UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

For the transition period from to

Commission file number: 001-37372

Collegium Pharmaceutical, Inc.
(Exact name of registrant as specified in its charter)

Virginia	**03-0416362**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
780 Dedham Street, Suite 800 Canton, MA	**02021**
(Address of principal executive offices)	(Zip Code)

(781) 713-3699
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer☐	Accelerated filer ☐
Non-accelerated filer ☒ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

As of July 30, 2016 there were **23,528,440** 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 candidate;
- our plans to commercialize our product candidates and grow sales of our products;
- the size and growth potential 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 reimbursement for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the rate and degree of market acceptance of our products and product candidates;
- changing market conditions for our products and product candidates:
- the outcome of any patent infringement or other litigation that may be brought against us, including litigation with Purdue Pharma, L.P.;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success, cost and timing of our product development activities, studies and clinical trials;
- our ability to obtain funding for our operations;
- regulatory developments in the United States and foreign countries;
- our expectations regarding our ability to obtain and adequately 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;
- the loss of key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing.

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 our Annual Report on Form 10-K, filed with the United States Securities and Exchange Commission, or the SEC, on March 18, 2016 for the year ended December 31, 2015, or Annual Report, and those risks described from time to time in other reports which we file with the SEC. 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

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 110,747	$ 95,697
Accounts receivable, net	2,952	—
Inventory	1,214	—
Prepaid expenses and other current assets	1,537	1,186
Total current assets	116,450	96,883
Property and equipment, net	676	738
Intangible assets, net	2,500	—
Restricted cash	97	97
Total assets	$ 119,723	$ 97,718
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 6,074	$ 3,537
Accrued expenses	5,536	2,228
Deferred revenue	3,926	—
Current portion of term loan payable	2,667	2,667
Total current liabilities	18,203	8,432
Lease incentive obligation	51	68
Term loan payable, long-term	2,813	4,146
Total liabilities	21,067	12,646
Commitments and contingencies (see note 11)		
Preferred stock, $0.001 par value; authorized shares 5,000,000 at June 30, 2016 and December 31, 2015; issued and outstanding shares - none at June 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at June 30, 2016 and December 31, 2015; issued and outstanding shares - 23,528,119 at June 30, 2016 and 20,739,351 at December 31, 2015	24	21
Additional paid-in capital	267,815	214,062
Accumulated deficit	(169,180)	(129,008)
Treasury stock	(3)	(3)
Total shareholders' equity	98,656	85,072
Total liabilities and shareholders' equity	$ 119,723	$ 97,718

See accompanying notes to the condensed consolidated financial statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 4,301	$ 1,641	$ 8,363	$ 3,086
Selling, general and administrative	20,173	2,934	31,698	5,120
Total operating expenses	24,474	4,575	40,061	8,206
Loss from operations	(24,474)	(4,575)	(40,061)	(8,206)
Other expense (income):				
Interest expense, net	46	99	111	254
Gain on extinguishment of debt	—	—	—	(91)
Total other expense, net	46	99	111	163
Net loss	$ (24,520)	$ (4,674)	$ (40,172)	$ (8,369)
Earnings (loss) per share - basic and diluted	$ (1.05)	$ (0.45)	$ (1.73)	$ (0.18)
Weighted-average shares - basic and diluted	23,417,378	11,791,546	23,273,765	6,426,431

See accompanying notes to the condensed consolidated financial statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Six Months Ended June 30,	
	2016	**2015**
Operating activities		
Net loss	$ (40,172)	$ (8,369)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	87	92
Lease incentive	(17)	(16)
Stock-based compensation expense	2,496	714
Non cash interest expense	—	7
Changes in operating assets and liabilities:		
Accounts receivable	(2,952)	—
Inventories	(1,214)	—
Prepaid expenses and other current assets	(351)	(692)
Refundable PDUFA fee	—	2,335
Accounts payable	2,537	32
Deferred revenue	3,926	—
Accrued expenses	3,308	(195)
Net cash used in operating activities	(32,352)	(6,092)
Investing activities		
Purchase of intangible assets	(2,500)	—
Purchases of property and equipment	(25)	(23)
Net cash used in investing activities	(2,525)	(23)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs of $526 and $2,408	51,174	72,029
Proceeds from issuance of Series D convertible redeemable preferred stock, net of issuance costs of $193	—	44,807
Repayment of term note	(1,333)	(368)
Repayment of lease note payable	—	(29)
Restricted cash	—	(16)
Proceeds from the exercise of stock options	86	471
Net cash provided by financing activities	49,927	116,894
Net increase in cash and cash equivalents	15,050	110,779
Cash and cash equivalents at beginning of period	95,697	1,634
Cash and cash equivalents at end of period	$ 110,747	$ 112,413
Supplemental disclosure of cash flow information		
Cash paid for offering costs	$ 512	$ 1,598
Cash paid for interest	$ 159	$ 202
Supplemental disclosure of non-cash activities		
Accruals of offering costs	$ —	$ 105
Preferred stock conversion to common stock	$ —	$ 120,302
Accruals of dividends and accretion to redemption value	$ —	$ 24,572
Conversion of bridge note to preferred stock	$ —	$ 5,000

See accompanying notes to the condensed consolidated financial statements.

Collegium Pharmaceutical, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

1. Nature of Business

Collegium Pharmaceutical, Inc. (the ‘‘Company’’) was incorporated in Delaware in April 2002 and then reincorporated in Virginia in July 2014. The Company has its principal operations in Canton, Massachusetts. The Company is a specialty pharmaceutical company developing and beginning to commercialize next-generation abuse-deterrent products that incorporate the Company’s patented DETERx® technology platform for the treatment of chronic pain and other diseases. The Company’s first product, Xtampza ER®, or Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. On April 26, 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. On June 20, 2016, the Company announced the commercial launch of Xtampza.

The Company’s operations are subject to certain risks and uncertainties. The principal risks include inability to successfully commercialize products, negative outcome of clinical trials, inability or delay in completing clinical trials or obtaining regulatory approvals, changing market conditions for products and product candidates (including development of competing products), the need to retain key personnel and protect intellectual property, patent infringement litigation and the availability of additional capital financing on terms acceptable to the Company.

The Company has an accumulated deficit of $169,180 at June 30, 2016. The Company has financed its operations primarily through private placements of its preferred stock, proceeds from borrowings, an initial public offering completed in 2015 and a follow-on offering completed in 2016. The Company anticipates that it will continue to incur losses for the next several years, and it expects the losses to increase as it continues the development of, and seeks regulatory approvals for its product candidates, and begins to commercialize Xtampza. The Company believes that its cash, cash equivalents and marketable securities at June 30, 2016, together with expected cash inflows from the commercialization of Xtampza, will enable the Company to fund its operating expenses, debt service and capital expenditure requirements for at least twelve months from the filing date of this Quarterly Report on Form 10-Q.

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, a wholly-owned subsidiary requiring consolidation. The financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements.
In the opinion of the Company’s management, the accompanying unaudited condensed consolidated financial statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to fairly present the financial position as of June 30, 2016, the results of operations for the three and six months ended June 30, 2016 and 2015, and cash flows for the six months ended June 30, 2016 and 2015. The results of operations for the three and six month periods ended June 30, 2016 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 affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. 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.

Public Offerings of Common Stock

In May 2015, the Company closed an initial public offering ("IPO") of its common stock, which resulted in the sale of 6,670,000 shares of its common stock at a public offering price of $12.00 per share, including 870,000 shares of common stock upon the exercise by the underwriters of their option to purchase additional shares at the public offering price. The Company received proceeds from the IPO of approximately $72,029, after deducting underwriting discounts, commissions and expenses payable by the Company.

In connection with preparing for the IPO, the Company's Board of Directors and shareholders approved a one-for-6.9 reverse stock split of the Company's common stock. The reverse stock split became effective in April 2015. All share and per share amounts in the consolidated interim financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. In connection with the closing of the IPO, all of the Company's outstanding convertible preferred stock automatically converted to common stock in May 2015, resulting in an additional 12,591,456 shares of common stock of the Company becoming outstanding.

In January 2016, the Company issued and sold in a public offering an aggregate of 2,750,000 shares of its common stock at $20.00 per share. This public offering resulted in approximately $51,174 of net proceeds, after deduction of underwriting discounts and commissions and expenses payable by the Company.

The significant increase in common stock outstanding in June 2016 is expected to impact the year-over-year comparability of the Company's net loss per share calculations in future periods.

Subsequent Events

We consider 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.

Significant Accounting Policies

Inventory

Inventories are stated at the lower of cost or market. Inventory costs consist of costs related to the manufacturing of Xtampza, which are primarily the costs of contract manufacturing. The Company determines the cost of its inventories on a specific identification basis. If the Company identifies excess, obsolete or unsalable items, inventories are written down to their realizable value in the period in which the impairment is identified. Estimates of excess inventory consider various factors, including inventory levels, the level of product in the distribution channel, the Company's projected sales of the product, as well as the remaining shelf lives of the product. Inventories that are not expected to be used within one year are recorded as a non-current asset.

The Company outsources the manufacturing of Xtampza to a sole contract manufacturer that produces the finished product. In addition, the Company currently relies on a sole supplier for the active pharmaceutical ingredient for Xtampza. Accordingly, the Company has concentration risk associated with its manufacturing for supply of Xtampza.

Prior to receiving approval from the FDA in April 2016, to market Xtampza, the Company expensed all costs incurred related to the manufacturing of Xtampza as research and development costs because of the inherent risks associated with the development of a product candidate, the uncertainty about the regulatory approval process and the lack of regulatory approval history for the Company's product candidates.

The Company has capitalized $1,214 of inventory as of June 30, 2016. Certain materials used in the manufacture of Xtampza were expensed prior to FDA approval. The Company expects sales of the capitalized units to occur during the next twelve months. The Company expects the cost of product revenue to increase as the Company begins to sell inventory that was produced entirely after the FDA approval of Xtampza.

Revenue Recognition

Revenue for product sales is recognized when there is persuasive evidence of an arrangement, title and risk of loss have passed to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns are reasonably determinable, and when collectability is reasonably assured. Product sales are recorded net of estimated chargebacks, rebates, sales incentives and allowance, distribution service fees, as well as estimated product returns.

The Company has not yet recorded any product revenue, as it has not yet concluded that it meets the revenue recognition criteria under current accounting guidance The requisite historical data on which to base estimates of returns is insufficient due to the uniqueness of the product as compared to other products in the industry. Therefore revenue is deferred until such time that an estimate can be determined, all the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

Advertising and Product Promotion Costs

Advertising and product promotion costs are included in selling, general and administrative expenses and were $4,680 and $7,006 in the three and six months ended June 30, 2016. Advertising and product promotion costs are expensed as incurred.

Recent 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, FASB issued Accounting Standard Update, or ASU, 2014-09 (ASC 606), *Revenue from Contracts with Customers*, which affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will replace most existing revenue recognition guidance in GAAP when it becomes effective. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. ASU 2014-09 was initially to be effective for annual periods beginning after December 15, 2016, including interim periods within that period. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers*, which delays the effective date of ASU 2014-09 by one year to annual periods beginning after December 15, 2017. The standard allows for early adoption as of the original effective date. In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations,* or ASU 2016-08, which clarifies certain principal versus agent considerations. The Company is currently evaluating its effect on the Company's consolidated financial statements.

In June 2014, the FASB issued ASU 2014-12, *Compensation — Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved After the Requisite Service Period*. ASU 2014-12 applies to all reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. The standard is required to be adopted by public business entities in annual periods beginning on or after December 15, 2015 and interim periods within those annual periods. The Company adopted this standard in the first quarter of fiscal year 2016 and it did not have a material impact on our financial statements as of and for the quarter and six months ended June 30, 2016. The Company has stock options with a performance based vesting condition, which if achieved would result in the recognition of $193 in stock compensation expense in the period vested.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* ASU 2014-15 requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist that raise substantial doubt about an entity's ability to continue

as a going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and earlier application is permitted. The adoption of ASU 2014-15 is not expected to have a material effect on the Company's financial statements or disclosures.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*, or ASU 2015-11. ASU 2015-11 applies to all inventory, except for inventory measured using the last-in, first-out method or the retail inventory method. The guidance allows an entity to measure inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments in ASU 2015-11 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and may be applied prospectively with earlier adoption permitted. As the Company is in the early stages of commercialization of Xtampza, the Company has adopted ASU 2015-11 upon the initial capitalization of inventory.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes (Topic 740)*. ASU 2015-17 simplifies the presentation of deferred income taxes by eliminating the separate classification of deferred income tax assets and liabilities into current and noncurrent amounts in the consolidated balance sheet statement of financial position. The amendments in the update require that all deferred tax assets and liabilities be classified as noncurrent in the consolidated balance sheet. The amendments in this update are effective for annual periods beginning after December 15, 2017, and interim periods therein and may be applied either prospectively or retrospectively to all periods presented. Early adoption is permitted. The Company is currently evaluating its effect on the Company's consolidated financial statements.

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, *Leases (Topic 842)*. The ASU requires lessees to put most leases on their balance sheets as a liability for the obligation to make lease payments and as a right-of-use asset, but recognize expenses on the income statements in a manner similar to today's accounting. The guidance also eliminates the current real estate-specific provisions for all entities. For calendar-year public entities, the guidance becomes effective in 2019 and interim periods within that year. Early adoption is permitted for all entities. The Company has not chosen early adoption for this ASU and is currently evaluating its effect on the Company's consolidated financial statements

In March 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. ASU 2016-09 intends to simplify various aspects of how share-based payments are accounted for and presented in the financial statements. The main provisions include: all tax effects related to stock awards will now be recorded through the statement of operations instead of through equity, all tax-related cash flows resulting from stock awards will be reported as operating activities on the cash flow statement, and entities can make an accounting policy election to either estimate forfeitures or account for forfeitures as they occur. The amendments in ASU 2016-09 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and may be applied prospectively with earlier adoption permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

3. Earnings (Loss) per Common Share

Earnings (loss) per common share is calculated using the two-class method, which is an earnings allocation formula that determines earnings (loss) per share for the holders of the Company's common shares and participating securities. All series of preferred stock contain participation rights in any dividend paid by the Company and are deemed to be participating securities. Earnings available to common shareholders and participating convertible redeemable preferred shares is allocated first to the preferred shareholders based upon the distribution criteria in the Company's Articles of Incorporation then the remainder to the common shareholders. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss.

Diluted earnings per share is computed using the more dilutive of (a) the two-class method, or (b) the if-converted method. The Company allocates earnings first to preferred shareholders based on dividend rights and then to common and preferred shareholders based on ownership interests. The weighted-average number of common shares included in the computation of diluted earnings (loss) gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, convertible redeemable preferred stock and the potential issuance of stock

upon the conversion of the Company's convertible notes. Common stock equivalent shares are excluded from the computation of diluted earnings (loss) per share if their effect is antidilutive.

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Net loss	$ (24,520)	$ (4,674)	$ (40,172)	$ (8,369)
Extinguishment of preferred stock - see note 9	—	—	—	31,806
Accretion of prior preferred stock	—	—	—	(23,327)
Accretion and dividends of series D preferred stock	—	(641)	—	(1,245)
Loss attributable to common shareholders — basic and diluted	$ (24,520)	$ (5,315)	$ (40,172)	$ (1,135)
Weighted-average number of common shares used in net loss per share - basic and diluted	23,417,378	11,791,546	23,273,765	6,426,431
(Loss) earnings per share - basic	$ (1.05)	$ (0.45)	$ (1.73)	$ (0.18)

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

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Outstanding stock options	2,290,112	1,086,789	2,290,112	1,086,789
Warrants	2,445	2,445	2,445	2,445
Redeemable convertible preferred stock	—	—	—	—
Unvested restricted stock	59,494	164,539	59,494	164,539

4. Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy is now established that prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

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

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at June 30, 2016 and December 31, 2015.

Description	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
June 30, 2016				
Money market funds, included in cash equivalents	$89,883	$ 89,883	$ —	$ —
December 31, 2015				
Money market funds, included in cash equivalents	$94,912	$ 94,912	$ —	$ —

The Company's cash equivalents are comprised of money market funds that are measured on a recurring basis based on quoted market prices. As of June 30, 2016 and December 31, 2015, the carrying amounts of cash and cash equivalents, accounts payable, loan payable and accrued expenses approximated their estimated fair values because of the short-term nature of these financial instruments.

