateral is not in the possession of any third party bailee (such as a warehouse) except as otherwise provided in the Perfection Certificate. None of the components of the Collateral shall be maintained at locations other than as provided in the Perfection Certificate or as permitted pursuant to Section 7.2.

All Inventory is in all material respects of good and marketable quality, free from material defects.

Borrower is the sole owner of the Intellectual Property which it owns or purports to own except for (a) licenses permitted hereunder, (b) over-the-counter software that is commercially available to the public, and (c) material Intellectual Property licensed to Borrower and noted on the Perfection Certificate. Each Patent which it owns or purports to own and which is material to Borrower's business is valid and enforceable, and no part of the Intellectual Property which Borrower owns or purports to own and which is material to Borrower's business has been judged invalid or unenforceable, in whole or in part. To the best of Borrower's knowledge, no claim has been made that any part of the Intellectual Property violates the rights of any third party except to the extent such claim would not reasonably be expected to have a material adverse effect on Borrower's business.

Except as noted on the Perfection Certificate, Borrower is not a party to, nor is it bound by, any Restricted License.

5.3 Litigation. Except as disclosed on the Perfection Certificate or as required to be disclosed pursuant to Section 6.2(h), there are no actions or proceedings pending or, to the knowledge of any Responsible Officer, threatened in writing by or against Borrower or any of its Subsidiaries that could reasonably be expected to result in damages, individually or in the aggregate, of Two Hundred Fifty Thousand Dollars ($250,000.00), or more.

5.4 Financial Statements; Financial Condition. All consolidated financial statements for Borrower and any of its Subsidiaries delivered to Bank fairly present in all material respects Borrower's consolidated financial condition and Borrower's consolidated results of operations. There has not been any material deterioration in Borrower's consolidated financial condition since the date of the most recent financial statements submitted to Bank.

5.5 Solvency. The fair salable value of Borrower's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of Borrower's liabilities; Borrower is not left with unreasonably small capital after the transactions in this Agreement; and Borrower is able to pay its debts (including trade debts) as they mature.

5.6 Regulatory Compliance. Borrower is not an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Borrower is not engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower has complied in all material respects with all Requirements of Law, and has not violated any Requirements of Law, in each case, the violation of which could reasonably be expected to have a material adverse effect on its business. None of Borrower's or any of its Subsidiaries' properties or assets has been used by Borrower or any Subsidiary or, to the best of Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than legally. Borrower and each of its Subsidiaries have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

5.7 Subsidiaries; Investments. Borrower does not own any stock, partnership, or other ownership interest or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except (a) to the extent such taxes are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as such reserve or other appropriate provision, if any, as shall be required in conformity with GAAP shall have been made therefor, or (b) if such taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Fifty Thousand Dollars ($50,000.00).

To the extent Borrower defers payment of any contested taxes, Borrower shall (i) notify Bank in writing of the commencement of, and any material development in, the proceedings, and (ii) post bonds or take any other steps required to prevent the governmental authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a Permitted Lien. Borrower is unaware of any claims or adjustments proposed for any of Borrower's prior tax years which could result in additional taxes becoming due and payable by Borrower. Borrower has paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and Borrower has not withdrawn from participation in, and has not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other governmental agency.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions as working capital and to fund its general business requirements and not for personal, family, household or agricultural purposes.

5.10 Full Disclosure. No written representation, warranty or other statement of Borrower in any certificate or written statement given to Bank, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Bank, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized by Bank that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.11 Definition of "Knowledge." For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of any Responsible Officer.

6. AFFIRMATIVE COVENANTS

Borrower shall do all of the following. Borrower and Bank hereby agree that the covenants set forth in this Section 6 do not apply to NewCo:

6.1 Government Compliance.

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so qualify would reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower shall comply, and have each Subsidiary comply, in all material respects, with all laws, ordinances and regulations to which it is subject.

(b) Obtain all of the Governmental Approvals necessary for the performance by Borrower of its obligations under the Loan Documents to which it is a party and the grant of a security interest to Bank in all of its property. Borrower shall promptly provide copies of any such obtained Governmental Approvals to Bank.

6.2 Financial Statements, Reports, Certificates. Provide Bank with the following:

(a) Quarterly Financial Statements. As soon as available, but no later than forty-five (45) days after the last day of each fiscal quarter, a company prepared consolidated and consolidating balance sheet, income statement, covering Borrower's consolidated operations for such month certified by a Responsible Officer and in a form acceptable to Bank (the "**Quarterly Financial Statements**");

(b) Quarterly Compliance Certificate. Within forty-five (45) days after the last day of each fiscal quarter and together with the Quarterly Financial Statements, a duly completed Compliance Certificate signed by a Responsible Officer, certifying that as of the end of such month, Borrower was in full compliance with all of the terms and conditions of this Agreement, and setting forth calculations showing compliance with the financial covenants set forth in this Agreement (if any) and such other information as Bank may reasonably request;

(c) Board-Approved Projections. Within sixty (60) days after the end of each fiscal year of Borrower, and contemporaneously with any updates or changes thereto, annual Board-approved operating budget and financial projections, in a form acceptable to Bank;

(d) Annual Audited Financial Statements. As soon as available, but no later than one hundred eighty (180) days after the last day of Borrower's fiscal year, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm reasonably acceptable to Bank.

(e) Other Statements. Within five (5) days of delivery, copies of all statements, reports and notices made available to Borrower's security holders or to any holders of Subordinated Debt;

(f) SEC Filings. In the event that Borrower becomes subject to the reporting requirements under the Exchange Act within five (5) days of filing, copies of all periodic and other reports, proxy statements and other materials filed by Borrower with the SEC, any Governmental Authority succeeding to any or all of the functions of the SEC or with any national securities exchange, or distributed to its shareholders, as the case may be;

(g) Beneficial Ownership Information. Prompt written notice of any changes to the beneficial ownership information set out in Sections 2(c), 2(d), 2(e) and 2(f) of the Perfection Certificate. Borrower understands and acknowledges that Bank relies on such true, accurate and up-to-date beneficial ownership information to meet Bank's regulatory obligations to obtain, verify and record information about the beneficial owners of its legal entity customers;

(h) Legal Action Notice. A prompt report of any legal actions pending or threatened in writing against Borrower or any of its Subsidiaries that could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of, individually or in the aggregate, Two Hundred Fifty Thousand Dollars ($250,000.00) or more; and

(i) Other Financial Information. Other financial information reasonably requested by Bank.

Documents required to be delivered pursuant to the terms clauses (a), (d), (e) or (f) of this Section 6.2 (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the Internet at Borrower's website address; provided, however, Borrower shall promptly notify Bank in writing (which may be by electronic mail) of the posting of any such documents.

6.3 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower and its Account Debtors shall follow Borrower's customary practices as they exist at the Effective Date. Borrower must promptly notify Bank of all returns, recoveries, disputes and claims that involve more than One Million Seven Hundred Fifty Thousand Dollars ($1,750,000.00).

6.4 Taxes; Pensions. Timely file, and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower and each of its Subsidiaries, except for deferred

payment of any taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Bank, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms.