5. Inventory

Upon approval of Xtampza by the FDA in April 2016, the Company began capitalizing inventory costs for Xtampza manufactured in preparation for the product launch. In periods prior to April 2016, the Company expensed costs associated with Xtampza, including raw materials, work in process and finished goods, as development expenses. The Company has not capitalized inventory costs related to its other drug development programs.

The following table sets forth the Company's inventories as of June 30, 2016:

	June 30, 2016
Raw materials	$ 46
Work in process	—
Finished goods	1,168
Total inventory	$ 1,214

6. 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) in the United States. ONSOLIS is a Transmucosal Immediate-Release Fentanyl (TIRF) film indicated for the management of breakthrough pain in certain cancer patients. The Company expects to launch the product after the completion of the transfer of manufacturing and required submission to the FDA of a Prior Approval Supplement. Subject to FDA approval of the Prior Approval Supplement, the Company expects to launch ONSOLIS during the second half of 2017. In addition, during the term of the License Agreement, milestone payments in the aggregate amount of $21.0 million may become payable by the Company subject to the satisfaction of certain commercialization, intellectual property, and net sales milestones, including $4 million upon the first commercial sale of the product in the U.S. Finally, the Company will be required to pay royalties in the upper teens based on annual net sales of the product in the U.S

The Company made an upfront payment of $2.5 million and is contractually committed to reimburse BDSI up to a maximum of $2.0 million for its out-of-pocket expenses incurred in conjunction with the manufacturing transfer. The Company recorded the upfront payment as an intangible asset on the Condensed Consolidated Balance Sheet at June 30, 2016 and will amortize it over the shorter of the remaining patent life or the estimated period of economic benefit.

7. Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2016	December 31, 2015
Accrued bonuses and incentive compensation	$ 2,281	$ 1,474
Accrued payroll and related benefits	991	93
Accrued sales & marketing	1,064	157
Accrued development costs	750	80
Accrued other operating costs	242	186
Accrued audit and legal	185	209
Accrued interest	23	29
Total accrued expenses	$ 5,536	$ 2,228

8. Convertible Bridge Note with Related Party

In November and December 2014, the Company entered into a Note Purchase Agreement (the "Bridge Notes") allowing for the issuance of $5,000 of convertible promissory notes to a group of investors (the "Holders") bearing interest at a rate per annum of 6.0%. The Holders are related parties of the Company. In connection with the Series D convertible preferred stock financing (see note 8), the Bridge Notes converted into Series D convertible preferred stock. Upon the conversion, the Company recognized a gain on extinguishment of $91.

9. Convertible Preferred Stock and Equity

In March 2015, the Company issued and sold an aggregate of 41,666,667 shares of Series D convertible preferred stock for aggregate consideration of $50,000, comprised of $45,000 in cash and conversion of $5,000 in Bridge Notes. The accrued interest on the convertible notes was waived.

Concurrently with the issuance of the Series D convertible preferred stock, the Company amended and restated its Articles of Incorporation (the “Amended Articles”). The Company made certain amendments to the terms of the Series A, Series B, and Series C Preferred Stock (together, the “Prior Preferred Stock”). Prior to the adoption of the Amended Articles, the Series A, Series B, and Series C Preferred Stock accrued dividends at a rate of 4.5%, 8.0% and 8.0% per annum, respectively, per share. All accrued and unpaid dividends on the Prior Preferred Stock were automatically cancelled and forfeited and the Prior Preferred Stock no longer accrued dividends. Prior to the cancellation and forfeiture of accrued dividends, the Prior Preferred Stock had accrued dividends of $622 during 2015. The holders of outstanding shares of Prior Preferred Stock were entitled to receive dividends, when, as and if declared by the Board of Directors. The mandatory conversion for all series of Prior Preferred Stock was modified so as to occur upon an initial public offering with gross proceeds in excess of $50,000. The amendments to the Prior Preferred Stock were treated as an extinguishment which resulted in a gain on extinguishment of $31,806. The gain on extinguishment was added to net loss to arrive at income available to common shareholders in the calculation of earnings per share.

In connection with the closing of the IPO, all of the Company’s outstanding convertible preferred stock automatically converted to common stock in May 2015, resulting in an additional 12,591,456 shares of common stock of the Company becoming outstanding.

The changes in shareholders’ equity for the six-month period ended June 30, 2016 were as follows:

	Common Stock		Additional Paid- In	Treasury Stock,	Other Comprehensive	Accumulated	Total Shareholders’ Equity
	Shares	Amount	Capital	at cost	Income	Deficit	(Deficit)
Balance, January 1, 2016	20,739,351	$ 21	$ 214,062	$ (3)	$ —	$ (129,008)	$ 85,072
Public offering of common stock, net of issuance costs of $526	2,750,000	3	51,171	—	—	—	51,174
Stock-based compensation	-	—	2,496	—	—	—	2,496
Exercise of common stock options	38,768	—	86	—	—	—	86
Net loss	—	—	—	—	—	(40,172)	(40,172)
Balance, June 30, 2016	23,528,119	$ 24	$ 267,815	$ (3)	$ —	$ (169,180)	$ 98,656

10. Stock-based Compensation

Restricted Stock Awards 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 are authorized for issuance to employees, officers, directors, consultants and advisors of the Company, plus an annual increase to be added on the first day of each fiscal year until the expiration of the Plan equal to 4% of the total number of outstanding shares of common stock on December 31st of the immediately preceding calendar year (or a lower amount as otherwise determined by the board of directors prior to January 1st). As of June 30, 2016, there were 1,358,694 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 ("ISOs") and non-qualified options ("NQs"), restricted stock awards ("RSAs") and restricted stock units ("RSUs"). Stock options generally vest over a four year period of service; however, certain options are also subject to performance conditions. The 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.

Restricted common stock

A summary of the Company's restricted stock award (RSAs) activity for the six months ended June 30, 2016 and related information is as follows:

	Shares	Weighted average purchase price per share
Unvested at December 31, 2015	75,718	$ 5.73
Granted	—	—
Vested	(16,224)	5.73
Unvested at June 30, 2016 (1)	59,494	$ 5.73

(1) Excludes 48,307 shares of unvested restricted stock remaining from the early exercise of stock options as of June 30, 2016.

A summary of the Company's restricted stock units (RSUs) activity for the six months ended June 30, 2016 and related information is as follows:

	Shares	Average grant date fair value
Outstanding at December 31, 2015	—	$ —
Granted	41,739	16.15
Settled	—	—
Forfeited	—	—
Outstanding at June 30, 2016	41,739	$ 16.15

Stock options

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 (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	1,452,149	$ 10.37	10.4	$ 24,887
Granted	924,981	16.60		
Exercised	(38,768)	2.22		
Cancelled	(48,250)	16.07		
Outstanding at June 30, 2016	2,290,112	$ 12.90	9.1	$ 5,208
Exercisable at June 30, 2016	383,239	$ 7.54	8.2	$ 2,135
Vested and expected to vest at June 30, 2016	2,262,479	$ 12.96	9.1	$ 5,339

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

	Six months ended	
	2016	2015
Risk-free interest rate	1.5 %	1.7 %
Volatility	77 %	77 %
Expected term (years)	6.02	6.25
Expected dividend yield	-	-

A summary of the Company's compensation expense from stock-based payment awards follows:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Research and development expenses	$ 165	$ 55	$ 303	$ 76
Selling, general and administrative expenses	1,230	546	2,193	638
Total stock-based compensation expense	$ 1,395	$ 601	$ 2,496	$ 714

At June 30, 2016, there was approximately $17,483 of unrecognized compensation expense related to unvested options, restricted stock units and restricted stock awards under the Plan, which is expected to be recognized as expense over a weighted average period of approximately 3.2 years.

11. Commitments and Contingencies

From time to time, the Company may be subject to various claims and legal proceedings. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount is reasonably estimated, the Company will accrue a liability for the estimated loss. 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.

The Company's NDA filing for Xtampza is 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. In connection with the 505(b)(2) process, the Company certified to the FDA and notified 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. Under the Hatch-Waxman Act of 1984 (the "Hatch-Waxman Act"), Purdue had the option to sue the Company for infringement and receive a stay of up to 30 months before the FDA can issue a final regulatory approval for Xtampza, unless the stay is earlier terminated. Purdue exercised its option and elected to sue the Company for

infringement in the District of Delaware in March 2015 asserting infringement of three of Purdue's Orange Book-listed patents and one non-Orange Book-listed patent. Purdue filed another case in Massachusetts asserting the same four patents as in the Delaware case. In October 2015, the Delaware case was transferred to Massachusetts. In November 2015, Purdue filed suit asserting infringement of another non-Orange Book-listed patent. On November 9, 2015, the Company filed a motion for partial judgment on the pleadings in relation to three Orange Book-listed patents asserted against the Company, which had been previously invalidated by the court in the Southern District of New York in Purdue's suit against another company. On February 1, 2016, the Court of Appeals for the Federal Circuit affirmed the New York judgment of invalidity. On May 4, 2016, the Court of Appeals for the Federal Circuit denied Purdue's request for rehearing and rehearing *en banc* review was denied. On February 9, 2016, the District Court of Massachusetts ordered judgment in favor of the Company on the three Orange Book-listed patents that were the basis of the 30-month stay, Patent Nos. 7,674,799, 7,674,800, and 7,683,072 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. Purdue continues to assert infringement of two patents against the Company, neither of which is associated with any stay of FDA approval.

At this time the Company is unable to provide meaningful quantification of how this litigation may impact its future financial condition, results of operations, or cash flows.

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. 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, including those set forth under "Forward-looking Statements" and "Risk Factors", under the heading "Risk Factors" in the Company's Annual Report and those risks described from time to time in other reports which we file with the SEC.

OVERVIEW

We are a specialty pharmaceutical company developing and beginning to commercialize next-generation abuse-deterrent products that incorporate our patented DETERx platform technology for the treatment of chronic pain and other diseases. Our first product, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. On April 26, 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 via an NG/G Tube. On June 20, 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 $2.5 billion in U.S. sales in 2014. We conducted a comprehensive preclinical and clinical program for Xtampza consistent with FDA guidance on abuse-deterrence. These studies and clinical trials demonstrated that chewing, crushing and/or dissolving Xtampza, and then taking it orally or smoking, snorting, or injecting it did not meaningfully change its drug release profile or safety characteristics. By contrast, clinical trials performed by us and others — including a head-to-head clinical trial comparing Xtampza with OxyContin OP — have shown that drug abusers can 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 addition, our preclinical studies and clinical trials have shown that the contents of the Xtampza capsule can be removed from the capsule and sprinkled on food or into a cup, and then directly into the mouth, or administered through feeding tubes, without compromising their drug release profile, safety or abuse-deterrent characteristics. By contrast, OxyContin OP, which is formulated in hard tablets, has a black box warning label stating that crushing, dissolving, or chewing can cause rapid release and absorption of a potentially fatal dose of the active ingredient. We believe that Xtampza can address the pain management needs of the approximately 11 million patients in the United States who suffer from chronic pain and have difficulty swallowing.

In May 2016, we entered into a License and Development Agreement with BioDelivery Science International, Inc., or BDSI, which grants us an exclusive license to make, use, sell, offer for sale, import, develop and commercialize ONSOLIS in the United States. We plan to commercialize ONSOLIS upon receipt of FDA approval of a Prior Approval Supplement for the manufacturing transfer. Subject to such approval, we expect to launch ONSOLIS during the second half of 2017.

Since 2010, when we divested our former subsidiary, Onset Therapeutics, LLC, to PreCision Dermatology, Inc., we have devoted substantially all of our resources to the development of our patented DETERx platform technology, the preclinical and clinical advancement of our product candidates, and the creation and protection of related intellectual property. Since 2011, we have not generated any revenue from product sales and we continue to incur significant research, development and other expenses related to our ongoing operations. Prior to our initial public offering of common stock, or IPO, in May 2015, we funded our operations primarily through the private placement of preferred stock, convertible notes and commercial bank debt. Since our IPO, we have funded our operations primarily through the public offering and sale of our equity securities.

Outlook

We expect to incur significant commercialization expenses related to marketing, manufacturing, distribution, product sales and reimbursement activities. Initially, we plan to detail Xtampza to approximately 11,000 physicians who write more than 55% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 120 sales representatives. In addition, we are deploying a separate, focused sales team to detail Xtampza to nursing homes, hospices and other institutions treating large populations of the elderly and other patients who need chronic pain relief and have difficulty swallowing. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop and generate revenues from our products and product candidates.

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $40.2 million and $8.4 million for the six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, we had an accumulated deficit of $169.2 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 foreseeable future as we begin to commercialize Xtampza. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase substantially in connection with our ongoing activities as we:

- expand our sales and marketing efforts for Xtampza, including hiring additional personnel to expand our commercial organization;
- expand our regulatory and compliance functions;
- conduct clinical trials of our product candidates;
- continue scale-up and improvement of our manufacturing processes;
- continue our research and development efforts;
- manufacture preclinical study and clinical trial materials;
- maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and technical personnel to conduct our clinical trials;
- hire additional scientific personnel to support our product development efforts;
- implement operational, financial and management systems; and
- hire additional general and administrative personnel to operate as a public company.

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 our Annual Report related to accrued expenses, impairment of long-lived assets, convertible redeemable preferred stock, stock-based compensation and income taxes. We have identified critical accounting policies related to inventory and revenue recognition in the quarter ended June 30, 2016. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in the Annual Report.

Inventory

Upon approval of Xtampza by the FDA in April 2016, we began capitalizing inventory costs for Xtampza manufactured in preparation for the product launch. In periods prior to April 2016, we expensed costs associated with Xtampza, including raw materials, work in process and finished goods, as development expenses. We have not capitalized inventory costs related to its other drug development programs.

We have capitalized $1.2 million of inventory as of June 30, 2016. Certain materials used in the manufacture of Xtampza were expensed prior to FDA approval. We expect sales of the capitalized units to occur during the next twelve months. We expect the cost of product revenue to increase as we begin to sell inventory that was produced entirely after the FDA approval of Xtampza.

Revenue Recognition

Our accounting policy for revenue recognition will have a substantial impact on reported results and relies on certain estimates. Revenue for product sales is recognized when there is persuasive evidence of an arrangement, title and risk of loss have passed to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns are reasonably determinable, and when collectability is reasonably assured. Product sales are recorded net of estimated chargebacks, rebates, sales incentives and allowance, distribution service fees, as well as estimated product returns.

We have not yet recorded any product revenue, as we have not yet concluded that we meet the revenue recognition criteria under current accounting guidance. The requisite historical data on which to base estimates of returns is insufficient due to the uniqueness of the product as compared to other products in the industry. Therefore, revenue is deferred until such time that an estimate can be determined, all the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

RESULTS OF OPERATIONS

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Research and development expenses	$ 4,301	$ 1,641	$ 8,363	$ 3,086
Selling, general and administrative expenses	20,173	2,934	31,698	5,120
Other expense, net	46	99	111	163
Net loss	$ 24,520	$ 4,674	$ 40,172	$ 8,369

Comparison of the six months ended June 30, 2016 and June 30, 2015

Research and development expenses were $3.1 million for the six months ended June 30, 2015, or the 2015 Period, compared to $8.4 million for the six months ended June 30, 2016, or the 2016 Period. The $5.3 million increase was primarily related to:

- an increase in clinical trial costs of $3.5 million due to the commencement of clinical trials with Xtampza and our second product candidate;
- an increase in salaries, wages and benefits of $892,000 primarily due to increased headcount and stock-based compensation expense;and
- an increase in manufacturing costs of $668,000 related to Xtampza.

Selling, general and administrative expenses were $5.1 million for the 2015 Period compared to $31.7 million for the 2016 Period. The $26.6 million increase was primarily related to:

- an increase in sales and marketing costs of $12.0 million primarily due to preparation for the commercial launch of Xtampza;
- an increase in salaries, wages and benefits of $11.3 million primarily due to an increase from 12 to 208 employees and an increase in stock-based compensation expense; and
- an increase in commercial costs of $1.5 million primarily due to consultant costs related to analytics and strategies for the commercialization of Xtampza.

Comparison of the three months ended June 30, 2016 and June 30, 2015

Research and development expenses were $1.6 million for the three months ended June 30, 2015, or the 2015 Quarter, compared to $4.3 million for the three months ended June 30, 2016, or the 2016 Quarter. The $2.7 million increase was primarily related to:

- an increase in clinical trial costs of $1.7 million due to the commencement of clinical trials with Xtampza and our second product candidate;
- an increase in salaries, wages and benefits of $522,000 primarily due to increased headcount and stock-based compensation expense; and
- an increase in manufacturing costs of $228,000 mainly due to costs incurred for validation batches of Xtampza.

General and administrative expenses were $2.9 million for the 2015 Quarter compared to $20.2 million for the 2016 Quarter. The $17.3 million increase was primarily related to:

- an increase in sales and marketing costs of $8.5 million primarily due to preparation for the commercial launch of Xtampza;
- an increase in salaries & wages of $7.4 million primarily due to an increase from 12 to 208 employees and an increase in bonuses and stock compensation expense;
- an increase in commercial costs of $676,000 primarily due to consultant costs related to analytics and strategies for the commercialization of Xtampza.

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 placement of our preferred stock, our IPO, convertible notes and commercial bank debt. As of June 30, 2016, we had $110.7 million in cash and cash equivalents.

In January 2016, the Company issued and sold in a public offering an aggregate of 2,750,000 shares of its common stock at $20.00 per share. This public offering resulted in net proceeds of $51.2 million, after deducting underwriting discounts and commissions and expenses payable by the Company.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash will be sufficient to fund our operations into early 2018, including the commercialization of Xtampza and the continuation of our development of our product candidates. We have based this estimate on assumptions that may prove to be incorrect and we could use our available capital resources sooner than we currently expect. We may never become profitable, or if we do, we may not be able to sustain profitability.

Cash flows

Operating activities. Cash used in operating activities was $32.4 million in the 2016 Period and $6.1 million in the 2015 Period. The increase in cash used in operating activities was due primarily to the change in net loss partially offset by changes in the working capital accounts. We expect cash used in operating activities to increase for the

foreseeable future as we continue to commercialize Xtampza and fund research, development and clinical activities for additional product candidates.

Investing activities. Cash used for investing activities was $2.5 million in the 2016 Period and nominal in the 2015 Period. The increase in cash used in investing activities was due to the payment of a one-time upfront fee to BDSI for the ONSOLIS License Agreement.

Financing activities. Cash provided by financing activities for the 2016 Period primarily represents net proceeds of $51.2 million from the issuance of common stock partially offset by the repayment of term notes. Cash provided by financing activities for the 2015 Period primarily reflects net proceeds from the IPO and from the sale of Series D convertible preferred stock of $72.0 million and $44.8 million respectively.

Funding requirements

Since 2011, we have not generated any product revenue. We are in the early stages of commercialization of Xtampza. We anticipate that we will continue to incur losses for the next several years, and we expect the losses to increase as we begin to commercialize Xtampza and continue the development of, and seek regulatory approvals for other product candidates. We are subject to all of 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. We will also incur additional costs associated with operating as a commercial stage company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of cash flow from the sale of our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if 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 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 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. 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 cost of establishing sales, marketing and distribution capabilities for Xtampza and any other products for which we may receive regulatory approval;
- the generation of reasonable levels of revenue from the sale of Xtampza;
- the design, initiation, progress, size, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;
- the timing and costs associated with manufacturing Xtampza and our product candidates for preclinical studies, clinical trials and, if approved, for commercial sale;
- the number and characteristics of product candidates that we pursue;
- the cost of patent infringement litigation, including the Company's litigation with Purdue Pharma, L.P., or Purdue, relating to Xtampza or our product candidates, which may be expensive to defend and delay the commercialization of Xtampza or our product candidates;
- our need to expand our research and development activities, including our need and ability to hire additional employees;

- our need to implement additional infrastructure and internal systems and hire additional employees to operate as a public company;
- 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.

CONTRACTUAL OBLIGATIONS

There have been no material changes to the contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report, apart from our commitment to reimburse BioDelivery Sciences International, Inc. up to a maximum of $2.0 million for its out-of-pocket expenses incurred in conjunction with the manufacturing transfer of ONSOLIS.

OFF-BALANCE SHEET ARRANGEMENTS

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2016, we had cash and cash equivalents consisting of cash and money market funds of $110.7 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our money market funds are short-term highly liquid investments. Due to the short-term duration and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2016, 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

No change in our internal control over financial reporting occurred during the fiscal quarter ended June 30, 2016 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We filed the NDA for Xtampza as a 505(b)(2) application, which allows us 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 we certify to the FDA and notify Purdue, as the holder of the NDA and any other Orange Book-listed patent owners, that we do not infringe any of the patents listed for OxyContin OP in the Orange Book, or that the patents are invalid. We 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 stand invalidated by the Federal District Court for the Southern District of New York, subject to a pending appeal. Under the Hatch-Waxman Act of 1984, Purdue had the option to sue us for infringement and receive a stay of up to 30 months before the FDA can issue a final approval for Xtampza, unless the stay is earlier terminated.

Purdue exercised its option and elected to sue us for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (all of which stand invalidated subject to a pending appeal by Purdue) and a non-Orange Book-listed patent, and accordingly, received a stay of up to 30 months before the FDA can issue a final approval for Xtampza.

On October 7, 2015, the Delaware court transferred the case to the District of Massachusetts. In November 2015, Purdue filed suit asserting infringement of another non-Orange Book-listed patent. On November 9, 2015, the Company filed a motion for partial judgment on the pleadings in relation to three Orange Book-listed patents asserted against the Company, which had been previously invalidated by the court in the Southern District of New York in Purdue's suit against another company. On February 1, 2016, the Court of Appeals for the Federal Circuit affirmed the New York judgment of invalidity. On February 9, 2016, the District Court of Massachusetts ordered judgment in favor of the Company on the three Orange Book-listed patents that were the basis of the 30-month stay, Patent Nos. 7,674,799, 7,674,800, and 7,683,072 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. Purdue continues to assert infringement of two patents against the company, neither of which is associated with any stay of FDA approval. We plan to continue to take all steps necessary to vigorously defend ourselves against these claims.

From time to time, the Company may be subject to various claims and legal proceedings. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount is reasonably estimated, the Company will accrue a liability for the estimated loss.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You 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 you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are an early commercial-stage pharmaceutical company. To date, we have focused on developing our first product, Xtampza. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront

capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. Since 2010, when we divested our former subsidiary, Onset Therapeutics, LLC, to PreCision Dermatology, Inc., we have not generated any material revenue from product sales, and we continue to incur significant research, development, commercialization and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since January 1, 2011. For the year ended December 31, 2015, we reported a net loss of $27.3 million, and we had an accumulated deficit of $129.0 million at December 31, 2015. We incurred a net loss of $40.2 million for the six months ended June 30, 2016. As of June 30, 2016, we had an accumulated deficit of $169.2 million.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize Xtampza. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fails in clinical trials or does not gain final regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital.

We currently generate no material revenue from the sale of products and may never become profitable.

We began the commercial launch of our first product, Xtampza, in June 2016. Accordingly, we have not generated any material revenue from product sales since we divested our former subsidiary in 2010. Our ability to generate additional revenue and become profitable depends upon our ability to successfully commercialize Xtampza, our existing product candidates, and any other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know when any of these product candidates will generate revenue for us, if at all. Our ability to generate revenue from our current or future product candidates depends on a number of factors, including our ability to:

- successfully commercialize Xtampza;
- successfully satisfy FDA post-marketing requirements for Xtampza, including studies and clinical trials that have been required for other extended release/long acting opioid analgesics and individual studies and clinical trials of Xtampza;
- successfully complete development activities, including the necessary clinical trials, with respect to our product candidates;
- complete and submit NDAs to the FDA and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize our product candidates outside the United States;

- set a commercially viable price for our products;

- manufacture commercial quantities of our products at acceptable cost levels;

- develop a commercial organization capable of sales, marketing and distribution for the products we intend to sell ourselves in the markets in which we have retained commercialization rights;

- find suitable distribution collaborators to help us market, sell and distribute our products, if approved, in markets outside the United States; and

- obtain coverage and adequate reimbursement from third parties, including government payors.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the safety and efficacy (including the efficacy of our abuse-deterrent technology) endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Furthermore, we anticipate incurring significant costs associated with commercializing these products.

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

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

Our operations have consumed substantial amounts of cash. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize Xtampza and any product candidates for which we may receive regulatory approval. We believe that our existing cash and cash equivalents, including the net proceeds from our January 2016 follow-on offering, will be sufficient to fund our operations into 2018, including the commercialization of Xtampza, and the continuation of our development of our product candidates. However, we may require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner in order to accelerate development of our product candidates.

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

- significantly delay, scale back or discontinue the development or the commercialization of Xtampza, our product candidates or one or more of our other research and development initiatives;

- seek collaborators for Xtampza and/or one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;

- relinquish or license on unfavorable terms our rights to technologies, products or product candidates that we otherwise would seek to develop or commercialize ourselves; or

- significantly curtail operations.

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

- the ability to obtain and maintain abuse-deterrent claims in the product labels for our products and product candidates;

- our ability to successfully satisfy the FDA post-marketing requirements of Xtampza, including studies and clinical trials that have been required for other extended release/long acting opioid analgesics and individual studies and clinical trials of Xtampza;

- clinical development plans for our product candidates;

- the outcome, timing and cost of the regulatory approval process by the FDA and foreign regulatory authorities, including the potential for regulatory authorities to require that we perform more studies than those that we currently expect;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including defending Purdue's remaining patent infringement claims against us;

- the cost and timing of completion of existing or expanded commercial-scale outsourced manufacturing activities;

- the cost of maintaining, and if appropriate, expanding, sales, marketing and distribution capabilities for Xtampza and any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and

- the initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to Xtampza, 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 beyond our existing indebtedness with Silicon Valley Bank 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 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 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 product development or commercialization 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. Although the FDA has approved Xtampza, we have not yet obtained final regulatory approval for any of our product candidates or demonstrated an ability to commercialize a product successfully. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history.

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

As of December 31, 2015, we had net operating loss, or NOL, carryforwards of approximately $104.9 million for U.S. federal income tax and state tax purposes available to offset future taxable income and U.S. federal and state research and development tax credits of $59.9 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382. These carryforwards begin to expire in 2022. 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 performed any current analyses under Section 382 and cannot forecast or otherwise rely on deriving benefit from our various federal or state tax attribute carryforwards. 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.

Risks Related to our Products and Product Candidates

Our success depends in large part on the commercial success of our lead product, Xtampza.

To date, we have invested substantial resources in the development of our lead product, Xtampza, which has been approved by the FDA. Our business and future success are substantially dependent on our ability to successfully and timely commercialize this product, which may never occur. We currently generate no material revenues from product sales and we may never be able to commercialize Xtampza, 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 and clinical trials of Xtampza;
- the ability to manufacture commercial quantities of Xtampza at reasonable cost and with sufficient speed to meet commercial demand;
- our ability to build a sales and marketing organization to market Xtampza;
- our success in educating physicians, patients and caregivers about the benefits, administration and use of Xtampza;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments for chronic pain and chronic pain with dysphagia;
- our ability to successfully defend any challenges to our intellectual property relating to Xtampza;
- the availability of coverage and adequate reimbursement for Xtampza; and
- a continued acceptable safety profile of Xtampza following approval.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this “Risk Factors” section and in the “Risk Factors” section of our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 18, 2016. Accordingly, we cannot assure you that we will be able to successfully commercialize or generate revenue from Xtampza. 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, and our ability to successfully market Xtampza may be adversely affected.

It is estimated that the U.S. market includes approximately 11 million patients with chronic pain with dysphagia. Our Xtampza microspheres are designed to be removed from the capsule and sprinkled on food or into a cup, and then directly into the mouth, or in feeding tubes, without compromising their extended-release properties. On April 26, 2016, the FDA granted approval for the Xtampza NDA, including an approved product label. The FDA could change the product labeling. If the product label for Xtampza is modified in the future so as to exclude the flexible dose administration options, including the ability to sprinkle the Xtampza microspheres on food or into a cup, then directly in the mouth, or in feeding tubes, 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 alternative dosing options, and we may not be able to market Xtampza to patients with chronic pain with dysphagia. As a result, this may have an adverse effect on our business and our prospects for future growth.

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

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

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

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

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

Our decision to seek approval of our product candidates, including Xtampza, 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.

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 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 launch any of our product candidates, if we receive final regulatory approval by the FDA, including Xtampza, 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.

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

The time required to obtain approvals by the FDA and foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval varies among jurisdictions and may change during the course of a product candidate's clinical development. Although the FDA has approved Xtampza, it is possible that none of our product candidates or any future product candidates that we may in-license, acquire or develop will ever obtain final regulatory approval from the FDA or any foreign regulatory authority. Moreover, even after any product candidate receives final regulatory approval, the FDA may require, as it has for Xtampza, 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 could fail to receive regulatory approval from the FDA or a foreign regulatory authority, or we may be required to conduct more extensive studies and clinical trials in order to receive such approval, for many reasons, including, but not limited to:

- the FDA and/or foreign regulatory authorities may disagree with or disapprove of the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure to demonstrate that a product candidate is bioequivalent to its listed drug;
- failure of clinical trials to meet criteria required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA or foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- deficiencies in the manufacturing processes or failure of third-party manufacturing facilities with whom we contract for clinical and commercial supplies to pass inspection;

- the FDA or foreign regulatory authorities may not approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; or

- insufficient data collected from clinical trials of our product candidates or changes in the approval policies or regulations that render our preclinical and clinical data insufficient to support the submission and filing of an NDA or to obtain regulatory approval.

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

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

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

In order to market and sell our products outside the United States, we will likely need to obtain separate marketing approvals and comply with numerous and varied regulatory requirements and regimes, which can involve additional testing, may take substantially longer than the FDA approval process, and still generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. FDA approval does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by the FDA or regulatory authorities in other countries or jurisdictions. We may not obtain any regulatory approvals on a timely basis, if at all. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in countries outside the United States, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

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

We recently began the commercial launch of Xtampza, our first approved product, in June 2016. Accordingly, we have not generating any material revenues from product sales. To be profitable, and in addition to commercializing Xtampza, we must successfully research, develop, obtain regulatory approval for, manufacture, launch, market and distribute products and product candidates under development. For each product candidate that we intend to commercialize, we must successfully meet a number of critical developmental milestones, including:

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

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

We are continuing to test and develop our product candidates and may explore possible design or formulation changes to address bioavailability, safety, efficacy, manufacturing efficiency and performance issues. We may not be able to complete development of any product candidates that will be safe and effective and that will have a commercially reasonable treatment and storage period. If we are unable to complete development of our product candidates, we will not be able to earn revenue from them.

Xtampza is, and we anticipate that our product candidates, if approved, will be, subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of such product and product candidates.

The FDA has approved a 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. One of the primary goals of the ER/LA opioid REMS is to ensure that the benefits of these drugs continue to outweigh the risks.

The ER/LA opioid REMS introduces new safety measures designed to reduce risks and improve the safe use of ER/LA opioids, while continuing to provide access to these medications for patients in pain. The ER/LA opioid REMS applies to more than 20 companies that manufacture opioid analgesics. Under the ER/LA opioid 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 ER/LA opioid 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 ER/LA opioid 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. As part of its approval of the Xtampza NDA, the FDA indicated that the REMS requirement for ER/LA opioids will apply to Xtampza. The 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 ER/LA opioid REMS requirements, which could reduce the commercial benefits to us from the sale of these product candidates.

If we fail to obtain the necessary final regulatory approvals, or if such approvals are limited, we will not be able to commercialize our product candidates, and we will not generate product revenues.