6.5 Insurance.

(a) Keep its business and the Collateral insured for risks and in amounts standard for companies in Borrower's industry and location and as Bank may reasonably request. Insurance policies shall be in a form, with financially sound and reputable insurance companies that are not Affiliates of Borrower, and in amounts that are satisfactory to Bank. All property policies shall have a lender's loss payable endorsement showing Bank as lender loss payee. All liability policies shall show, or have endorsements showing, Bank as an additional insured. Bank shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral.

(b) Ensure that proceeds payable under any property policy are, at Bank's option, payable to Bank on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to One Hundred Thousand Dollars ($100,000.00) with respect to any loss, but not exceeding Two Hundred Thousand Dollars ($200,000.00) in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Bank has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Bank, be payable to Bank on account of the Obligations.

(c) At Bank's request, Borrower shall deliver certified copies of insurance policies and evidence of all premium payments. Each provider of any such insurance required under this Section 6.5 shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to Bank, that it will give Bank thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled (other than cancellation for non-payment of premium, in which case ten (10) days' prior written notice shall be required). If Borrower fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons and Bank, Bank may make all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Bank deems prudent.

6.6 Operating Accounts.

(a) Maintain all of its and all of its Subsidiaries' (excluding NewCo and Securities Corp.) operating, depository and securities accounts with Bank and Bank's Affiliates; provided that, Borrower (individually and not on a consolidated basis) shall at all times have on deposit in operating, depository and securities accounts maintained with Bank or Bank's Affiliates, cash in an amount equal to or greater than the lesser of (x) one hundred percent (100.0%) of the dollar value of all of Borrower's consolidated cash, including any Subsidiaries', Affiliates', or related entities' cash, in the aggregate at all financial institutions, and (y) one hundred five percent (105.0%) of the then-outstanding Obligations of Borrower to Bank; provided that, Borrower shall be permitted to maintain one (1) clearing account with Wells Fargo, so long as all of the amounts on deposit in such account shall (i) be used exclusively for rebate payments to third parties and (ii) not exceed the amount of all rebate payments required to be made from such account within three (3) Business Days of deposit into such account (the "**Permitted Account**"). Bank may restrict withdrawals or transfers by or on behalf of Borrower that would violate this provision, regardless of whether an Event of Default exists at such time. In addition to the foregoing, Borrower shall conduct all of its cash management, Letters of Credit, and foreign exchange banking with Bank and Bank's Affiliates.

(b) Provide Bank five (5) days prior written notice before establishing any Collateral Account at or with any bank or financial institution other than Bank or Bank's Affiliates. For each Collateral Account that Borrower at any time maintains, Borrower shall cause the applicable bank or financial institution (other than Bank) at or with which any Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Bank's Lien in such Collateral Account in accordance with the terms hereunder which Control Agreement may not be terminated without the prior written consent of Bank.

The provisions of the previous sentence shall not apply to (i) the Permitted Account or (ii) deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's employees and identified to Bank by Borrower as such.

6.7 Financial Covenant – Liquidity Ratio. Maintain at all times, to be tested as of the last day of each fiscal quarter, a Liquidity Ratio of at least 1.5 to 1.0.

6.8 Protection of Intellectual Property Rights.

(a) (i) Protect, defend and maintain the validity and enforceability of its Intellectual Property material to Borrower's business; (ii) promptly advise Bank in writing of material infringements or any other event that could reasonably be expected to materially and adversely affect the value of its Intellectual Property; and (iii) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Bank's written consent.

(b) Provide written notice to Bank within ten (10) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Borrower shall take such steps as Bank requests to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (i) any Restricted License to be deemed Collateral and for Bank to have a security interest in it that might otherwise be restricted or prohibited by law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (ii) Bank to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Bank's rights and remedies under this Agreement and the other Loan Documents.

6.9 Litigation Cooperation. From the date hereof and continuing through the termination of this Agreement, make available to Bank, without expense to Bank, Borrower and its officers, employees and agents and Borrower's books and records, to the extent that Bank may deem them reasonably necessary to prosecute or defend any third-party suit or proceeding instituted by or against Bank with respect to any Collateral or relating to Borrower.

6.10 Access to Collateral; Books and Records. Allow Bank, or its agents, at reasonable times, on five (5) Business Days' notice (provided no notice is required if an Event of Default has occurred and is continuing), to inspect the Collateral and audit and copy Borrower's Books. Such inspections or audits shall be conducted no more often than once every twelve (12) months unless an Event of Default has occurred and is continuing in which case such inspections and audits shall occur as often as Bank shall determine is necessary.

6.11 Further Assurances. Execute any further instruments and take further action as Bank reasonably requests to perfect or continue Bank's Lien in the Collateral or to effect the purposes of this Agreement. Deliver to Bank, within ten (10) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority regarding compliance with or maintenance of Governmental Approvals or Requirements of Law or that could reasonably be expected to have a material effect on any of the Governmental Approvals or otherwise on the operations of Borrower or any of its Subsidiaries.

6.12 Guaranty of NewCo Reimbursement Obligations. Borrower hereby irrevocably, absolutely, and unconditionally guarantee to Bank the prompt and complete payment and performance when due (whether at stated maturity by acceleration or otherwise) of all of the obligations in connection with any sum, now or hereafter due relating to the NewCo Letter of Credit (including the NewCo Reimbursement Obligations).

7. NEGATIVE COVENANTS

Borrower shall not do any of the following without Bank's prior written consent. Borrower and Bank hereby agree that the covenants set forth in this Section 7 do not apply to NewCo:

7.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn-out or obsolete Equipment that is, in the reasonable judgment of Borrower, no longer economically practicable to maintain or useful in the ordinary course of business of

Borrower; (c) consisting of Permitted Liens and Permitted Investments; (d) consisting of the sale or issuance of any stock of Borrower permitted under Section 7.2 of this Agreement; (e) consisting of Borrower's use or transfer of money or Cash Equivalents in a manner that is not prohibited by the terms of this Agreement or the other Loan Documents; and (f) consisting of non-exclusive licenses for the use of the property of Borrower or its Subsidiaries in the ordinary course of business and licenses that could not result in a legal transfer of title of the licensed property but that may be exclusive in respects other than territory and that may be exclusive as to territory only as to discreet geographical areas outside of the United States.

7.2 Changes in Business, Management, Control or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses currently engaged in by Borrower and such Subsidiary, as applicable, or reasonably related thereto; (b) liquidate or dissolve; (c) fail to provide notice to Bank of any Key Person departing from or ceasing to be employed by Borrower within five (5) days after such Key Person's departure from Borrower; or (d) permit or suffer any Change in Control.

Borrower shall not, without at least thirty (30) days prior written notice to Bank: (1) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Two Hundred Fifty Thousand Dollars ($250,000.00) in Borrower's assets or property) or deliver any portion of the Collateral valued, individually or in the aggregate, in excess of Two Hundred Fifty Thousand Dollars ($250,000.00) to a bailee at a location other than to a bailee and at a location already disclosed in the Perfection Certificate, (2) change its jurisdiction of organization, (3) change its organizational structure or type, (4) change its legal name, or (5) change any organizational number (if any) assigned by its jurisdiction of organization. If Borrower intends to deliver any portion of the Collateral valued, individually or in the aggregate, in excess of Two Hundred Fifty Thousand Dollars ($250,000.00) to a bailee, and Bank and such bailee are not already parties to a bailee agreement governing both the Collateral and the location to which Borrower intends to deliver the Collateral, then Borrower will first receive the written consent of Bank, and such bailee shall execute and deliver a bailee agreement in form and substance satisfactory to Bank.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person (including, without limitation, by the formation of any Subsidiary). A Subsidiary may merge or consolidate into another Subsidiary or into Borrower.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, permit any Collateral not to be subject to the first priority security interest granted herein (subject to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Bank's Lien under this Agreement), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Bank) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower or any Subsidiary from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or any Subsidiary's Intellectual Property in favor of Bank, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens" herein.