Even if we comply with all FDA pre-approval regulatory requirements, the FDA may determine that our product candidates are not safe or effective, and we may never obtain final regulatory approval for such product candidates. If we fail to obtain final regulatory approval for some or all of our product candidates, we will have fewer commercial products, if any, and correspondingly lower product revenues, if any. Even if our product candidates receive final regulatory approval, such final regulatory approval may involve limitations on the indications and conditions of use or marketing claims for our products, or may not include certain abuse-deterrence claims or clinical trial data that we have sought, and will seek, to include in the product label for our product candidates. If we do not receive regulatory approval to include certain abuse-deterrence claims, or certain clinical data, in our product labels, our ability to successfully commercialize our products may be limited and our financial results may be adversely impacted. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products and addition of warnings or other statements on the product label. The FDA is likely to require us to perform lengthy Phase 4 post-approval clinical efficacy or safety trials. As part of the FDA's approval of Xtampza, the FDA identified a number of studies that we will have to conduct, including required pediatric assessments and the post-marketing studies that have been required for other ER/LA opioid analgesics to estimate the serious risks of misuse, abuse, addiction, overdose, and death associated with long-term use of these medications for the management of chronic pain. The FDA will also require studies specific to Xtampza, including: (i) an epidemiologic study to evaluate whether the abuse-deterrent properties of Xtampza actually result in a significant and meaningful decrease in misuse and abuse, and their consequences with respect to addiction, overdose, and death; (ii) several long-term animal studies to evaluate the mixture of beeswax, carnauba wax, and myristic acid that is representative of Xtampza's composition; (iii) a study to characterize the levels of lead in Xtampza to inform a proposed release specification to adequately control levels of lead; and (iv) an evaluation of the beeswax employed in Xtampza's composition for potential residual levels of contaminants. The FDA also requires us to participate, with other manufacturers of ER/LA opioid analgesics, in a clinical trial of at least a year in length that would assess the known serious risk of hyperalgesia, or increased sensitivity to pain, with ER/LA opioid analgesics and the development of tolerance following use of these medications. The FDA may also impose additional post-marketing requirements, which will be very expensive to satisfy.

In jurisdictions outside the United States, we must receive marketing authorizations from the appropriate regulatory authorities before commercializing our product candidates. Regulatory approval processes outside the United States generally include requirements and risks similar to, and in many cases in excess of, those associated with FDA approval.

The FDA may not approve product labeling for our product candidates that would permit us to market and promote our products in the United States by describing their abuse-deterrent features.

We will invest substantial time and money conducting Category 1, Category 2 and Category 3 abuse deterrent studies to ensure that our product candidates developed with our DETERx technology comply with the FDA's April 2015 guidance regarding opioid abuse deterrence. Our failure to achieve FDA approval of product labeling containing such information will prevent or substantiality limit our promotion of the abuse deterrent features of our product candidates in order to differentiate them from other opioid products containing the same active ingredients. This would make our products less

competitive in the market. There can be no assurance that any of our product candidates will receive final FDA-approved product labeling that describes the abuse deterrent features of such products. Furthermore, the FDA's April 2015 final guidance on abuse deterrent opioids makes clear that the FDA expects sponsors to compare their formulations against approved abuse deterrent versions of the same opioid based on the relevant categories of testing. If a proposed product is less resistant to manipulation than an approved product, the FDA has stated that the proposed product may not be eligible for product labeling regarding abuse deterrent properties. If the FDA does not approve product labeling containing abuse deterrence claims, we will not be able to promote such products based on their abuse deterrent features, may not be able to differentiate such products from other opioid products containing the same active ingredients, and may need to lower the price of our products to the extent that there are competing products with abuse deterrent claims on their product labels.

Because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse deterrent characteristics of our product, 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 our products.

Even if any of our product candidates are approved for marketing with certain abuse-deterrence claims, 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.

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 is approved, we will 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 Xtampza or any product candidate that receives marketing approval, or if FDA approval of such materials is contingent upon substantial modifications, our promotional efforts relating to Xtampza and any approved product candidate may be impaired, and sales of such products may suffer.

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

- issue warning letters or untitled letters;

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

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

- seek an injunction or impose civil, criminal and/or administrative penalties, damages, monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;

- suspend or withdraw regulatory approval;

- suspend any ongoing clinical trials;

- refuse to approve pending applications or supplements to applications filed by us;

- suspend or impose restrictions on operations, including costly new manufacturing requirements;

- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or

- refuse to allow us to enter into government contracts.

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

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

Failure to comply with ongoing governmental regulations for marketing Xtampza or our product candidates 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 candidate that obtains approval in the United States, including Xtampza, will be heavily scrutinized by, among others, the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress and the public. Violations, including promotion of Xtampza, and any product candidates for which we receive final regulatory approval, for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies. Additionally, advertising and promotion of any product candidate that obtains approval outside the United States will be heavily scrutinized by foreign regulatory authorities.

In the United States, engaging in off-label promotion of Xtampza, or any of our product candidates for which we receive final regulatory approval, 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. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This increasing 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 product candidates, if approved, 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 product candidates:

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

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

Xtampza and our product candidates contain, and our future product candidates will likely contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza's active ingredient, oxycodone, is classified as a controlled substance 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, 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. The active ingredient in Xtampza, oxycodone, is listed by the DEA as a Schedule II controlled substance under the CSA. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. We may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand.

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 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 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 product candidates containing controlled substances.

Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development. If we are unable to design, conduct and complete clinical trials successfully, our product candidates will not be able to receive regulatory approval.

In order to obtain FDA approval for any of our product candidates, we must submit to the FDA an NDA with substantial evidence that demonstrates that the product candidate is both safe and effective in humans for its intended use. This demonstration requires significant research, preclinical studies and clinical trials.

Other than Xtampza, all of our product candidates are in preclinical and clinical development. Clinical trials are time-consuming, expensive and difficult to design and implement, in part because they are subject to rigorous requirements and their outcomes are inherently uncertain. Clinical testing may take many years to complete, and failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as being safe and effective. We could encounter problems that halt our clinical trials or require us to repeat such clinical trials. If patients participating in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we or the FDA believe that patients are being exposed to unacceptable health risks, such clinical trials may have to be suspended or terminated. Suspensions, termination or the need to repeat a clinical trial can occur at any stage.

The clinical trial success of each of our product candidates depends on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. There is a lack of consensus regarding standardized processes for assessing clinical outcomes based on clinician-rated scales. Accordingly, the scores from our clinical trials may not be reliable, useful or acceptable to the FDA or other regulatory agencies.

Changes in standards related to clinical trial design could have a material adverse effect on our ability to design and conduct clinical trials as planned. For example, we have conducted or will conduct clinical trials comparing our product candidates to both placebo and other approved drugs, but regulatory authorities may not allow us to compare our product candidates to a placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct a clinical trial could increase. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the product labeling claims or removal of certain warnings that we believe are necessary or desirable for the successful commercialization of our product candidates.

Approval may be contingent on a REMS, which could have a material adverse effect on the product labeling, distribution or promotion of a drug product.

Any of these delays or additional requirements could cause our product candidates to not be approved, or if approved, significantly impact the timing and commercialization of our product candidates and significantly increase our overall costs of drug development.

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.

Other than Onsolis, 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 reporting promising 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, other than Onsolis, may be compromised.

Conducting clinical trials of Xtampza and our product candidates and any commercial sales of Xtampza 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 with coverage up to approximately $5 million, which covers liability relating to our clinical trials. We may face product liability claims, regardless of FDA approval for commercial manufacturing and sale. Product liability claims may be brought against us by patients enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue;

- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

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

Xtampza and our product candidates may be associated with undesirable adverse reactions or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of their approved product label, or result in significant negative consequences following any marketing approval.

Undesirable adverse reactions associated with Xtampza and our product candidates could cause us, our IRBs, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in a restrictive product label or the delay, denial or withdrawal of regulatory approval by the FDA or foreign regulatory authorities. For example, even though Xtampza has generally been 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 Xtampza or any of our product candidates, for which receive final regulatory approval, we or others may later identify undesirable adverse events associated with such product, a number of potentially significant negative consequences could result, including:

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

Any of these events could prevent us from achieving or maintaining market acceptance of Xtampza or any of our product candidates, if approved.

Risks Related to Intellectual Property

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

Our commercial success depends upon our ability to develop product candidates and commercialize products without infringing the intellectual property rights of others. Our current or future product candidates or products, or any uses of them, may now or in the future infringe third-party patents or other intellectual property rights. This is due in part to the considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the United States and elsewhere in the world and, to date, there is no consistency regarding the breadth of claims allowed in pharmaceutical patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products. In part as a result of this uncertainty, there has been, and we expect that there will continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights.

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

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing or commercializing 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 our product candidates or force us to cease some of our business operations.

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

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

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

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

If we are unable to obtain or maintain intellectual property rights for our technology, products and product candidates, we may lose valuable assets or experience reduced market share.

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

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

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

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

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

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

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

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

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

Recent 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, only became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

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

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

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

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

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

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and

our overall financial condition. In addition, an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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

While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing or obtaining such an agreement with each party who, in fact, develops intellectual property that we regard as our own. In addition, they may breach the assignment agreements or such agreements may not be self-executing, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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

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

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

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

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

Risks Related to the Commercialization of Our Product Candidates

We currently have limited sales and marketing capabilities and, if we are unable to expand our own sales and marketing capabilities or enter into strategic alliances with marketing collaborators, we may not be successful in commercializing Xtampza and our product candidates and may be unable to generate any material product revenue.

Although our executive officers have experience marketing pharmaceutical products, we currently have limited sales, marketing or distribution capabilities. We have recently hired field sales representatives. Therefore, our sales and marketing team has worked together for only a limited period of time. We cannot guarantee that we will be successful in marketing Xtampza or any of our product candidates which may be approved in the United States. In addition, we will have to 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 establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate material product revenue and may not become profitable. Factors that may inhibit our efforts to commercialize our 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 obtain access to or persuade adequate numbers of physicians to prescribe our product candidates;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating 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 product candidates. To the extent we commercialize our product candidates by entering into agreements with third-party collaborators, we may have limited or no control over the sales, marketing and distribution activities of these third parties, in which case our future revenues would depend heavily on the success of the efforts of these third parties.

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

Even if the FDA approves our product candidates, physicians, patients, healthcare payors and the medical community may not accept and use them. Acceptance and use of Xtampza 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 Xtampza and the product candidates as well as competitive products;

- approved indications, warnings and precautions language that may be less desirable than anticipated;

- perceptions by members of the healthcare community, including physicians, about the safety and efficacy of Xtampza and our product candidates, and, in particular, the efficacy of our abuse deterrent technology in reducing potential risks of unintended use;

- perceptions by physicians regarding the cost benefit of Xtampza and our product candidates in reducing potential risks of unintended use;

- published studies demonstrating the cost-effectiveness of Xtampza and our product candidates relative to competing products;

- the potential and perceived advantages of Xtampza and our product candidates over alternative treatments;

- the convenience and ease of administration to patients of Xtampza and our product candidates;

- availability of coverage and adequate reimbursement for Xtampza and our product candidates from government or other third-party payors;

- any negative publicity related to our or our competitors' products that include the same active ingredient as Xtampza 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 other licensees and distributors.

If our product candidates, including our recently approved product, Xtampza, are approved for marketing but fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable. Because we expect to rely on sales generated by Xtampza for substantially all of our revenues for the foreseeable future, the failure of Xtampza to find market acceptance would harm our business prospects.

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

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial new provisions intended to, among other things, broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, and impose additional health policy reforms, any of which could have a material adverse effect on our business. A significant number of provisions are not yet, or have only recently become, effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Other legislative changes have also been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to 2% per fiscal year, starting in 2013 and, due to the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional action is taken by Congress. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could impose additional financial pressure on our customers, which could in turn diminish demand for our products or result in pricing pressure on us. In addition, drug pricing by pharmaceutical companies has recently come under close scrutiny. For example, the U.S. House of Representatives recently formed an Affordable Drug Pricing Task Force to advance legislation intended to control pharmaceutical drug costs and investigate pharmaceutical drug pricing, and the U.S. Senate has requested information from certain pharmaceutical companies in connection with an investigation into pharmaceutical drug pricing practices. If healthcare policies or reforms intended to curb healthcare costs are adopted, or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved

products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

We expect that 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.

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

Even if we are able to commercialize Xtampza and any of our product candidates, our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business.

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

Our ability to commercialize any products 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 predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage

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 any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory efforts to combat abuse, could decrease the potential market for Xtampza 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 that seek to limit the availability of opioids. Such efforts may inhibit our ability to commercialize Xtampza 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; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for Xtampza 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 opioids.

Efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for our 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 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 Scientific Board to broaden the understanding of the public risks of opioid abuse. The FDA's Scientific Advisory Board met to address these issues on March 1, 2016. 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. Also 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 new 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. Prior to this action, in September 10, 2013, the FDA announced its intention to effect product labeling changes to all approved extended release/long acting opioids. In particular, the FDA announced its intention to update the indication for extended release/long acting opioids so that extended release/long acting opioids will be indicated only 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. On April 16, 2014, the FDA updated these indications. Many of these changes could cause us to expend additional resources in developing and commercializing Xtampza and our product candidates to meet additional requirements. Advancements in development and approval of generic abuse-deterrent opioids could also compete with and potentially impact physician use of our product candidates and cause our product candidates to be less commercially successful.

If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with Xtampza 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 product and product candidates.

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

Government agencies promulgate regulations and guidelines directly applicable to us and to Xtampza 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, our product launch may be delayed and our costs may be higher than expected and could have a material adverse effect on our business.

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 one contract manufacturer, Patheon, as well as other vendors to formulate, test, supply, store and distribute Xtampza and our product candidates for our clinical trials and FDA registration, and we control only certain aspects of their activities. 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, as our single manufacturer, 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, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical 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 its agreement with us to meet our requirements for commercialization of Xtampza.

- 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 before we may use the alternative manufacturer to produce Xtampza.

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

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

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require that Xtampza and our product candidates that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to 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.

Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredient of Xtampza, 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 we intend to contract with this supplier, as necessary, for commercial supply of our products. Although we have identified an alternate source for oxycodone base, it would be time-consuming and costly to qualify this source. Since we currently obtain our active ingredient from this manufacturer on a purchase-order basis, either we or our supplier may terminate our arrangement, without cause, at any time without notice. If our supplier were to terminate our arrangement 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 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 preclinical and clinical programs. We rely on these parties for execution of our 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.

Because we have relied on third parties, 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.

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

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop or commercialize Xtampza and our product candidates. These collaborations, including our license agreement for the development and marketing of Onsolis, 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 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 products may not commit sufficient resources to the marketing and distribution of such products.

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our 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 product 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.

We may rely on collaborators to market and commercialize Xtampza and, if approved, our product candidates, who may fail to effectively commercialize our products.

We may utilize strategic collaborators or contract sales forces, where appropriate, to assist in the commercialization of Xtampza 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 product 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.

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 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 Purdue, Johnson & Johnson, Pfizer, Endo, Mallinckrodt, Pernix, Actavis 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 product 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, we believe that several competitors are developing extended-release hydrocodone products, and if the FDA approves a competitor's 505(b)(2) application for an extended-release hydrocodone product and grants exclusivity before the FDA grants final regulatory approval to our hydrocodone product candidate, we could be subject to a delay that would dramatically reduce the expected market penetration for our hydrocodone product candidate. Additionally, even if our 505(b)(2) application is approved for marketing first, we may still be subject to competition from other hydrocodone products, including approved products or other approved 505(b)(2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us.

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 product candidates will compete may limit market acceptance of our 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 product and product candidates, if approved, and the established use of these competitive products may limit the potential for our product and product candidates to receive widespread acceptance if commercialized.

The use of legal and regulatory strategies by competitors with innovator products, including the filing of citizen petitions, 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 product candidates.

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

- filing "citizen petitions" with the FDA that may delay competition by causing delays of our product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a product's bioequivalence or "sameness" to the related innovator product;
- filing suits for patent infringement that automatically delay FDA approval of products seeking approval based on the Section 505(b)(2) pathway;
- obtaining extensions of market exclusivity by conducting clinical trials of innovator drugs in pediatric populations or by other methods;

- persuading the FDA to withdraw the approval of innovator drugs for which the patents are about to expire, thus allowing the innovator company to develop and launch new patented products serving as substitutes for the withdrawn products;

- seeking to obtain new patents on drugs for which patent protection is about to expire; and

- initiating legislative and administrative efforts in various states to limit the substitution of innovator products by pharmacies.

These strategies could delay, reduce or eliminate our entry into the market and our ability to generate revenues associated with our 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, Michael T. Heffernan, and our Chief Commercial Officer, Barry Duke. Each employee is employed by us at will and is permitted to terminate his employment with us at any time pursuant to the terms of his employment agreement. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of Mr. Heffernan or Mr. Duke 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.

As we prepared for the commercial launch for Xtampza, 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 our ongoing 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;

- developing our compliance infrastructure and processes to ensure compliance with regulations applicable to public companies; and

- expanding our facilities.

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 product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or product candidates, businesses or 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 forming strategic alliances and collaborations. We may not be able to find suitable acquisition candidates, and if we make an acquisition, we may not be able to 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 alliance or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, 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 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 be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, 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, or CMO, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, 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 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 various 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 product 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 against us, including the ongoing Purdue litigation;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product and product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product 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 July 30, 2016, we had 23,528,440 shares of common stock outstanding. Holders of an aggregate of approximately[[12.8]] 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 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.

We expect that significant additional capital will 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 majority of our stock and have the ability to exert significant control over matters subject to shareholder approval.

As of December 31, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a majority of our voting stock, including shares subject to outstanding options and warrants. As a result, if these shareholders were to choose to act together, they would be able to significantly influence the outcome of all matters requiring shareholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest. The interests of this group of shareholders may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. Such concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and/or the board of directors; or

- impede a merger, consolidation, takeover or other business combination involving us that other shareholders may desire.

In addition, persons associated with Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P., and TPG Biotechnology Partners IV, L.P. currently serve on our board of directors. The interests of Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P., and TPG Biotechnology Partners IV, L.P. may not always coincide with the interests of the other shareholders, and the concentration of control in Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P., and TPG Biotechnology Partners IV, 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, should they choose to do so, 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.

We are an "emerging growth company" and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our shares of common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various reporting requirements applicable to other public companies, but not to emerging growth companies, including, but not limited to, an exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act, reduced disclosure about executive compensation arrangements pursuant to the rules applicable to smaller reporting companies and no requirement to seek non-binding advisory votes on executive compensation or golden parachute arrangements. We will remain an emerging growth company until the earliest of (i) December 31, 2020, (ii) the first fiscal year after our annual gross revenue are $1.0 billion or more, (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended transition period and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We cannot predict if investors will find our common stock less attractive as a result of our taking advantage of these exemptions. If some investors find our common stock less attractive as a result of our choices, there may be a less active trading market for our common stock and our stock price may be more volatile.

If investors find our common stock less attractive as a result of our reduced reporting requirements, there may be a less active trading market for our common stock and our stock price may be more volatile. We may also be unable to raise additional capital as and when we need it.

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. Commencing with our annual report on Form 10-K for the year ending December 31, 2016, we will be 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 will need to 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. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting

and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion, which could potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. 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 December 31, 2015, there were (a) outstanding options to purchase an aggregate of 1,452,149 shares of our common stock at a weighted average exercise price of $10.37 per share, of which options to purchase 205,891 shares of our common stock were then exercisable, and (b) 2,445 shares of common stock issuable upon the exercise of warrants to purchase common stock at a weighted-average exercise price of $12.27 per share. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

Any issuance of our common stock that is not made solely to then-existing shareholders proportionate to their interests, such as in the case of a stock dividend or stock split, will result in dilution to each shareholder by reducing his, her or its percentage ownership of the total outstanding shares. Moreover, if we issue options or warrants to purchase our common stock in the future and those options or warrants are exercised you may experience further dilution. Holders of shares of

our common stock have no preemptive rights that entitle them to purchase their pro rata share of any offering of shares of any class or series.

We have broad discretion in the use of our cash and cash equivalents, and, despite our efforts, we may use them in a manner that does not increase the value of your 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 development of our product candidates. Pending their use, 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 your 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 your 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.

USE OF PROCEEDS

Our IPO was effected through a Registration Statement on Form S-1 (File No. 333-203208) that was declared effective by the SEC on May 6, 2015, which registered an aggregate of 6,670,000 shares of our common stock. On May 12, 2015, 6,670,000 shares of common stock were sold on our behalf at an initial public offering price of $12.00 per share, including 870,000 shares of common stock upon the exercise by the underwriters of their option to purchase additional shares at the public offering price, for aggregate gross proceeds of $74.4 million. As of the date of filing this report, the offering has terminated, and all of the securities registered pursuant to the offering have been sold prior to termination. Jefferies LLC and Piper Jaffray & Co. acted as joint book-running managers. Wells Fargo Securities, LLC acted as lead manager and Needham & Company, LLC acted as co-manager in the offering.

The net proceeds of the offering to us, after deducting underwriting discounts and commissions of $5.6 million and offering expenses of $2.4 million, were approximately $72.0 million. On May 12, 2015, the closing date of the offering, we received the proceeds from the offering, $58.8 million of which have been utilized for the development of our commercial infrastructure, research and development of our product candidates and general corporate purposes, including working capital.

The foregoing expenses are a reasonable estimate of the expenses incurred by us in the offering and do not represent the exact amount of expenses incurred. All of the foregoing expenses were direct or indirect payments to

persons other than (i) our directors, officers or any of their associates; (ii) persons owning 10% or more of our common stock; or (iii) our affiliates.

There has been no material change in the use of proceeds from the IPO as described in the Prospectus dated May 6, 2015 filed pursuant to Rule 424 (b) (4) under the Securities Act of 1933, as amended, with the SEC on May 7, 2015 in conjunction with the Company's IPO under "Use of Proceeds".

PURCHASE OF EQUITY SECURITIES

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

Not applicable

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

COLLEGIUM PHARMACEUTICAL, INC.

Date: August 11. 2016

By: /s/ MICHAEL HEFFERNAN
Michael Heffernan
Chief Executive Officer
(Principal executive officer)

Date: August 11. 2016

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

EXHIBIT INDEX

10.1	License and Development Agreement, dated as of May 11, 2016, by and between Collegium Pharmaceutical, Inc. and BioDelivery Systems International, 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

*Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the U.S. Securities andExchange Commission.

Portions of this exhibit have been omitted and filed separately with the Secretary of the Securities and Exchange Commission (the "Commission") pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Such portions are marked as indicated below.

LICENSE AND DEVELOPMENT AGREEMENT

This License and Development Agreement ("*Agreement*") is made as of May 11, 2016 (the "*Effective Date*") by and between BioDelivery Sciences International, Inc., a Delaware corporation with its principal offices at 4131 Parklake Avenue, Suite 225, Raleigh, North Carolina 27612 ("*Parent*"), its wholly-owned subsidiary Arius Pharmaceuticals, Inc., a Delaware corporation with an office at the same address ("*Arius*", and together with Parent, "*BDSI*"), and Collegium Pharmaceutical, Inc., a Virginia corporation with its principal office at 780 Dedham Street, Suite 800, Canton, MA 02021 ("*Collegium*"). BDSI and Collegium are sometimes referred to collectively herein as the "Parties" or singly as a "Party."

R E C I T A L S

WHEREAS, BDSI wishes to grant to Collegium, and Collegium wishes to obtain from BDSI, an exclusive license to develop, manufacture (or have manufactured), market, advertise, promote, distribute, offer for sale, sell, export, and import BDSI's BEMA fentanyl product called ONSOLIS® in the United States on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants and agreements contained herein, the Parties hereto, intending to be legally bound, do hereby agree as follows:

ARTICLE I

DEFINITIONS

Section 1.01 ***Definitions***. In addition to the capitalized terms defined elsewhere in this Agreement, the following terms used in this Agreement shall have the meaning set forth below:

*"$*** Notice*" shall have the meaning set forth in Section 4.01(c).

"*AAA*" shall have the meaning set forth in Section 14.03(c).

"*Acquiring Entity*" means any Third Party that acquires all or substantially all of the stock, assets, or business of a Party (or all or substantially all of the assets or business thereof related, in either case, to this Agreement) or otherwise obtains control of a Party (with "*control*", for purposes of this definition, having the meaning set forth below in the definition of "*Affiliate*"), or any Affiliate of such Third Party.

"*Actavis Litigation*" has the meaning set forth in Section 9.04.

"*ADE*" means any Adverse Event associated with any BEMA Fentanyl Product or Demonstration Sample (including Adverse Drug Reactions).

"*Adverse Event*" or "*AE*" means any untoward medical occurrence in a patient or clinical investigation subject administered BEMA Fentanyl Products or Demonstration Samples and which does not necessarily have to have a causal relationship with such treatment.

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

"*Adverse Reaction*" or "*Adverse Drug Reaction*" or "*ADR*" means a response to any BEMA Fentanyl Product or Demonstration Sample which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function.

"*Affiliate*" means an individual, trust, business trust, joint venture, partnership, corporation, association or any other entity which controls, is controlled by or is under common control with, a Party. For the purposes of this definition, the term "*control*" (including, with correlative meanings, the terms "*controlled by*" and "*under common control with*") as used with respect to any Party, shall mean the possession (directly or indirectly) of (a) more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the outstanding voting securities of a corporation or comparable equity interest in any other type of entity or (b) the power to direct or cause the direction of the management or policies of any such Party (whether through ownership of securities or other ownership interests, by contract or otherwise).

"*Agreement*" shall have the meaning set forth in the introduction.

"*Annual Net Sales*" means the total Net Sales for all Licensed Products sold in the Territory during a particular Calendar Year.

"*API*" means an active pharmaceutical ingredient.

"*Applicable Laws*" means all applicable laws, rules, regulations and guidelines that may apply to the development, marketing, manufacturing or sale of any Licensed Product or the performance of either Party's obligations under this Agreement, including but not limited to all laws, regulations and guidelines governing the import, export, development, marketing, distribution and sale of any Licensed Product in the Territory, to the extent relevant, all "current Good Manufacturing Practices" or "current Good Clinical Practices" standards or guidelines promulgated by the FDA or other Competent Authorities, all laws, rules, regulations, and guidelines applicable to the manufacture, use, shipment, handling, sale, marketing, and distribution of fentanyl as a Schedule II controlled substance under the United States' Controlled Substances Act of 1970 and any similar foreign laws, rules, and regulations, where applicable.

"*Arius*" shall have the meaning set forth in the introduction.

"*Arius Two*" shall have the meaning set forth in Section 11.13.

"*Arius Two Agreement*" shall have the meaning set forth in Section 11.13.

"*Arius Two Consent*" shall have the meaning set forth in Section 11.13.

"*Audited Party*" shall have the meaning set forth in Section 14.11.

"Bad Debt Adjustment" shall have the meaning set forth in Section 4.01(b).

"*BDSI*" shall have the meaning set forth in the introduction.

"*BDSI Indemnitees*" shall have the meaning set forth in Section 10.02.

"*BEMA*" means the proprietary bioerodible, mucoadhesive multi-layer polymer film technology Controlled by BDSI, as embodied in the Current Product, as it exists as of the Effective Date, or described in or claimed in any Licensed Patents, and as such may be improved or enhanced by any Licensed Improvement and "*BEMA-based Product*" means any product that incorporates or is based directly on the use of the BEMA technology.

"*BEMA Fentanyl Product"* means any Licensed Product or other BEMA-based Product which (a) contains fentanyl as its sole API and (b) does not contain naloxone as an additional ingredient.

"*Books and Records*" means, in whatever media, any and all books and records, reports and accounts in connection with or related to any Licensed Product in the Territory, the research, Development, manufacture, or Commercialization thereof in the Territory, Competent Authorities, Applicable Laws, or this Agreement, as the context requires. Books and Records shall also include any market research and competitive reports, marketing reports, and related data with respect to the Territory.

"*Calendar Quarter*" means each of those three (3) calendar month periods of each Calendar Year ending March 31, June 30, September 30 and December 31, provided, that the initial Calendar Quarter shall begin on the Effective Date and end June 30, 2016.

"*Calendar Year*" means (a) for the first Calendar Year, the period commencing on the Effective Date and ending on December 31 of the same year, (b) for the Calendar Year in which this Agreement expires or is terminated, the period beginning on January 1 of such Calendar Year and ending on the effective date of such expiration or termination, and (c) for all other years, each successive twelve (12) consecutive month period beginning on January 1 and ending December 31.

"*CDC Agreement*" means that certain Clinical Development and License Agreement between BDSI and CDC IV, LLC ("*CDC*") dated July 14, 2005, as amended, and subject to that certain Sublicensing Consent and Amendment dated on or about the Effective Date of this Agreement, between Parent, Arius, CDC, and NB Athyrium LLC (the "*CDC Consent*").

"*CIOMS Form*" shall have the meaning set forth in Section 6.04(d)(iii).

"*CIOMS Line Listings*" shall have the meaning set forth in Section 6.04(d)(iv).

"*Claims*" shall have the meaning set forth in Section 10.01.

"*Collegium*" shall have the meaning set forth in the introduction.

"*Collegium Affiliates*" shall have the meaning set forth in Section 3.02(c).

"*Collegium BEMA Improvement*" means any Improvement directly concerning BEMA (or the manufacture or use thereof) that is invented, conceived, or developed by or on behalf of Collegium, any of its Affiliates, any Sublicensees, or any of its or their employees, agents, contractors, or other representatives, whether alone or jointly with BDSI, any Affiliate thereof, or any Third Party or any of its or their employees, agents, or other representatives, in the course of the exercise of the rights granted to Collegium with respect to any Licensed Product hereunder or in connection with or as a result of their access to, or use or knowledge of, BDSI's Confidential Information or BEMA.

"*Collegium Change*" shall have the meaning set forth in Section 4.01(e)(i).

"*Collegium Documentation*" means all documentation, reports, case report forms, data, information and the like, including all notes, summaries and analyses related thereto, in whatever form or media, in the possession or Control of Collegium or any Affiliate thereof, which result from or otherwise describe (i) pre-clinical, clinical, or other research and development activities related to any Licensed Product conducted by or for Collegium, its Affiliates, or any Sublicensees in the Territory, including but not limited to Phase IV Studies or manufacturing- or formulation-related activities, and/or any results thereof, (ii) information obtained by or on behalf of Collegium or Affiliate thereof concerning the use or administration of Licensed Products, including but not limited to AEs, ADRs, ADEs, and/or SAEs, or (iii) or other Collegium Know-How contained or referenced in any Governmental Approvals or Regulatory Filings.

"*Collegium Improvements*" shall have the meaning set forth in Section 3.05.

"*Collegium Indemnitees*" shall have the meaning set forth in Section 10.01.

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

"*Collegium Know-How*" means any Know-How generated by or on behalf of Collegium or any Affiliate thereof during the Term, or that otherwise comes under the Control of Collegium or any Affiliate thereof following the Effective Date and during the Term, that relates to or results from the Development, manufacture, or Commercialization of any Licensed Product hereunder by or on behalf of Collegium, its Affiliates, or any Sublicensees, as applicable, or Collegium's, its Affiliates', or Sublicensees' access to, or use or knowledge of, BDSI's Confidential Information or BEMA, as applicable, including any Know-How coming under the Control of Collegium or any Affiliate thereof relating to any Collegium Improvement.

"*Collegium Marks*" means any trademarks, service marks, trade dress, or logos used by Collegium, any Affiliate thereof, or any Sublicensee specifically for any Licensed Product at any time in connection with the use, development, promotion, marketing, distribution, offer for sale, or sale of any Licensed Product in the Territory, other than (a) the Licensed Marks and (b) any trademarks, trade names, service marks, trade dress, or logos that are generally representative of Collegium, any Affiliate thereof, or any Sublicensee as a business.

"*Collegium Patents*" means any Patents under the Control of Collegium or any Affiliate thereof during the Term that (a) Cover any Collegium Know-How or any Collegium Improvement or (b) are otherwise necessary for the Development, manufacture, or Commercialization of any BEMA Fentanyl Product; provided that, notwithstanding anything to the contrary, Collegium Patents shall not include any Patents that are owned, licensed, or otherwise controlled at any time by any Acquiring Entity of Collegium except to the extent that they come under the Control of Collegium during the Term pursuant to a transfer or assignment to Collegium from any such Acquiring Entity or were already included within the Collegium Patents immediately prior to the date of the transaction by which such Acquiring Entity first became an Acquiring Entity.

"*Collegium Product-Specific Improvements"* means any Collegium Improvement, other than a Collegium BEMA Improvement, that is specifically related to a BEMA Fentanyl Product (or the use or manufacture or manufacture of the foregoing).

"*Commercialization*" means the marketing, promotion, advertising, selling and/or distribution of any Licensed Product while Governmental Approval therefor is effective, including the conduct of any Phase IV Studies; and the term "*Commercialize*" has a corresponding meaning.

"*Commercially Reasonable Efforts*" means, with respect to the efforts to be expended by a Party with respect to any objective hereunder, those ***. "*Comparable market potential*" shall be ***. The term "*Commercially Reasonable*" has a corresponding meaning. Commercially Reasonable Efforts requires ***. Further, to the extent that ***.

"*Competent Authorities*" means, collectively, the Governmental Authorities in the Territory responsible for the regulation of medicinal products intended for human use, including the FDA.

"*Competing Product*" means a pharmaceutical product that incorporates fentanyl as its sole API, with such API intended to be delivered orally through the mucosal surface; *provided*, that any product containing naloxone shall not be a Competing Product.