7.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6(b) hereof.

7.7 Distributions; Investments. (a) Pay any dividends or make any distribution or payment or redeem, retire or purchase any capital stock provided that Borrower may repurchase the stock of former employees or consultants pursuant to stock repurchase agreements so long as an Event of Default does not exist at the time of such repurchase and would not exist after giving effect to such repurchase, provided that the aggregate amount of all such repurchases does not exceed One Hundred Fifty Thousand Dollars ($150,000.00) in any twelve (12) month period; or directly or indirectly make any Investment (including, without limitation, by the formation of any Subsidiary) other than Permitted Investments, or permit any of its Subsidiaries (other than Securities Corp.) to do so.

7.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower, except for transactions that are in the ordinary course of Borrower's business, upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's length transaction with a non-affiliated Person.

7.9 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof, provide for earlier or greater principal, interest, or other payments thereon, or adversely affect the subordination thereof to Obligations owed to Bank.

7.10 Compliance. Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to (a) meet the minimum funding requirements of ERISA, (b) prevent a Reportable Event or Prohibited Transaction, as defined in ERISA, from occurring, or (c) comply with the Federal Fair Labor Standards Act, the failure of any of the conditions described in clauses (a) through (c) which could reasonably be expected to have a material adverse effect on Borrower's business; or violate any other law or regulation, if the violation could reasonably be expected to have a material adverse effect on Borrower's business, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other governmental agency.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Credit Extension when due, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day cure period shall not apply to payments due on the Term Loan Maturity Date). During the cure period, the failure to make or pay any payment specified under clause (b) hereunder is not an Event of Default (but no Credit Extension will be made during the cure period);

8.2 Covenant Default.

(a) Borrower fails or neglects to perform any obligation in Sections 6.2, 6.4, 6.5, 6.6, 6.7, 6.8, or 6.12 or violates any covenant in Section 7; or

(b) Borrower fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Cure periods provided under this section shall not apply, among other things, to financial covenants or any other covenants set forth in clause (a) above;

8.3 Material Adverse Change. A Material Adverse Change occurs;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or of any entity under the control of Borrower (including a Subsidiary), or (ii) a notice of lien or levy is filed against any of Borrower's assets by any Governmental Authority, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; or

(b) (i) any material portion of Borrower's assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower from conducting all or any material part of its business;

8.5 Insolvency. (a) Borrower is unable to pay its debts (including trade debts) as they become due or otherwise becomes insolvent; (b) Borrower begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower and is not dismissed or stayed within thirty (30) days (but no Credit Extensions shall be made while any of the conditions described in clause (a) exist and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is, under any agreement to which Borrower is a party with a third party or parties, (a) any default resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount individually or in the aggregate in excess of One Hundred Thousand Dollars ($100,000.00); or (b) any breach or default by Borrower, the result of which could reasonably be expected to have a material adverse effect on Borrower's business;

8.7 Judgments; Penalties. One or more fines, penalties or final judgments, orders or decrees for the payment of money in an amount, individually or in the aggregate, of at least of One Hundred Thousand Dollars ($100,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower by any Governmental Authority, and the same are not, within ten (10) days after the entry, assessment or issuance thereof, discharged, satisfied, or paid, or after execution thereof, stayed or bonded pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Credit Extensions will be made prior to the satisfaction, payment, discharge, stay, or bonding of such fine, penalty, judgment, order or decree);

8.8 Misrepresentations. Borrower or any Person acting for Borrower makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Bank or to induce Bank to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

8.9 Subordinated Debt. Any document, instrument, or agreement evidencing any Subordinated Debt shall for any reason be revoked or invalidated or otherwise cease to be in full force and effect, any Person shall be in breach thereof or contest in any manner the validity or enforceability thereof or deny that it has any further liability or obligation thereunder, or the Obligations shall for any reason be subordinated or shall not have the priority contemplated by this Agreement;

8.10 [Reserved.]

8.11 Governmental Approvals. Any Governmental Approval shall have been (a) revoked, rescinded, suspended, modified in an adverse manner or not renewed in the ordinary course for a full term or (b) subject to any decision by a Governmental Authority that designates a hearing with respect to any applications for renewal of any of such Governmental Approval or that could result in the Governmental Authority taking any of the actions described in clause (a) above, and such decision or such revocation, rescission, suspension, modification or non-renewal (i) causes, or could reasonably be expected to cause, a Material Adverse Change, or (ii) adversely affects the legal qualifications of Borrower or any of its Subsidiaries to hold such Governmental Approval in any applicable jurisdiction and such revocation, rescission, suspension, modification or non-renewal could reasonably be expected to adversely affect the status of or legal qualifications of Borrower or any of its Subsidiaries to hold any Governmental Approval in any other jurisdiction; or

8.12 Minimum Quarterly Payments. Borrower fails to cause NewCo to transfer all balances in the Sales Account within one (1) Business Day after the Minimum Quarterly Payment for such calendar quarter has been satisfied (as provided in the Commercialization Agreement), to an account in the name of Borrower maintained with Bank.

9. BANK'S RIGHTS AND REMEDIES

9.1 Rights and Remedies. Upon the occurrence and during the continuance of an Event of Default, Bank may, without notice or demand, do any or all of the following:

(a) declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations are immediately due and payable without any action by Bank);

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Bank;

(c) demand that Borrower (i) deposit cash with Bank in an amount equal to at least (x) one hundred five percent (105.0%) of the Dollar Equivalent of the aggregate face amount of all Letters of Credit denominated in Dollars remaining undrawn, and (y) one hundred ten percent (110.0%) of the Dollar Equivalent of the aggregate face amount of all Letters of Credit denominated in a Foreign Currency remaining undrawn (plus, in each case, all interest, fees, and costs due or to become due in connection therewith (as estimated by Bank in its good faith business judgment)), to secure all of the Obligations relating to such Letters of Credit, as collateral security for the repayment of any future drawings under such Letters of Credit, and Borrower shall forthwith deposit and pay such amounts, and (ii) pay in advance all letter of credit fees scheduled to be paid or payable over the remaining term of any Letters of Credit;

(d) terminate any FX Contracts;

(e) verify the amount of, demand payment of and performance under, and collect any Accounts and General Intangibles, settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Bank considers advisable, and notify any Person owing Borrower money of Bank's security interest in such funds;

(f) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Bank requests and make it available as Bank designates. Bank may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Bank a license to enter and occupy any of its premises, without charge, to exercise any of Bank's rights or remedies;

(g) apply to the Obligations (i) any balances and deposits of Borrower it holds, or (ii) any amount held by Bank owing to or for the credit or the account of Borrower;

(h) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. Bank is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's labels, Patents, Copyrights, mask works, rights of use of any name, trade secrets, trade names, Trademarks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Bank's exercise of its rights under this Section, Borrower's rights under all licenses and all franchise agreements inure to Bank's benefit;

(i) place a "hold" on any account maintained with Bank and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(j) demand and receive possession of Borrower's Books; and

(k) exercise all rights and remedies available to Bank under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

9.2 Power of Attorney. Borrower hereby irrevocably appoints Bank as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's name on any checks or other forms of payment or security; (b) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Bank determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Bank or a third party as the Code permits. Borrower hereby appoints Bank as its lawful attorney-in-fact to sign Borrower's name on any documents necessary to perfect or continue the perfection of Bank's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations have been satisfied in full and Bank is under no further obligation to make Credit Extensions hereunder. Bank's foregoing appointment as Borrower's attorney in fact, and all of Bank's rights and powers, coupled with an interest, are irrevocable until all Obligations have been fully repaid and performed and Bank's obligation to provide Credit Extensions terminates.