"*Confidential Information*" means all information and know-how and any tangible embodiments thereof provided by or on behalf of one Party to the other Party or an Affiliate thereof either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing under this Agreement, which may include data, knowledge, practices, processes, ideas, research plans, formulation or manufacturing processes and techniques, scientific, manufacturing, marketing and business plans, and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business, and information, strategies and other matters relating to regulatory filings (including pursuant to any securities law, regulation or rule); provided, that, information or know-how of a Party will not be deemed Confidential Information of such Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party, as can be shown by written records; (b) was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party; (c) became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain,

after its disclosure to such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the disclosing Party not to disclose such information or know-how to others, as can be shown by written records; or (e) was independently discovered or developed by such receiving Party, as can be shown by its written records, without the use or benefit of, or reliance on, Confidential Information of the disclosing Party. Notwithstanding anything to the contrary, and regardless of which Party or Affiliate thereof first discloses any information concerning Collegium BEMA Improvements to the other Party or any Affiliate thereof, any information related to Collegium BEMA Improvements shall be the Confidential Information of BDSI, and BDSI shall be deemed the disclosing Party, and Collegium the receiving Party, with respect to such Confidential Information.

"*Control*" means, with respect to any intellectual property right, regulatory documentation, clinical data, trademark or trade name, the possession of the ability or right, whether by ownership, license or otherwise, to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing on the Effective Date or, with respect to any intellectual property rights, regulatory documentation, clinical data, trademark or trade name acquired from a Third Party following the Effective Date, any agreements in effect at the time such rights are acquired or licensed. For Know-How or Patents to which a Party obtains control pursuant to a written agreement executed between such Party or any Affiliate thereof and a Third Party after the Effective Date, "Control" shall only be deemed to exist pursuant to the first sentence of this definition if the grant of a license or sublicense thereunder in accordance with this Agreement does not result in such Party or any Affiliate thereof owing payment to a Third Party, unless the other Party agrees to pay the resulting amounts due to the applicable Third Party as a condition of receiving such grant of rights.

"*Controlled Collegium BEMA Improvement"* means any Collegium BEMA Improvement that is (i) invented, conceived, or developed by or on behalf of any Sublicensees or any of their employees, agents, contractors, or other representatives, whether alone or jointly with Collegium, BDSI, any Affiliate thereof, or any Third Party or any of its or their employees, agents, or other representatives and (ii) not assigned to Parent pursuant to Section 3.05.

"*Cover*" means that the use, manufacture, sale, offer for sale, development, commercialization or importation of the subject matter in question by an unlicensed entity would infringe a Valid Claim of a Patent.

"*Current Product*" means that certain Licensed Product that is the subject of NDA 022266 (the "*Current Product NDA*").

"*Debarred Entity*" shall have the meaning set forth in Section 9.14.

"*Defense/Enforcement Costs*" shall have the meaning set forth in Section 4.01(e)(ii).

"*Demonstration Samples*" means a BEMA-based Product, lacking fentanyl or any other API, that otherwise would constitute a BEMA Fentanyl Product and is used to demonstrate the manner in which a BEMA Fentanyl Product is prepared and used, and labeled "demonstration samples, for demonstration purposes only."

"*Development*" or "*Develop*" means engaging in preclinical, clinical, and other research or development activities, which may include but is not limited to research, pre-clinical, clinical and regulatory activities directed towards obtaining Governmental Approval of any Licensed Product, and manufacturing, using, exporting and importing a product for any of the foregoing purposes.

"*Effective Date*" shall have the meaning set forth in the introduction.

"Excess Requirement" shall have the meaning set forth in Section 13.06(e).

"*FDA*" means the United States Food and Drug Administration or any successor agency thereto.

"*FDCA*" means the U.S. Food, Drug and Cosmetic Act, (21 U.S.C. §301 et seq.), as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder.

"*Fentanyl-Specific Patent*" shall have the meaning set forth in Section 7.01.

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

"*First Commercial Sale*" means the first sale, or other transfer, exchange, or disposition for value, of a Licensed Product in the Territory by Collegium, an Affiliate thereof, or a Sublicensee following the Effective Date.

"*Force Majeure*" shall have the meaning set forth in Section 14.02.

"*Generic Product*" means, with respect to a Licensed Product, a product sold by a Third Party that ***.

"*Generic Saturation*" means, with respect to a particular Licensed Product, ***. For purposes of this definition, a ***.

"*Governmental Approval*" means all permits, licenses and authorizations, including but not limited to, import permits and Marketing Authorizations, required by any Competent Authority as a prerequisite to the manufacturing, marketing, or selling of a Licensed Product for human therapeutic use in the Territory.

"*Governmental Authority*" means any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (a) any government of any country, (b) a federal, state, province, county, city or other political subdivision thereof or (c) any supranational body, including the FDA.

"*Hatch-Waxman Act*" shall have the meaning set forth in Section 7.04.

"*HSR Act*" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

"*Improvements*" means any and all developments, enhancements, inventions or discoveries relating to BEMA, the Licensed Technology, or any Licensed Product invented, conceived, developed or acquired by a Party, any Affiliate thereof, or any employees, agents, or other representatives of any of the foregoing, or otherwise coming under the Control of a Party or an Affiliate thereof, at any time during the Term, including any of the foregoing intended to enhance the safety and/or efficacy of a Licensed Product.

"*Joint Improvement"* shall have the meaning set forth in Section 3.05.

"*Know-How*" means all know-how, trade secrets, inventions, data, processes, techniques, procedures, compositions, devices, methods, formulas, protocols and information, whether or not patentable, which are not generally publicly known, including, without limitation, all chemical, biochemical, toxicological, and scientific research information, whether in written, graphic or video form or any other form or format.

"*Knowledge*" of a Party means (a) actual knowledge of any senior officer of such Party or Affiliate thereof or (b) any fact or matter known to an employee of such Party or an Affiliate thereof of which any such senior officer of such Party or Affiliate would reasonably be expected to discover or otherwise become aware of in the course of the reasonable conduct of his or her duties.

"*Licensed Improvement*" means (i) any Improvement, including any Joint Improvement, directly concerning BEMA (or the manufacture or use thereof) that is invented, conceived, or developed in whole or in part by or on behalf of BDSI, any of its Affiliates, or any of its or their employees, agents, contractors, or other representatives following the Effective Date, to the extent Controlled by BDSI or any of its Affiliates during the Term and (ii) any Collegium BEMA Improvement.

"*Licensed Know-How*" means all Know-How that is (a) under the Control of BDSI or any of its Affiliates as of the Effective Date or comes under BDSI's or any of its Affiliates' Control during the Term and (b) necessary or useful to Develop, manufacture, or Commercialize Licensed Products in the Territory, including any such Know-How concerning Licensed Improvements, provided that, notwithstanding anything to the contrary, Licensed Know-How shall not include any Know-How that is owned, licensed, or otherwise controlled at any time by any Acquiring Entity of BDSI, except to the extent such Know-How comes under the Control of BDSI during the Term pursuant to a transfer or assignment to BDSI from any such Acquiring Entity or was already included within the BDSI Know-How immediately prior to the date of the transaction by which such Acquiring Entity first became an Acquiring Entity.

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

"*Licensed Marks*" means those logos, tradenames, trademarks, and associated registrations or applications therefor in the Territory set forth on Exhibit A.

"*Licensed Patents*" means (a) those Patents set forth on Exhibit B attached hereto (the "*Initial Licensed Patents*"); (b) any additions, divisionals, continuations, continuations-in-part, conversion, supplemental examinations, extensions, term restorations, registrations, re-instatements, amendments, reissuances, corrections, substitutions, re-examinations, revalidations, supplementary protection certificates, and renewals of the Initial Licensed Patents in the Territory; (c) any other Patents in the Territory Controlled by BDSI claiming priority to any of the foregoing or any of the Patents referenced in clause (a) above; (d) all patents issuing in the Territory from any of the Patents mentioned in clause (a), (b), or (c) above; and (e) all Patents Controlled by BDSI in the Territory Covering or otherwise claiming any Licensed Improvement; provided that, notwithstanding anything to the contrary, Licensed Patents shall not include any patents or patent applications that are owned, licensed, or otherwise controlled at any time by any Acquiring Entity of BDSI except to the extent that they come under the Control of BDSI pursuant to a transfer or assignment to BDSI from any such Acquiring Entity or were already included within the Licensed Patents immediately prior to the date of the transaction by which such Acquiring Entity first became an Acquiring Entity of BDSI.

"*Licensed Product*" means the Current Product or any other BEMA-based Product which (a) contains fentanyl as its sole API, (b) does not contain naloxone as an additional ingredient, and (c) constitutes an alternative dosage or formulation of the Current Product permitted under Section 2.02.

"*Licensed Technology*" means the Licensed Patents and the Licensed Know-How.

"*Losses*" shall have the meaning set forth in Section 10.01.

"*Marketing Authorization*" means all necessary and appropriate regulatory approvals, including variations thereto, to put a Licensed Product on the market for sale for human therapeutic use in a particular jurisdiction in the Territory.

"*Meda*" means Meda AB.

"*Meda License*" shall have the meaning set forth in Section 8.02(d).

"*Meda Termination Agreement*" shall have the meaning set forth in Section 8.02(d).

"*Mfg Transfer Plan*" shall have the meaning set forth in Section 2.06.

"*NDA*" means a new drug application (as defined in the FDCA), all amendments and supplements thereto, and all additional documentation required to be filed with the FDA for approval to commence commercial sale of a Licensed Product in the United States, including supplemental NDAs.

"*NDA Assignment*" shall have the meaning set forth in Section 6.02.

"*Negotiation Notice*" shall have the meaning set forth in Section 11.10(a).

"*Negotiation Period*" shall have the meaning set forth in Section 11.10(b).

"*Net Sales*" means ***.

"*Orange Book*" means the Approved Drug Products with Therapeutic Equivalence Evaluations published by the FDA's Center for Drug Evaluation and Research (or any equivalent successor publication or listing in the United States), as updated and modified from time to time.

"*Paid Party*" shall have the meaning set forth in Section 4.03(e).

"*Parent*" shall have the meaning set forth in the introduction.

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"*Patents*" means all rights under patents and patent applications, and any and all patents issuing therefrom (including utility, model and design patents, and certificates of invention), together with any and all substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, divisionals, continuations, continuations-in-part, re-examinations, renewals and domestic and foreign counterparts of the foregoing, and all improvements, supplements, modifications or additions.

"*Paying Party*" shall have the meaning set forth in Section 4.03(e).

"*Phase IV Studies*" means any clinical study the results of which are intended to be used to support an expanded label claim for a Licensed Product in the Territory (even if such expanded label claims are marketed in the Territory under a different Marketing Authorization or trademark) such as new indications or formulations, or otherwise support marketing of a Licensed Product in the Territory.

"*Prime Rate of Interest*" means the prime rate of interest published from time to time in the Wall Street Journal as the prime rate; provided, however that if the Wall Street Journal does not publish the Prime Rate of Interest, then the term "Prime Rate of Interest" shall mean the rate of interest publicly announced by Bank of America, N.A., as its Prime Rate, Base Rate, Reference Rate or the equivalent of such rate, whether or not such bank makes loans to customers at, above, or below said rate.

"*Product Recall*" means any recall, market withdrawal, or field correction of a Licensed Product from or in the Territory.

"*Product-Related Contracts*" shall have the meaning set forth in Section 13.06.

"*Product-Related Materials*" means all advertising and promotional materials (including but not limited to flyers, brochures, pamphlets and electronic media), labeling and packaging materials, and any materials or items similar to the foregoing to the extent, in each case, pertaining exclusively to the Licensed Products and in the possession or control of Collegium or any Affiliate thereof, and all copyright and similar rights to the contents thereof, provided that the foregoing rights shall not include any rights to any trademark, logos, or the like other than Collegium Marks.

"*PSURs*" shall have the meaning set forth in Section 6.04(g).

"*Regulatory Filing*" means an NDA, investigational new drug application, any drug master files or the like in the Territory, and any other filings or submissions required by or provided to Competent Authorities in the Territory relating to the Development, manufacture, or Commercialization of any Licensed Product, including any supporting documentation, correspondence, meeting minutes, amendments, supplements, registrations, governmental licenses or permits, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, and manufacturing, shipping, or storage records with respect to any of the foregoing.

"*Relevant Factors*" means ***.

"*REMS*" shall have the meaning set forth in Section 6.01.

"*Requesting Party*" shall have the meaning set forth in Section 14.11.

"*Review Period*" shall have the meaning set forth in Section 8.03.

"*ROFN Notice*" shall have the meaning set forth in Section 11.10(a).

"*ROFN Notice Period*" shall have the meaning set forth in Section 11.10(a).

"*ROFN Product*" shall have the meaning set forth in Section 11.10(a).

"*Royalty Statement*" shall have the meaning set forth in Section 4.03(a).

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"*Royalty Term*" means, on a Licensed Product-by-Licensed Product basis, the period beginning on the Effective Date and ending on the later of (a) expiration of the last-to-expire Valid Claim of the Licensed Patents in the Territory Covering a particular Licensed Product or (b) Generic Saturation for such Licensed Product.

"*Rules*" shall have the meaning set forth in Section 14.03(c).

"*Serious Adverse Event*" or "*SAE*" means an Adverse Event that at any dose (a) results in death, (b) is life-threatening, (c) requires inpatient hospitalization or prolongation of existing hospitalization, (d) results in persistent or significant disability/incapacity, or (e) results in a congenital anomaly/birth defect. The term "life-threatening" in this definition refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it had been more severe. Important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or require intervention to prevent one of the other outcomes listed above should also be included in this definition to the extent reasonable medical and scientific judgement indicates that expedited reporting is appropriate under Applicable Laws.

"*Serious Adverse Reaction*" or "*SAR*" means an Adverse Reaction that at any dose (a) results in death, (b) is life-threatening, (c) requires inpatient hospitalization or prolongation of existing hospitalization, (d) results in persistent or significant disability/incapacity, or (e) results in a congenital anomaly/birth defect. The term "life-threatening" in this definition refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it had been more severe. Important medical events that may not immediately result in death or hospitalization but may jeopardize the patient or require intervention to prevent one of the other outcomes listed above should also be included in this definition to the extent reasonable medical and scientific judgement indicates that expedited reporting is appropriate under Applicable Laws.

"SKU" shall have the meaning set forth in Section 4.03(a).

"*SOPs*" shall have the meaning set forth in Section 6.04(g).

"*Sublicensee*" means any Third Party, other than an Affiliate of Collegium, to whom any of the rights granted to Collegium under this Agreement have been sublicensed as permitted hereby.

"*Supplement*" shall have the meaning set forth in Section 2.01.

"*Supplement Approval*" means FDA's approval of a filing intended to be made by BDSI to the FDA pursuant to 21 U.S.C. §314.70(b)(1) with respect to the proposed commercial manufacture of the Current Product by *** which, upon such approval, would permit the sale of Current Product manufactured by *** for human therapeutic use in the Territory under the Current Product NDA (such filing, the "*Supplemental Filing*").

"*Supplement Approval Notice*" shall have the meaning set forth in Section 2.01.

"*** *Agreement*" shall have the meaning set forth in Section 2.06.

"*Term*" shall have the meaning set forth in Section 13.01.

"*Territory*" means the United States of America and its territories and protectorates.

"*Therapeutic Equivalent*" has the meaning given to such term by the FDA in the current edition of the "Approved Drug Product with Therapeutic Equivalence Evaluations", as the same may be amended from time to time during the Term.

"*Third Party*" means any entity other than: (a) BDSI, (b) Collegium, or (c) an Affiliate of BDSI or Collegium.

"*Third Party Claim*" shall have the meaning set forth in Section 7.05.

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"*Third Party IP Costs*" shall have the meaning set forth in Section 4.01(e)(i).

"*Third Party License*" shall have the meaning set forth in Section 4.01(e)(i).

"*Third Party Offer*" shall have the meaning set forth in Section 11.10(e).

"*Third Party Royalties*" shall have the meaning set forth in Section 4.01(e)(i).

"*TIRF*" shall have the meaning set forth in Section 6.01.

"*TIRF Fees*" shall have the meaning set forth in Section 6.01

"*Valid Claim*" means a claim of any pending Patent application or issued and unexpired Patent that has not been disclaimed, revoked, held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through re-examination, re-issue, disclaimer or otherwise, or lost in an interference proceeding; provided, however, that a pending claim of a pending Patent application shall only be considered a Valid Claim if it (a) continues to be prosecuted in good faith during the Term, (b) has not been abandoned or finally rejected without the possibility of appeal or refiling, and (c) has not been pending for more than *** from the date of issuance of the first substantive patent office action considering the patentability of such claim by the applicable patent office in such country (at which time such pending claim shall cease to be a Valid Claim for purposes of this Agreement unless and until such claim becomes a claim of an issued Patent which is a Licensed Patent).

Section 1.02 ***Interpretation***. The Section headings contained in this Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Agreement. Except where the context clearly requires to the contrary: (a) each reference in this Agreement to a designated "Section" or "Exhibit" is to the corresponding Section or Exhibit of or to this Agreement; (b) instances of gender or entity-specific usage (e.g., "his" "her" "its" "person" or "individual") shall not be interpreted to preclude the application of any provision of this Agreement to any individual or entity; (c) "including" shall mean "including, without limitation"; (d) references to Applicable Laws shall mean such Applicable Laws in effect during the Term (taking into account any amendments thereto effective at such time without regard to whether such amendments were enacted or adopted after the Effective Date); (e) references to "$" or "dollars" shall mean the lawful currency of the United States; (f) references to "Federal" or "federal" shall be to laws, agencies or other attributes of the United States (and not to any State or locality thereof); (g) the meaning of the terms "domestic" and "foreign" shall be determined by reference to the United States; (h) references to "days" shall mean calendar days; (i) references to months or years shall be to the actual calendar months or years at issue (taking into account the actual number of days in any such month or year); and (j) days, business days and times of day shall be determined by reference to Raleigh, North Carolina.

ARTICLE II

DEVELOPMENT; FINAL APPROVAL; TRANSFER OF MANUFACTURING

Section 2.01 ***BDSI Development***. BDSI shall use Commercially Reasonable Efforts to obtain Supplement Approval as soon as reasonably possible following the Effective Date and, in any event, BDSI shall use Commercially Reasonable Efforts to make the supplemental filing contemplated by the definition of "Supplement Approval" to the FDA by December 31, 2016 (such filing, the "*Supplement*"). BDSI shall notify Collegium within *** business days following its receipt of an official written approval of the Supplement from the FDA (such notice, "*Supplement Approval Notice*"). BDSI acknowledges and agrees that, except to the extent such costs and expenses are incurred in connection with the performance of activities which are expressly set forth in the Mfg Transfer Plan, BDSI shall be responsible for all costs and expenses it incurs in connection with its performance of its obligations under this Section 2.01.

Section 2.02 ***Collegium Development***. Collegium shall use Commercially Reasonable Efforts to comply with and, upon Supplement Approval, maintain all Governmental Approvals in the Territory, including but not limited to the

Current Product NDA, and, subject to the remainder of this Section 2.02, Develop Licensed Products in the Territory. BDSI will have the right to review and comment, and have such comments reasonably considered by Collegium, reasonably in advance with regard to all Development-, manufacturing-, and formulation-related activities (including Phase IV Studies) proposed to be conducted by or on behalf of Collegium in regards to any Licensed Product. In addition, Collegium shall not, without BDSI's consent, Develop, Commercialize, or otherwise undertake any dosage-, manufacturing-, or formulation-related changes to the Current Product or any other Licensed Product that would, as reasonably determined by BDSI in good faith, have a material likelihood of adversely affecting BDSI's, its Affiliates', or its or their licensees' or sublicensees' development or commercialization of (a) BEMA Fentanyl Products or Competing Products outside the U.S., (b) any other BEMA-based Products outside the U.S., or (c) any BEMA-based Products, other than BEMA Fentanyl Products or Competing Products, in the U.S., provided that, notwithstanding the foregoing, BDSI's prior written consent shall not be required under this Section 2.02 for those activities specifically described on Exhibit C; and, provided, further, that if BDSI does not notify Collegium in writing of its determination of a material likelihood of adverse effect as described above in respect of any dosage-, manufacturing-, or formulation-related changes to the Current Product or any other Licensed Product proposed by Collegium in accordance with this Section 2.02 within *** days after BDSI's receipt of such proposal, then BDSI will be deemed to have waived its consent right with regards to the specific changes described in Collegium's proposal and Collegium will be free to engage in those activities without the need to seek further consent from BDSI hereunder.

Section 2.03 ***Regulatory Submissions***. At all times, the Party preparing, filing, and/or maintaining applications for Governmental Approval, or any supplements thereto, in the Territory shall (a) inform the other Party of all material communications with the relevant Competent Authority(ies) in the Territory concerning the Licensed Product and (b) provide copies of proposed material submissions to the relevant Competent Authority(ies) in the Territory concerning the Licensed Product to the other Party prior to their submission to such Competent Authority. To the extent either Party receives material written or material oral communication from the FDA relating to any Governmental Approval or related process in the Territory with respect to any Licensed Product, the Party receiving such communication shall promptly notify the other Party and provide a copy of any written communication as soon as reasonably practicable. In addition, prior to Supplement Approval, Collegium will have a reasonable right, but not the obligation, to participate in or review and comment on, as applicable, any and all filings, meetings, responses, submissions, communications and other interactions between BDSI or any of its Affiliates and the FDA in regards to the Supplement and/or the Current Product generally, including in regards to the Supplement Approval, provided that Collegium shall not (and shall ensure that its representatives participating in any such meetings with the FDA do not) make any statements or take any actions in connection therewith that it knows or reasonably should know will have a material likelihood of adversely affecting BDSI's efforts to obtain Supplemental Approval or the regulatory status of the Current Product.

Except as expressly set forth in the Mfg Transfer Plan, each Party will be responsible for its own costs and expenses incurred in connection with its performance of the activities set forth in this Section 2.03.

Section 2.04 ***Reporting***. ***, BDSI shall provide Collegium with summary updates regarding the progress of its activities with respect to its obligations under this Article II. Within *** after ***, Collegium shall provide to BDSI a reasonably detailed written report consisting of (a) an update on the progress of Collegium's, its Affiliates', and Sublicensees' Development and Commercialization activities, including (i) key achievements or milestones to date in the reporting period, and (ii) any clinical studies that are planned, were run or completed, or are in process and (b) a summary of the planned Development and Commercialization activities for the upcoming ***, such as anticipated commercial launches in the Territory and other commercial milestones, and, upon BDSI's request, BDSI shall have a reasonable opportunity to discuss any of the foregoing with Collegium. Without limiting the foregoing and in conformity with standard pharmaceutical industry practices and the terms and conditions of this Agreement, Collegium shall maintain complete and accurate written records of its Development and Commercialization of the Licensed Products for a minimum of *** following the end of the Calendar Year to which they pertain, which records may be subject to audit and inspection by BDSI pursuant to Section 14.11.

Section 2.05 ***Ownership of Regulatory and Clinical Documentation***. Subject to the terms of this Agreement, and without affecting ownership or title to any BDSI Know-How contained or referenced therein, BDSI shall, promptly following receipt of Supplement Approval of the Current Product, assign to Collegium all of BDSI's rights in and to the Current Product NDA, Governmental Approvals and all other Regulatory Filings related thereto in the Territory

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and transfer to Collegium a copy of BDSI's safety database concerning the Licensed Product in the Territory. The Parties acknowledge and agree that, except as set forth in Sections 2.06 and 9.15, Collegium is not, by virtue of its receipt of the Current Product NDA from BDSI, assuming any responsibility or liability for any costs, debts, expenses, commitments, agreements, obligations or other liabilities of any nature whatsoever of BDSI, whether known or unknown, accrued or not accrued, to the extent incurred or arising as a direct result of any actions or omissions by or on behalf of BDSI in regards to any Licensed Products or Licensed Technology in the Territory prior to the NDA Assignment, including any liability with respect to any actual or alleged injury to persons relating to the Licensed Products actually or allegedly caused by BDSI or its agents in the Territory prior to the NDA Assignment, all of which are retained by BDSI.

Section 2.06 ***Transfer of Commercial Manufacturing to ****. BDSI shall use Commercially Reasonable Efforts in good faith to (a) transfer the commercial manufacture of Current Product to *** pursuant to the plan attached hereto as Exhibit D (the "*Mfg Transfer Plan*") and, as soon as reasonably possible following the Effective Date, (b) negotiate and enter into a commercial supply agreement with *** for the supply of Current Products for sale in the Territory (the "*** *Agreement*"), provided that BDSI shall reasonably consult with Collegium in the negotiation of such agreement and BDSI will not execute such an agreement unless approved in writing by Collegium, such approval not to be unreasonably withheld. Collegium will reimburse BDSI for any of BDSI's reasonable, documented out-of-pocket costs and expenses (including any amounts due or payable to any Third Party contractor, including ***) incurred in connection with the performance of the Mfg Transfer Plan, up to a maximum aggregate amount of $2,000,000, within *** days of Collegium's receipt of any invoice with respect to any such reasonably documented out-of-pocket costs and expenses (including any amounts due or payable to any Third Party contractor, including ***), provided that Collegium acknowledges and agrees that (i) BDSI may have performed some of the above-referenced activities described in the Mfg Transfer Plan prior to the Effective Date and, for purposes of clarification but not limitation, (ii) Collegium shall be obligated to reimburse BDSI for costs incurred with respect to any such activities in accordance with the foregoing, whether such activities occurred, or such costs were incurred, prior to, on, or after the Effective Date. BDSI acknowledges and agrees that it shall bear and be solely responsible for all costs and expenses it may incur in connection with its performance of any activities under the Mfg Transfer Plan which are in excess of the $2,000,000 aggregate cap, as well as any and all costs and expenses it may incur in connection with the negotiation of the *** Agreement, and that it may not assert or rely on the occurrence of any such additional costs or expenses (whether planned or unplanned) as a justification for suspending its negotiations of or failing to execute the *** Agreement. To the extent Collegium requests any changes to the Mfg Transfer Plan that cause the budget therefor to exceed the $2,000,000 aggregate cap, (i) BDSI shall provide Collegium with an updated budget therefor reasonably demonstrating such increase, (ii) the aggregate cap on expenses shall not be increased without Collegium's agreement thereto, and (iii) the Mfg Transfer Plan shall not be amended to reflect Collegium's requested changes unless BDSI agrees thereto and Collegium agrees to increase the cap on the cost of the Mfg Transfer Plan to the extent resulting from Collegium's requested changes to the Mfg Transfer Plan. BDSI shall assign the *** Agreement to Collegium as soon as reasonably possible following Supplement Approval and assignment to Collegium of the Current Product NDA, all Governmental Approvals and all other Regulatory Filings related thereto in the Territory. Following execution of the *** Agreement (but prior to its assignment to Collegium), BDSI shall not have any obligations to provide any forecasts or orders to ***, or enter into any other financial commitments under the *** Agreement, except to the extent requested in writing in a timely fashion by Collegium, and Collegium shall reimburse BDSI, within *** of Collegium's receipt of an invoice, for any costs, expenses, or other financial liabilities incurred by BDSI as a direct result of complying with any such request by Collegium (i.e., submitting any such forecast or order or incurring any other financial commitment requested by Collegium).

ARTICLE III

LICENSES; IMPROVEMENTS

Section 3.01 ***License Fee***. In partial consideration for the licenses granted under Section 3.02(a), Collegium shall pay to BDSI an initial one-time non-refundable license fee of $2,500,000, by wire transfer of immediately available funds to an account to be designated by BDSI. Collegium shall pay such license fee within *** of the Effective Date.

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

Section 3.02 ***Licensed Technology.*** The terms and conditions of the license granted to Collegium shall be as follows:

(a) Subject to the terms and conditions of this Agreement, BDSI hereby grants to Collegium an exclusive (subject to the last sentence of this Section 3.02(a)), royalty-bearing, license under the Licensed Technology to make, have made, use, sell, offer for sale, import, Develop, and Commercialize the Licensed Product(s) in the Territory, which license shall be sublicensable as set forth in the second paragraph of this clause (a). Notwithstanding anything to the contrary (including but not limited to the exclusivity of the rights granted above or below), BDSI retains, on behalf of it, its Affiliates, and its or their contractors, licensees, or sublicensees, sublicensable rights, transferable in accordance with Section 14.01, under the Licensed Technology and Licensed Marks to (i) perform BDSI's obligations under Sections 2.01 and 2.06 and such other obligations as are necessary to reflect BDSI's status as the holder of the Current Product NDA, but only during the period from the Effective Date until the NDA Assignment, and (ii) research, develop, manufacture, have manufactured, use, or import BEMA Fentanyl Products, Competing Products, or Demonstration Samples in the Territory but solely for purposes of export, distribution, use, development, or commercialization thereof outside the Territory; provided, however, that neither BDSI nor any of its Affiliates', or any of its or their Third Party licensees', sublicensees', or contractors' may conduct any human clinical trials for any BEMA Fentanyl Product in the Territory without Collegium's prior written consent. For clarity, BDSI's or its Affiliates' purchase of BEMA Fentanyl Products, Competing Products, or Demonstration Samples in the Territory and its or their subsequent sale and export of such BEMA Fentanyl Products, Competing Products, or Demonstration Samples to BDSI's Affiliates or Third Parties located outside of the Territory for purposes of enabling the sale and/or use of such products outside the Territory are included within the scope of BDSI's retained rights set forth in clause (ii) above.

Collegium shall have the right to sublicense any rights granted to it under this clause (a) or Section 3.03(a) within the Territory, *provided* that (i) except in respect of sublicenses to Affiliates or to any of the other entities referenced in clauses (B) or (C) below, Collegium shall provide BDSI with a copy of any executed sublicense agreement, (ii) except with respect to sublicenses granted (A) to Collegium's Affiliates, (B) to Third Party contractors for purposes of manufacturing Licensed Products for use or sale in the Territory or performing Development on Collegium's or its Affiliates' behalf and limited to rights to use, make, have made, or import Licensed Products, or (C) to Third Party contract sales organizations for the sole purposes of promoting and marketing Licensed Products on behalf, and at the direction, of Collegium or an Affiliate thereof in cases in which Collegium or an Affiliate thereof (and not such Third Party) remains holder of the NDA and books all sales of Licensed Products, Collegium shall not enter into any such sublicense unless consented to in writing by BDSI, such consent not to be unreasonably withheld, conditioned or delayed (iii) Collegium shall secure all reasonably appropriate covenants, obligations and rights from each Sublicensee to ensure that Collegium can comply with its obligations under this Agreement, (iv) Collegium shall be responsible and liable for each Sublicensee's performance of Collegium's obligations hereunder and compliance with the terms of this Agreement, (v) all Sublicensees shall agree to be subject to the terms of this Agreement, and (vi) all sublicenses shall terminate upon the termination of this Agreement. The copy of any executed sublicense agreement provided by Collegium to BDSI pursuant to this paragraph may be redacted as determined by Collegium, in good faith, to be necessary to protect any of its or its Sublicensee's confidential or proprietary information unrelated to Collegium's compliance with its obligations to BDSI hereunder.

(b) Collegium acknowledges that it shall have no right, title or interest in or to the Licensed Technology, Licensed Products, or Licensed Marks except to the extent set forth in this Agreement, and BDSI reserves all rights to make, have made, use, sell, offer for sale, and import the Licensed Technology and Licensed Products except as otherwise expressly granted to Collegium pursuant to this Agreement. Nothing in this Agreement shall be construed to grant Collegium any rights or license to any intellectual property of BDSI or any Affiliate thereof other than as expressly set forth herein and nothing in this Agreement shall be construed to grant BDSI any rights or license to any intellectual property of Collegium or any Affiliate thereof other than as expressly set forth herein.

(c) All Affiliates of Collegium which (i) are involved or otherwise engaged in carrying out any of Collegium's activities, performing any of Collegium's obligations or exercising any of Collegium's rights under this Agreement, (ii) are granted any rights under this Agreement by Collegium or any other Affiliate thereof, (iii) have access to, or know or use, BDSI's Confidential Information, BEMA, or any Licensed Product, or (iv) did not become Affiliates of Collegium as a direct result of any transaction by which any Third Party first became an Acquiring Entity of Collegium (any such Affiliates, "Collegium Affiliates"), shall be subject to the terms of this Agreement. Collegium

shall be fully responsible and liable for the acts and omissions of Collegium Affiliates in the course of exercising any rights granted, or performing any obligations of Collegium, under this Agreement as if such acts or omissions had been those of Collegium, including but not limited to any breach of the provisions of this Agreement in connection therewith, and Collegium shall ensure that (i) all Collegium Affiliates shall comply with the terms of this Agreement and (ii) no Affiliates other than Collegium Affiliates obtain access to, or know or use, BDSI's Confidential Information, BEMA, or any Licensed Product.