9.3 Protective Payments. If Borrower fails to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Bank may obtain such insurance or make such payment, and all amounts so paid by Bank are Bank Expenses and immediately due and payable, bearing interest at the then highest rate applicable to the Obligations, and secured by the Collateral. Bank will make reasonable efforts to provide Borrower with notice of Bank obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Bank are deemed an agreement to make similar payments in the future or Bank's waiver of any Event of Default.

9.4 Application of Payments and Proceeds Upon Default. If an Event of Default has occurred and is continuing, Bank shall have the right to apply in any order any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Accounts or other disposition of the Collateral, or otherwise, to the Obligations. Bank shall pay any surplus to Borrower by credit to the Designated Deposit Account or to other Persons legally entitled thereto; Borrower shall remain liable to Bank for any deficiency. If Bank, directly or indirectly, enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, Bank shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by Bank of cash therefor.

9.5 Bank's Liability for Collateral. So long as Bank complies with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Bank, Bank shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Bank's failure, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Bank thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Bank's rights and remedies under this Agreement and the other Loan Documents are cumulative. Bank has all rights and remedies provided under the Code, by law, or in equity. Bank's exercise of one right or remedy is not an election and shall not preclude Bank from exercising any other remedy under this Agreement or other remedy available at law or in equity, and Bank's waiver of any Event of Default is not a continuing waiver. Bank's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Bank on which Borrower is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail or facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Bank or Borrower may change its mailing or electronic mail address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:	Collegium Pharmaceutical, Inc. 100 Technology Center Drive, Suite 300 Stoughton, Massachusetts 02072 Attn: Shirley Kuhlmann; Meg Magee Email: skuhlmann@collegiumpharma.com mmagee@collegiumpharma.com
If to Bank:	Silicon Valley Bank 275 Grove Street, Suite 2-200 Newton, Massachusetts 02466 Attn: Lauren Cole Email: LCole@svb.com
with a copy to:	Riemer & Braunstein LLP Three Center Plaza Boston, Massachusetts 02108 Attn: David A. Ephraim, Esquire Fax: (617) 880-3456 Email: DEphraim@riemerlaw.com

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

Except as otherwise expressly provided in any of the Loan Documents, Massachusetts law governs the Loan Documents without regard to principles of conflicts of law. Borrower and Bank each submit to the exclusive jurisdiction of the State and Federal courts in Boston, Massachusetts; provided, however, that nothing in this Agreement shall be deemed to operate to preclude Bank from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Bank. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

BORROWER AND BANK EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR

BOTH PARTIES TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

This Section 11 shall survive the termination of this Agreement.

12. GENERAL PROVISIONS

12.1 Termination Prior to Term Loan Maturity Date; Survival. All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to its terms and all Obligations have been satisfied. So long as Borrower has satisfied the Obligations (other than inchoate indemnity obligations, any other obligations which, by their terms, are to survive the termination of this Agreement, and any Obligations under Bank Services Agreements that are cash collateralized in accordance with Section 4.1 of this Agreement), this Agreement may be terminated prior to the Term Loan Maturity Date by Borrower, effective three (3) Business Days after written notice of termination is given to Bank. Those obligations that are expressly specified in this Agreement as surviving this Agreement's termination shall continue to survive notwithstanding this Agreement's termination.

12.2 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not assign this Agreement or any rights or obligations under it without Bank's prior written consent (which may be granted or withheld in Bank's discretion). Bank has the right, without the consent of or notice to Borrower, to sell, transfer, assign, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights, and benefits under this Agreement and the other Loan Documents (other than the Warrant, as to which assignment, transfer and other such actions are governed by the terms thereof).

Borrower shall maintain a register for the recordation in book entry form of the names and addresses of all Persons holding a beneficial interest in the Term Loan Advance, and principal amounts (and stated interest) of the outstanding Term Loan Advance, in which each such Person has a beneficial interest from time to time (the "**Register**"), and Borrower shall record the name and address of each assignee of a beneficial interest under this Agreement and the other Loan Documents as soon as practicably possible after receipt of written notice of such assignment by Bank. The entries in the Register shall be conclusive absent manifest error, and Borrower and Bank and their respective successors and assigns shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a beneficial owner of the right to receive amounts hereunder for all purposes of this Agreement, notwithstanding notice to the contrary.

12.3 Indemnification. Borrower agrees to indemnify, defend and hold Bank and its directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Bank (each, an "**Indemnified Person**") harmless against: (i) all obligations, demands, claims, and liabilities (collectively, "**Claims**") claimed or asserted by any other party in connection with the transactions contemplated by the Loan Documents; and (ii) all losses or expenses (including Bank Expenses) in any way suffered, incurred, or paid by such Indemnified Person as a result of, following from, consequential to, or arising from transactions between Bank and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. This Section 12.3 shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages, etc. arising from any non-Tax claim.

This Section 12.3 shall survive until all statutes of limitation with respect to the Claims, losses, and expenses for which indemnity is given shall have run.

12.4 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

12.5 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.6 Correction of Loan Documents. Bank may correct patent errors and fill in any blanks in the Loan Documents consistent with the agreement of the parties.

12.7 Amendments in Writing; Waiver; Integration. No purported amendment or modification of any Loan Document, or waiver, discharge or termination of any obligation under any Loan Document, shall be enforceable or admissible unless, and only to the extent, expressly set forth in a writing signed by the party against which enforcement or admission is sought. Without limiting the generality of the foregoing, no oral promise or statement, nor any action, inaction, delay, failure to require performance or course of conduct shall operate as, or evidence, an amendment, supplement or waiver or have any other effect on any Loan Document. Any waiver granted shall be limited to the specific circumstance expressly described in it, and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver. The Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of the Loan Documents merge into the Loan Documents.

12.8 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

12.9 Confidentiality. In handling any confidential information, Bank shall exercise the same degree of care that it exercises for its own proprietary information, but disclosure of information may be made: (a) to Bank's Subsidiaries or Affiliates (such Subsidiaries and Affiliates, together with Bank, collectively, "**Bank Entities**"); (b) to prospective transferees or purchasers of any interest in the Credit Extensions (provided, however, Bank shall use its best efforts to obtain any prospective transferee's or purchaser's agreement to the terms of this provision); (c) as required by law, regulation, subpoena, or other order; (d) to Bank's regulators or as otherwise required in connection with Bank's examination or audit; (e) as Bank considers appropriate in exercising remedies under the Loan Documents; and (f) to third-party service providers of Bank so long as such service providers have executed a confidentiality agreement with Bank with terms no less restrictive than those contained herein. Confidential information does not include information that is either: (i) in the public domain or in Bank's possession when disclosed to Bank, or becomes part of the public domain (other than as a result of its disclosure by Bank in violation of this Agreement) after disclosure to Bank; or (ii) disclosed to Bank by a third party, if Bank does not know that the third party is prohibited from disclosing the information.

Bank Entities may use anonymous forms of confidential information for aggregate datasets, for analyses or reporting, and for any other uses not expressly prohibited in writing by Borrower. The provisions of the immediately preceding sentence shall survive termination of this Agreement.

12.10 Right of Set Off. Borrower hereby grants to Bank, a lien, security interest and right of set off as security for all Obligations to Bank, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Bank or any entity under the control of Bank (including a Bank subsidiary) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Bank may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE BANK TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

12.11 Electronic Execution of Documents. The words "execution," "signed," "signature" and words of like import in any Loan Document shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act.

12.12 Captions. The headings used in this Agreement are for convenience only and shall not affect the interpretation of this Agreement.

12.13 Construction of Agreement. The parties mutually acknowledge that they and their attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty this Agreement shall be construed without regard to which of the parties caused the uncertainty to exist.

12.14 Relationship. The relationship of the parties to this Agreement is determined solely by the provisions of this Agreement. The parties do not intend to create any agency, partnership, joint venture, trust, fiduciary or other relationship with duties or incidents different from those of parties to an arm's-length contract.

12.15 Third Parties. Nothing in this Agreement, whether express or implied, is intended to: (a) confer any benefits, rights or remedies under or by reason of this Agreement on any persons other than the express parties to it and their respective permitted successors and assigns; (b) relieve or discharge the obligation or liability of any person not an express party to this Agreement; or (c) give any person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

12.16 Ratification of Stock Pledge Agreement. Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and conditions of the Stock Pledge Agreement, and agrees that that term "Loan Agreement" as used therein shall hereinafter refer to the "Loan Agreement" as defined herein. Borrower acknowledges, confirms and agrees that said Stock Pledge Agreement shall remain in full force and effect.

12.17 Amended and Restated Agreement. This Agreement amends and restates, in its entirety, and replaces, the Prior Loan Agreement. This Agreement is not intended to, and does not, novate the Prior Loan Agreement and Borrower reaffirms that the existing security interest created by the Prior Loan Agreement is and remains in full force and effect. In addition, Borrower hereby acknowledges and agrees that nothing in this Section or anywhere in this Waiver shall be deemed or otherwise construed as a waiver by Bank of any of its rights and remedies pursuant to the Prior Loan Agreement, applicable law or otherwise.

13. DEFINITIONS

13.1 Definitions. As used in the Loan Documents, the word "shall" is mandatory, the word "may" is permissive, the word "or" is not exclusive, the words "includes" and "including" are not limiting, the singular includes the plural, and numbers denoting amounts that are set off in brackets are negative. As used in this Agreement, the following capitalized terms have the following meanings:

"**Account**" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"**Account Debtor**" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"**Affiliate**" is, with respect to any Person, each other Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"**Agreement**" is defined in the preamble hereof.

"**Application**" means that certain Application and Letter of Credit dated as of January 9, 2018.

"**Authorized Signer**" is any individual listed in Borrower's Borrowing Resolutions who is authorized to execute the Loan Documents, including any Advance request, on behalf of Borrower.

"**Bank**" is defined in the preamble hereof.

"**Bank Entities**" is defined in Section 12.9.

"**Bank Expenses**" are all audit fees and expenses, costs, and expenses (including reasonable attorneys' fees and expenses) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred with respect to Borrower.

"**Bank Services**" are any products, credit services, and/or financial accommodations previously, now, or hereafter provided to Borrower or any of its Subsidiaries by Bank or any Bank Affiliate, including, without limitation, any letters of credit, cash management services (including, without limitation, merchant services, direct deposit of payroll, business credit cards, and check cashing services), interest rate swap arrangements, and foreign exchange services as any such products or services may be identified in Bank's various agreements related thereto (each, a "**Bank Services Agreement**").

"**Bank Services Agreement**" is defined in the definition of Bank Services.

"**Board**" means Borrower's board of directors.

"**Borrower**" is defined in the preamble hereof.

"**Borrower's Books**" are all Borrower's books and records including ledgers, federal and state tax returns, records regarding Borrower's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Borrowing Resolutions**" are, with respect to any Person, those resolutions adopted by such Person's board of directors (and, if required under the terms of such Person's Operating Documents, stockholders) and delivered by such Person to Bank approving the Loan Documents to which such Person is a party and the transactions contemplated thereby, together with a certificate executed by its secretary on behalf of such Person certifying (a) such Person has the authority to execute, deliver, and perform its obligations under each of the Loan Documents to which it is a party, (b) that set forth as a part of or attached as an exhibit to such certificate is a true, correct, and complete copy of the resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Person of the Loan Documents to which it is a party, (c) the name(s) of the Person(s) authorized to execute the Loan Documents, including any Credit Extension request, on behalf of such Person, together with a sample of the true signature(s) of such Person(s), and (d) that Bank may conclusively rely on such certificate unless and until such Person shall have delivered to Bank a further certificate canceling or amending such prior certificate.

"**Business Day**" is any day that is not a Saturday, Sunday or a day on which Bank is closed.

"**Cash Equivalents**" means (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.; (c) Bank's certificates of deposit issued maturing no more than one (1) year after issue; and (d) money market funds at least ninety-five percent (95.0%) of the assets of which constitute Cash Equivalents of the kinds described in clauses (a) through (c) of this definition.

"**Change in Control**" means (a) at any time, any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Exchange Act) shall become, or obtain rights (whether by means of warrants, options or otherwise) to become, the "beneficial owner" (as defined in Rules 13(d)-3 and 13(d)-5 under the Exchange Act), directly or indirectly, of forty-nine percent (49.0%) or more of the ordinary voting power for the election of directors of Borrower (determined on a fully diluted basis) other than by the sale of Borrower's equity securities in a public offering or to venture capital or private equity investors so long as Borrower identifies to Bank the venture capital or private equity investors at least seven (7) Business Days prior to the closing of the transaction and provides to Bank a description of the material terms of the transaction; (b) during any period of twelve (12) consecutive months, a majority of the members of the board of directors or other equivalent governing body of Borrower cease to be composed of individuals (i) who were members of that board or equivalent governing body on the first day of such period, (ii) whose election or nomination to that board or equivalent governing body was approved by individuals referred to in clause (i) above constituting at the time of such election or nomination at least a majority of that board or equivalent

governing body or (iii) whose election or nomination to that board or other equivalent governing body was approved by individuals referred to in clauses (i) and (ii) above constituting at the time of such election or nomination at least a majority of that board or equivalent governing body; or (c) at any time, Borrower shall cease to own and control, of record and beneficially, directly or indirectly, one hundred percent (100.0%) of each class of outstanding capital stock of each Subsidiary of Borrower free and clear of all Liens (except Liens created by this Agreement).

"**Claims**" is defined in Section 12.3.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the Commonwealth of Massachusetts; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Bank's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the Commonwealth of Massachusetts, the term "**Code**" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" is any and all properties, rights and assets of Borrower described on Exhibit A.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account.

"**Commercialization Agreement**" means that certain Commercialization Agreement by and among Depomed, Inc., NewCo, and Borrower, dated as of December 4, 2017, as amended by that certain Amendment No. 1, dated as of January 9, 2018, as in effect on January 9, 2018.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"**Compliance Certificate**" is that certain certificate in the form attached hereto as Exhibit B.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation, in each case, directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower maintains a Securities Account or a Commodity Account, Borrower, and Bank pursuant to which Bank obtains control (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"**Credit Extension**" is any Term Loan Advance or any other extension of credit by Bank for Borrower's benefit.

"**Default Rate**" is defined in Section 2.2(b).

"**Deposit Account**" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"**Designated Deposit Account**" is the account number ending 928 (last three digits) maintained by Borrower with Bank (provided, however, if no such account number is included, then the Designated Deposit Account shall be any deposit account of Borrower maintained with Bank as chosen by Bank upon consultation with Borrower).

"**Dollars**," "**dollars**" or use of the sign "**$**" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "$" sign to denote its currency or may be readily converted into lawful money of the United States.

"**Dollar Equivalent**" is, at any time, (a) with respect to any amount denominated in Dollars, such amount, and (b) with respect to any amount denominated in a Foreign Currency, the equivalent amount therefor in Dollars as determined by Bank at such time on the basis of the then-prevailing rate of exchange in San Francisco, California, for sales of the Foreign Currency for transfer to the country issuing such Foreign Currency.

"**EBITDA**" means, as calculated on a consolidated basis with respect to Borrower and its Subsidiaries, (a) Net Income, plus (b) Interest Expense, plus (c) to the extent deducted in the calculation of Net Income, depreciation expense and amortization expense, plus (d) income tax expense.

"**Effective Date**" is defined in the preamble hereof.

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**ERISA**" is the Employee Retirement Income Security Act of 1974, and its regulations.

"**Event of Default**" is defined in Section 8.

"**Exchange Act**" is the Securities Exchange Act of 1934, as amended.

"**Excluded Sublicenses**" are sublicenses granted by NewCo to Borrower pursuant to the Commercialization Agreement.

"**Excluded Taxes**" means any of the following Taxes imposed on or with respect to Recipient or required to be withheld or deducted from a payment to Recipient, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of Recipient being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) U.S. federal withholding Taxes imposed on amounts payable to or for the account of Recipient with respect to an applicable interest in the Term Loan Advance pursuant to a law in effect on the date on which (i) Recipient acquires such interest in the Term Loan Advance or (ii) Recipient changes its lending office, except in each case to the extent that, pursuant to Section 2.5, amounts with respect to such Taxes were payable either to such Recipient's assignor immediately before such Recipient became a party hereto or to such Recipient immediately before it changed its lending office, (c) Taxes attributable to such Recipient's failure to comply with Section 2.5(f), and (d) any U.S. federal withholding Taxes imposed under FATCA.

"**FATCA**" means Sections 1471 through 1474 of the Internal Revenue Code, as of the Effective Date (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreement entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code, any intergovernmental agreement entered into in connection with the

implementation of such sections of the Internal Revenue Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to, or official interpretations implementing such, intergovernmental agreements.

"**Final Payment**" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) equal to Seven Hundred Eighteen Thousand Seven Hundred Fifty Dollars ($718,750.00), due on the earliest to occur of (a) the Term Loan Maturity Date, (b) payment in full of the Term Loan Advance, (c) as required pursuant to Section 2.1.1(d) or Section 2.1.1(e), or (d) the termination of this Agreement.

"**Foreign Currency**" means lawful money of a country other than the United States.

"**Foreign Lender**" means (a) if Borrower is a US Person, a Recipient that is not a US Person, and (b) if Borrower is not a US Person, a Recipient that is resident or organized under the laws of a jurisdiction other than that in which Borrower is resident for tax purposes.

"**Funding Date**" is any date on which a Credit Extension is made to or for the account of Borrower which shall be a Business Day.

"**FX Contract**" is any foreign exchange contract by and between Borrower and Bank under which Borrower commits to purchase from or sell to Bank a specific amount of Foreign Currency on a specified date.

"**GAAP**" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination.

"**General Intangibles**" is all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all Intellectual Property, claims, income and other tax refunds, security and other deposits, payment intangibles, contract rights, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"**Governmental Approval**" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"**Guarantor**" means any Person providing a Guaranty in favor of Bank.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations (as such term is understood under GAAP as of the Effective Date), and (d) Contingent Obligations.

"**Indemnified Person**" is defined in Section 12.3.

"**Indemnified Taxes**" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of Borrower under any Loan Document and (b) to the extent not otherwise described in (a), Other Taxes.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"**Intellectual Property**" means, with respect to any Person, all of such Person's right, title, and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, and operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to such Person;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"**Interest Expense**" means for any fiscal period, interest expense (whether cash or non-cash) determined in accordance with GAAP for the relevant period ending on such date, including, in any event, interest expense with respect to any Credit Extension and other Indebtedness of Borrower and its Subsidiaries, including, without limitation or duplication, all commissions, discounts, or related amortization and other fees and charges with respect to letters of credit and bankers' acceptance financing and the net costs associated with interest rate swap, cap, and similar arrangements, and the interest portion of any deferred payment obligation (including leases of all types).

"**Interest Only Extension Event**" means confirmation by Bank in writing that Borrower has achieved (calculated on a consolidated basis with respect to Borrower and its Subsidiaries) EBITDA in excess of Two Million Five Hundred Thousand Dollars ($2,500,000.00) for two (2) consecutive calendar quarters for the period commencing as of January 9, 2018 and ending on June 30, 2019.

"**Internal Revenue Code**" means the Internal Revenue Code of 1986, as amended.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of Borrower's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

"**Key Person**" is each of Borrower's (a) Chief Executive Officer, who is Joseph J. Ciaffoni as of the Effective Date, and (b) Chief Financial Officer, who is Paul Brannelly as of the Effective Date.

"**Letter of Credit**" is a standby or commercial letter of credit issued by Bank upon request of Borrower based upon an application, guarantee, indemnity, or similar agreement.

"**Lien**" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Liquidity Ratio**" means, as of any date of determination, a ratio of (a) the aggregate amount of unrestricted and unencumbered cash and Cash Equivalents of Borrower maintained at Bank or Bank's Affiliates, to (b) the aggregate amount of outstanding obligations and liabilities with respect to (i) the NewCo Reimbursement Obligations plus (ii) Bank Services.

"**Loan Documents**" are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, the Warrant, the Perfection Certificate, the Stock Pledge Agreement, any Control Agreement, any Bank Services Agreement, any other subordination agreement, any note, or notes or guaranties executed by Borrower, and any other present or future agreement by Borrower with or for the benefit of Bank in connection with this Agreement or Bank Services, all as amended, restated, or otherwise modified.

"**Material Adverse Change**" is (a) a material impairment in the perfection or priority of Bank's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations, or condition (financial or otherwise) of Borrower; (c) a material impairment of the prospect of repayment of any portion of the Obligations; or (d) Bank determines, based upon information available to it and in its reasonable judgment, that there is a substantial likelihood that Borrower shall fail to comply with one or more of the financial covenants in Section 6 during the next succeeding financial reporting period.

"**Minimum Quarterly Payment**" has the meaning as defined in the Commercialization Agreement.

"**Net Income**" means, as calculated on a consolidated basis for Borrower and its Subsidiaries for any period as at any date of determination, the net profit (or loss), after provision for taxes, of Borrower and its Subsidiaries for such period taken as a single accounting period.

"**NewCo Letter of Credit**" means a certain letter of credit issued by Bank on behalf of NewCo in favor of Depomed, Inc., in the face amount of Thirty-Three Million Seven Hundred Fifty Thousand Dollars ($33,750,000.00), pursuant to the terms of the Application, which by its terms expires on the one (1) year anniversary thereof (as automatically extended in accordance with its terms), subject to extension pursuant to the terms thereof, as may be amended, modified, supplemented and/or restated from time to time.

"**NewCo Reimbursement Obligations**" means all of NewCo's obligations and liabilities under the NewCo Letter of Credit (including reimbursement obligations as provided under the Application).

"**Obligations**" are Borrower's obligations to pay when due any debts, principal, interest, fees, Bank Expenses, NewCo Reimbursement Obligations, and other amounts Borrower owes Bank now or later, whether under this Agreement, the other Loan Documents (other than the Warrant), or otherwise, including, without limitation, interest accruing after Insolvency Proceedings begin and debts, liabilities, or obligations of Borrower assigned to Bank, and to perform Borrower's duties under the Loan Documents (other than the Warrant).

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Other Connection Taxes**" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in the Term Loan Advance or Loan Document).

"**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or

registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"**Payment/Advance Form**" is that certain form attached hereto as Exhibit C.

"**Payment-Bearing Products**" has the meaning as defined in the Commercialization Agreement.

"**Payment Date**" is the first (1st) calendar day of each calendar month.

"**Perfection Certificate**" is defined in Section 5.1.

"**Permitted Account**" is defined in Section 6.6(a).

"**Permitted Indebtedness**" is:

(a) Borrower's Indebtedness to Bank under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and shown on the Perfection Certificate;

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(f) Indebtedness secured by Liens permitted under clauses (a) and (c) of the definition of Permitted Liens hereunder; and

(g) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (f) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be.

"**Permitted Investments**" are:

(a) Investments (including, without limitation, Subsidiaries) existing on the Effective Date and shown on the Perfection Certificate;

(b) (i) Investments consisting of Cash Equivalents, and (ii) any Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Bank;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by the Board;

(e) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(f) cash Investments by Borrower in Securities Corp.; provided that no Event of Default has occurred and is continuing or would result from such Investment; and

(g) other unsecured Investments not otherwise permitted by Section 7.7 not exceeding Twenty-Five Thousand Dollars ($25,000.00) in the aggregate outstanding at any time

"**Permitted Liens**" are:

(a) Liens existing on the Effective Date and shown on the Perfection Certificate or arising under this Agreement and the other Loan Documents;

(b) Liens for Taxes, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code, and the Treasury Regulations adopted thereunder;

(c) purchase money Liens or capital leases (i) on Equipment acquired or held by Borrower incurred for financing the acquisition of the Equipment securing no more than One Hundred Thousand Dollars ($100,000.00) in the aggregate amount outstanding, or (ii) existing on Equipment when acquired, if the Lien is confined to the property and improvements and the proceeds of the Equipment;

(d) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(e) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Fifty Thousand Dollars ($50,000.00) and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(f) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Bank a security interest therein;

(h) non-exclusive license of Intellectual Property granted to third parties in the ordinary course of business, and licenses of Intellectual Property that could not result in a legal transfer of title of the licensed property that may be exclusive in respects other than territory and that may be exclusive as to territory only as to discreet geographical areas outside of the United States;

(i) Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting an Event of Default under Sections 8.4 and 8.7;

(j) Liens in favor of other financial institutions arising in connection with Borrower's deposit and/or securities accounts held at such institutions, provided that Bank has a first priority perfected security interest in the amounts held in such deposit and/or securities accounts;

(k) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(l) easements, reservations, rights-of-way, restrictions, minor defects or irregularities in title and other similar charges or encumbrances affecting real property not likely to result in a material adverse change in Borrower's business; and

(m) liens arising from the filing of any financing statement on operating leases, to the extent such operating leases are permitted under this Agreement.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Prepayment Fee**" shall be an additional fee payable to Bank, with respect to the Term Loan Advance, in an amount equal to:

(a) for a prepayment of the Term Loan Advance made on or prior to January 9, 2019, three percent (3.0%) of the then outstanding principal amount of the Term Loan Advance immediately prior to such prepayment;

(b) for a prepayment of the Term Loan Advance made after the January 9, 2019, but on or prior to January 9, 2020, two percent (2.0%) of the then outstanding principal amount of Term Loan Advance immediately prior to such prepayment; and

(c) for a prepayment made after January 9, 2020, but prior to the Term Loan Maturity Date, one percent (1.0%) of the then outstanding principal amount of the Term Loan Advance immediately prior to such prepayment.

Notwithstanding the foregoing, Bank agrees to waive the Prepayment Fee if Bank closes on the refinance and re-documentation of the Term Loan Advance (in its sole and absolute discretion) on or prior to the Term Loan Maturity Date.

"**Prime Rate**" is the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal or any successor publication thereto as the "prime rate" then in effect; provided that, in the event such rate of interest is less than zero, such rate shall be deemed to be zero for purposes of this Agreement and provided further that if such rate of interest, as set forth from time to time in the money rates section of The Wall Street Journal, becomes unavailable for any reason as determined by Bank, the "Prime Rate" shall mean the rate of interest per annum announced by Bank as its prime rate in effect at its principal office in the State of California (such Bank announced Prime Rate not being intended to be the lowest rate of interest charged by Bank in connection with extensions of credit to debtors); provided that, in the event such rate of interest is less than zero, such rate shall be deemed to be zero for purposes of this Agreement.

"**Prior Loan Agreement**" is defined in the preamble hereof.

"**Quarterly Financial Statements**" is defined in Section 6.2(a).

"Recipient" means, Bank or any other Person holding a beneficial interest in the Term Loan Advance.

"**Repayment Schedule**" means, forty-two (42) monthly payments of principal; provided that, upon the occurrence of the Interest Only Extension Event, the Repayment Schedule shall be thirty-six (36) monthly payments of principal."

"**Register**" is defined in Section 12.2.

"**Registered Organization**" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"**Responsible Officer**" is any of the Chief Executive Officer, President, Chief Financial Officer and Controller of Borrower.

"**Restricted License**" is any material license or other material agreement with respect to which Borrower is the licensee (a) that prohibits or otherwise restricts Borrower from granting a security interest in Borrower's interest in such license or agreement or any property subject to such license or material agreement, or (b) for which a default under or termination of could interfere with the Bank's right to sell any Collateral.

"**Sales Account**" means account number ending in 370 in the name of NewCo and maintained with Bank.

"**SEC**" shall mean the Securities and Exchange Commission, any successor thereto, and any analogous Governmental Authority.

"**Securities Account**" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"**Securities Corp.**" is Collegium Securities Corporation, a corporation organized under the laws of the Commonwealth of Massachusetts and a Subsidiary of Borrower.

"**Stock Pledge Agreement**" means that certain Stock Pledge Agreement executed by Borrower in favor of Bank dated as of December 31, 2015, as may be amended, modified, supplemented or restated from time to time.

"**Subordinated Debt**" is indebtedness incurred by Borrower subordinated to all of Borrower's now or hereafter indebtedness to Bank (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Bank entered into between Bank and the other creditor), on terms acceptable to Bank.

"**Subsidiary**" is, as to any Person, a corporation, partnership, limited liability company or other entity of which shares of stock or other ownership interests having ordinary voting power (other than stock or such other ownership interests having such power only by reason of the happening of a contingency) to elect a majority of the board of directors or other managers of such corporation, partnership or other entity are at the time owned, or the management of which is otherwise controlled, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of Borrower.

"**Tax**" and "**Taxes**" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"**Term Loan Advance**" is defined in Section 2.1.1(a).

"**Term Loan Amortization Date**" is July 1, 2019; provided that, upon the occurrence of the Interest Only Extension Event, the Term Loan Amortization Date is January 1, 2020.

"**Term Loan Maturity Date**" is December 1, 2022.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"**Transfer**" is defined in Section 7.1.

"**US Person**" means any Person that is a "United States Person" as defined in Section 7701(a)(30) of the Internal Revenue Code.

"**Warrant**" means collectively, (i) that certain warrant to purchase stock by and between Borrower and Bank dated as of August 28, 2012, and (ii) that certain warrant to purchase stock by and between Borrower and Bank dated as of January 31, 2014, in each case, as may be amended, modified, supplemented or restated from time to time.

[Signature page follows.**]**

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

COLLEGIUM PHARMACEUTICAL, INC.

By _____
Name: _____
Title: _____

BANK:

SILICON VALLEY BANK

By _____
Name: _____
Title: _____

EXHIBIT A – COLLATERAL DESCRIPTION

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as provided below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

all Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (a) any equity interests of Borrower in NewCo, (b) the Excluded Sublicenses, (c) any accounts directly resulting from the sale of the Payment-Bearing Products and any cash, royalty fees, revenues, proceeds or income directly resulting from any of the foregoing Payment-Bearing Products; provided, however, the Collateral shall include all cash deposited in accounts in Borrower's bank or securities accounts in Borrower's name, including transfers by NewCo to Borrower pursuant to Section 7.7(b)(ii) of the Commercialization Agreement, or (d) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Bank's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property.

Pursuant to the terms of a certain negative pledge arrangement with Bank, Borrower has agreed not to encumber any of its Intellectual Property without Bank's prior written consent.

EXHIBIT B

COMPLIANCE CERTIFICATE

TO: SILICON VALLEY BANK Date: _____
FROM: COLLEGIUM PHARMACEUTICAL, INC.

The undersigned authorized officer of COLLEGIUM PHARMACEUTICAL, INC., ("Borrower") certifies that under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (the "Agreement"):

(1) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below; (2) there are no Events of Default; (3) all representations and warranties in the Agreement are true and correct in all material respects on this date except as noted below; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date; (4) Borrower, and each of its Subsidiaries, has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except as otherwise permitted pursuant to the terms of Section 5.8 of the Agreement; and (5) no Liens have been levied or claims made against Borrower relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Bank.

Attached are the required documents supporting the certification. The undersigned certifies that these are prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. The undersigned acknowledges that no borrowings may be requested at any time or date of determination that Borrower is not in compliance with any of the terms of the Agreement, and that compliance is determined not just at the date this certificate is delivered. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenants	**Required**	**Complies**
Monthly financial statements	Quarterly within 45 days	Yes No
Compliance Certificate	Quarterly within 45 days	Yes No
Annual financial statement (CPA Audited)	FYE within 180 days	Yes No
Board projections	60 days after each FYE and contemporaneously with any updates or changes thereto	Yes No
10-Q, 10-K and 8-K	Within 5 days after filing with SEC	Yes No

Financial Covenant	**Required**	**Actual**	**Complies**
Maintain as indicated:			
Liquidity Ratio	≥ 1.50:1.0	_____:1.0	Yes No

The following financial covenant analyses and information set forth in Schedule 1 attached hereto are true and accurate as of the date of this Certificate.

Other Matters

Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate. Yes No

The following are the exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions to note.")

COLLEGIUM PHARMACEUTICAL, INC.

By: _____
Name: _____
Title: _____

BANK USE ONLY

Received by: _____
AUTHORIZED SIGNER

Date: _____

Verified: _____
AUTHORIZED SIGNER

Date: _____

Compliance Status: Yes No

Schedule 1 to Compliance Certificate

Financial Covenants of Borrower

Dated: _____

I. **Liquidity Ratio** (Section 6.7)

Required: ≥ 1.50:1.00

Actual:

A. Aggregate amount of unrestricted and unencumbered cash and Cash Equivalents of Borrower maintained at Bank or Bank's Affiliate $ _____

B. Aggregate amount of outstanding obligations and liabilities with respect to (i) the NewCo Reimbursement Obligations plus (ii) Bank Services $ _____

C. Liquidity Ratio (line A divided by line B) _____

Is line C equal to or greater than 1.50:1:00?

_____ No, not in compliance _____ Yes, in compliance

EXHIBIT C – LOAN PAYMENT/ADVANCE REQUEST FORM

DEADLINE FOR SAME DAY PROCESSING IS NOON EASTERN TIME

Fax To: Date: _____

LOAN PAYMENT:

COLLEGIUM PHARMACEUTICAL, INC.

From Account # _____ To Account # _____
(Deposit Account #) (Loan Account #)

Principal $ _____ and/or Interest $ _____

Authorized Signature: _____ Phone Number: _____

Print Name/Title:

LOAN ADVANCE:

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account # _____ To Account # _____
(Loan Account #) (Deposit Account #)

Amount of Credit Extension $ _____

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects on the date of the request for a Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date:

Authorized Signature: _____ Phone Number: _____

Print Name/Title:

OUTGOING WIRE REQUEST:

Complete only if all or a portion of funds from the loan advance above is to be wired.

Deadline for same day processing is noon, Eastern Time

Beneficiary Name: Amount of Wire: $ _____

Beneficiary Bank: _____ Account Number: _____

City and State: _____

Beneficiary Bank Transit (ABA) #: _____ Beneficiary Bank Code (Swift, Sort, Chip, etc.): _____

(For International Wire Only)

Intermediary Bank: _____ Transit (ABA) #: _____

For Further Credit to: _____

Special Instruction: _____

By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature: _____ 2nd Signature (if required): _____

Print Name/Title: _____ Print Name/Title: _____

Telephone #: _____ Telephone #: _____

Exhibit 31.1

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

I, Joseph Ciaffoni, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ JOSEPH CIAFFONI

Joseph Ciaffoni
President and Chief Executive Officer

Date: November 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: November 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 September 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: November 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 September 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: November 8, 2018