Section 3.03 ***Licensed Marks***.

(a) ***License.*** Subject to the terms and conditions of this Agreement, BDSI hereby grants to Collegium an exclusive, paid-up, sub-licensable (subject to the constraints on sublicensing described in Section 3.02 above), royalty-free license in the Territory to use the Licensed Marks during the Term solely in connection with the Development, manufacture, and Commercialization of the Licensed Products in the Territory. Collegium acknowledges that it shall have no right, title or interest in or to the Licensed Marks except to the extent set forth in the license granted to Collegium under this Section 3.03, and BDSI reserves all rights to use the Licensed Marks other than those rights granted herein. Notwithstanding anything to the contrary, Collegium shall be entitled to use any trademark other than the Licensed Marks, together with the Licensed Marks or otherwise, in connection with the use, development, promotion, marketing, distribution, offer for sale, and sale of the Licensed Products in the Territory.

(b) ***Use of Licensed Marks.*** Collegium shall comply with all Applicable Laws pertaining to the proper use and designation of the Licensed Marks. Additionally, Collegium shall:

(i) ensure that the Licensed Marks are accompanied by words accurately describing the nature of the goods or services to which it relates and that the Licensed Marks are displayed as set forth in Exhibit E;

(ii) to the extent reasonably practicable after receipt of a written request from BDSI, comply with the reasonable requirements of BDSI as to the form, manner, scale and context of use of the Licensed Marks, the use of the statements to accompany them, as well as the appearance of the Licensed Marks on containers, packaging and related marketing and promotional materials to be used for Licensed Product;

(iii) display the proper form of trademark and service mark notice associated with each Licensed Mark in accordance with instructions received from BDSI;

(iv) include, on any item which bears a Licensed Mark, a statement identifying BDSI as the owner of such Licensed Mark and stating that Collegium is an authorized user of such Licensed Mark;

(v) not conduct, without the written consent of BDSI, the whole or any part of its business under a business name or trading style which incorporates any of the Licensed Marks;

(vi) neither use nor display any of the Licensed Marks in such relation to any other mark or marks owned by any Third Party, Collegium, or an Affiliate of Collegium as to suggest that the multiple marks constitute a single or composite trademark, service mark, or are under the same proprietorship; and

(vii) ensure the Licensed Marks are only used with Licensed Products that are made, used, and sold in compliance with Applicable Laws, Governmental Approvals therefor, and Collegium's quality standards with respect to their pharmaceutical products generally.

(c) ***Additional Terms.*** Collegium shall not take any action inconsistent with BDSI's ownership of the Licensed Marks. Any benefits (including goodwill) accruing from Collegium's use of the Licensed Marks shall automatically vest in BDSI. Collegium shall not form any combination trademarks or trade names with the Licensed Marks. Collegium shall grant BDSI reasonable access to Collegium's and its Affiliates' facilities, records, packaging and promotional materials for the purpose of inspecting the use of the Licensed Marks pursuant to this Agreement.

(d) ***Termination of License.*** BDSI shall be entitled to terminate the rights to Licensed Marks granted above on written notice to Collegium if Collegium does not use the Licensed Marks with respect to the Licensed Product for any consecutive period of twelve (12) months or more.

Section 3.04 ***Limitations Prior to NDA Assignment***. Collegium shall ensure that neither Collegium, any Affiliate thereof, nor any Third Party acting on behalf of either of the foregoing shall engage in any activity with respect to

Licensed Products prior to NDA Assignment except as permitted by this Agreement and except as may be performed in accordance with Applicable Law by a party that does not hold the NDA for any Licensed Products, provided that Collegium shall provide BDSI with prior written notice describing in reasonable detail any proposed such activity and, unless (x) BDSI reasonably determines in good faith that such proposed activity has a material likelihood of adversely effecting (i) BDSI's efforts to obtain Supplement Approval, (ii) the status of the Current NDA, or (iii) the Commercialization of Licensed Products in the Territory and (y) BDSI provides notice of such determination to Collegium within *** of BDSI's receipt of the above-referenced notice from Collegium describing such proposed activity, Collegium shall be free to engage in such activity, subject to the terms of this Agreement.

Section 3.05 ***Ownership of Improvements***. Each Party will own all right, title and interest in and to any Improvements conceived, developed, invented or otherwise generated solely by such Party, its Affiliates, and all intellectual property rights related thereto (such Improvements and intellectual property rights related thereto (other than Collegium BEMA Improvements and all intellectual property rights related thereto) to be owned solely by Collegium or any Affiliate thereof pursuant to the foregoing, "*Collegium Improvements*"), and the Parties shall jointly own all right, title, and interest in and to any Improvements conceived, developed, invented or otherwise generated jointly by (a) BDSI, any Affiliate thereof, or any officer, director, employee, agent, or other representative of either of the foregoing and (b) Collegium, any Affiliate thereof, or any officer, director, employee, agent, or other representative of either of the foregoing, and all intellectual property rights related thereto (such Improvements and intellectual property rights to be owned jointly by the Parties pursuant to the foregoing, "*Joint Improvements*"), provided that, notwithstanding anything to the contrary, Parent shall own, and Collegium shall assign and hereby assigns to Parent, all of Collegium's and Collegium Affiliates' right, title, and interest in and to any Collegium BEMA Improvements and all intellectual property rights related thereto, free and clear of all security interests and similar liens. Collegium shall ensure that that its Affiliates assign any and all of their rights, including all intellectual property rights, in any Collegium BEMA Improvements to Collegium and Collegium shall use, and ensure that its Affiliates use, Commercially Reasonable Efforts to cause their respective Sublicensees to assign or exclusively license any and all rights they may have in any Collegium BEMA Improvements (and any Know-How with respect thereto and/or Patents Covering such Collegium BEMA Improvements) to Collegium and, in the case that such rights are licensed (rather than assigned) to Collegium or any of its Affiliates, that those rights be freely sublicensable by Collegium or its Affiliate, as applicable, to BDSI pursuant to Section 3.06. Except as expressly provided in this Agreement and subject to any restrictions herein, each joint owner of a Joint Improvement may make, sell, use, license, assign, mortgage or keep Joint Improvements, and otherwise undertake all activities a sole owner might undertake with respect to such inventions, discoveries and know-how, without the consent of and without accounting to the other joint owner, provided that any assignment, license or other disposition or use (i) shall at all times be and remain subject to the grants of rights and licenses and accompanying conditions and obligations with respect thereto under this Agreement, including under Section 3.02(a) and Section 13.06(a) and (ii) allow the Parties to exercise their rights and perform their obligations under this Agreement, in particular to develop, manufacture, and commercialize Licensed Products or BEMA Fentanyl Products in at least the same scope as prior to such assignment, license or other such disposition. Each Party shall take all actions and execute all documents necessary to effect the purposes of the foregoing, as requested by the other Party, and cause its respective Affiliates, and its and their officers, directors, employees, agents, representatives, contractors, and other representatives to do the same. During the Term, each Party shall promptly notify the other Party in writing and in reasonable detail of any Improvements generated or Controlled by such Party or any Affiliate thereof to which the other Party has any rights under this Agreement.

Section 3.06 ***Licenses to BDSI.*** Collegium hereby grants to BDSI (I) a non-exclusive, royalty-free, fully-paid, transferable, freely sublicensable, worldwide, perpetual, irrevocable license and right of reference, transferable in accordance with Section 14.01, (X) under the Collegium Documentation, Governmental Approvals, Regulatory Filings, and, to the extent contained or referenced in any of the foregoing, Collegium Know-How to (i) make, have made, use, sell, offer for sale, import, research, develop, and commercialize any BEMA-based Products other than BEMA Fentanyl Products and (Y) under the Collegium Product-Specific Improvements (and any directly related Collegium Know-How and Collegium Patents), Collegium Documentation, Governmental Approvals, Regulatory Filings, and, to the extent contained or referenced in any of the foregoing, Collegium Know-How to (1) make, have made, use, import, research, and develop BEMA Fentanyl Products and Demonstration Samples and (2) sell, offer for sale, and otherwise commercialize BEMA Fentanyl Products and Demonstration Samples outside the Territory and, upon termination of this Agreement, inside the Territory, and, subject to the rights granted to Collegium under Section 3.02(a), (II) a royalty-free, fully-paid, transferable, freely sublicensable, worldwide, perpetual, irrevocable,

exclusive license, transferable in accordance with Section 14.01, under all Controlled Collegium BEMA Improvements, any Know-How with respect thereto, and/or any Patents Covering such Collegium BEMA Improvements to the extent, in each case, Controlled by Collegium or an Affiliate thereof to make, have made, use, sell, offer for sale, and import any product, method, process, or service. Collegium shall, upon reasonable request of BDSI, promptly provide BDSI with copies of any Collegium Documentation, Collegium Know-How, Collegium Patents, or Patents Covering any Collegium Product-Specific Improvements or Controlled Collegium BEMA Improvements (and any Know-How with respect thereto and/or Patents Covering such Collegium BEMA Improvements) to the extent not previously provided to BDSI and BDSI has been granted rights thereto pursuant to this Agreement.

ARTICLE IV

ROYALTY AND MILESTONE PAYMENTS

Section 4.01 ***Payments on Sales***.

(a) Except as otherwise set forth in this Agreement, Collegium will make quarterly royalty payments to BDSI equaling the applicable percentage of Annual Net Sales set forth below. Such royalty payments shall be calculated based on Annual Net Sales of all Licensed Products by applying the tiered royalty rate shown below:

Annual Net Sales	**Royalty**
Annual Net Sales up to and including $***	***%
Annual Net Sales over $***	***%

For example, if, during a Calendar Year, Annual Net Sales of Licensed Products were equal to $***, then the royalties payable for such Calendar Year would be calculated by adding (a) the royalties with respect to the first $*** at *** percent (***%) [***] and (b) the royalties with respect to the next ***, for a total royalty of $***.

(b) Upon ***, the royalty rate ***, provided that, ***.

(c) If, for any full Calendar Year that begins following ***. If Collegium reasonably determines in good faith ***. If Collegium does not ***.

(d) Collegium's payment obligations under this Section 4.01 shall in any event expire, on a Licensed Product-by-Licensed Product basis, on the expiration of each Licensed Product's Royalty Term, provided that, notwithstanding anything to the contrary, if (A) all Valid Claims of the Licensed Patents in the Territory Covering a particular Licensed Product have expired, (B) no commercial sale by a Third Party in the Territory of a Generic Product with respect to such Licensed Product has occurred, and (C) a Licensed Patent that contains one or more Valid Claims Covering such Licensed Product issues in the Territory and is published in the Orange Book prior to the end of the applicable Royalty Term, the royalties set forth in Section 4.01 shall be payable with respect to all Net Sales of such Licensed Product occurring on or after the date of such publication until all Valid Claims of the Licensed Patents in the Territory Covering a particular Licensed Product have again expired, at which point the adjustments set forth in Sections 4.01(b) and/or 4.01(c) shall apply as set forth therein.

(e) Payment for Third Party Licenses and Defense/Enforcement Costs.

(i) If, following the Effective Date, it is necessary for Collegium to license one or more Patents in the Territory from one or more Third Parties in order to Commercialize any Licensed Product in the Territory, *** will have the right to, and may, in its sole discretion, negotiate and obtain a license under such Patents with respect to Licensed Products (each such Third Party license is referred to herein as a "*Third Party License*"). A license to Third Party Patents will be deemed "necessary" under this Section 4.01(e)(i) (A) if ***. Except as set forth in clause (ii) below, Collegium shall bear (x) any payments associated with such Third Party License, including any sales-based running royalties on sales of Licensed Products that may be owed to any Third Party for such a Third Party License (collectively, such running royalties, the "*Third Party Royalties*"), (y) any Losses paid by Collegium to a Third

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Party with respect to any Claim for which Collegium is obligated to indemnify, defend, and hold harmless pursuant to clause (I)(d) of the first sentence of Section 10.02 to the extent such Losses (or the associated Claim) are not the direct result of any Collegium Change(s), and (z) any damages, liabilities, expenses and/or losses paid by Collegium, other than those Losses described in the preceding clause (y), with respect to any suits, claims, proceedings or causes of action by Third Parties made with respect to Collegium's, its Affiliates', Sublicensees', or any of Collegium's, its Affiliates', or Sublicensees' directors', officers', employees', agents', or other representatives' infringement or misappropriation of any Third Party's Patent or other intellectual property rights in the manufacture, use, sale, offer for sale, Development, Commercialization, import, or export of any Licensed Product(s) in the Territory to the extent any such suits, claims, proceedings or causes of action or associated damages, liabilities, expenses and/or losses are not the direct result of any Collegium Change(s) (collectively, Third Party Royalties, such Losses, and such damages, liabilities, expenses and/or losses, "Third Party IP Costs").

(ii) If Collegium undertakes to defend any of the Fentanyl-Specific Patents against any Third Party challenge to the validity, enforceability, or scope thereof under Section 7.01 and/or to enforce any of the Fentanyl-Specific Patents against any Third Party infringer thereof under Section 7.03(b) and, in either case, prevails in such defense or enforcement as determined by final decision of a court or other Governmental Authority of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, then the amount by which the reasonable, documented out-of-pocket costs and expenses (including attorneys' fees) Collegium incurs in connection with such activities exceed any damages, monetary awards, or other amounts recovered or received in settlement by Collegium or any Affiliate thereof with respect to such defense, enforcement, or voluntary disposition or settlement thereof ("*Defense/Enforcement Costs*") shall ***, Collegium shall, without limitation of any reimbursement obligations for the benefit of BDSI under Article VII, not be entitled to take into account such Defense/Enforcement Costs that have been offset when calculating the Parties' split of any damages, monetary awards, or other amounts recovered or received in settlement by Collegium with respect to the defense, enforcement, or voluntary disposition or settlement of such action.

(iii) Collegium may ***, provided that ***.

Section 4.02 ***Milestone Payments***. Collegium shall pay to BDSI, as additional license fees, the following non-refundable, non-creditable milestone payments upon the occurrence of the specified milestone event:

(a) $4,000,000 upon First Commercial Sale of any Licensed Product;

(b) $*** upon the publication in the Orange Book of a Patent that issues from (i) ***, (ii) ***, or (iii) any continuation application claiming priority to either of the foregoing Patent applications or any other application or patent within the priority claim of those applications and the subject of which claims the Current Product and/or the use of fentanyl, provided, however, that ***; and, provided further, that ***;

(c) $*** when Annual Net Sales first exceed $***

(d) $*** when Annual Net Sales first exceed $***; and

(e) $*** when Annual Net Sales first exceed $***.

For the avoidance of doubt, each milestone payment referred to in this Section 4.02 shall be paid only once by Collegium, the first time the relevant milestone is achieved. Collegium shall provide BDSI written notice of the achievement of milestone specified in clause (a) above, and Collegium shall pay BDSI the designated amount for such milestone, within *** of such achievement. BDSI shall provide Collegium written notice of the achievement of the milestone specified in clause (b) above, and Collegium shall pay BDSI the designated amount for such milestone within *** of its receipt of such notice. Collegium shall provide BDSI written notice of the achievement of each milestone specified in clauses (c), (d) and (e) above, and pay the indicated amount, within *** of the achievement of the relevant milestone.

Section 4.03 ***Reports and Payments***.

(a) Collegium, on behalf of itself and its Affiliates, shall, beginning with the initial Calendar Quarter during which the First Commercial Sale occurs, furnish to BDSI a quarterly written report (each, a "*Royalty Statement*") showing

in reasonably specific detail (i) Collegium's, its Affiliates', and Sublicensees' inventory on hand of each stock keeping unit ("*SKU*") of Licensed Products, sales of Licensed Products per SKU and Net Sales; (ii) amounts payable under this Agreement based upon such Net Sales (which shall include an accounting of all amounts and calculations required to determine Net Sales and the amounts payable under this Agreement consistent with Sections 4.01 and 4.02, including the amount of any bad debt or recovered bad debt used to calculate Net Sales pursuant to the Bad Debt Adjustment); (iii) withholding taxes, if any, required by law to be deducted with respect to any payments due BDSI under this Agreement; and (iv) the date of the First Commercial Sale of any Licensed Product in the Territory during the reporting period. Royalty Statements shall be due no later than *** following the close of each Calendar Quarter.

(b) All payments due BDSI under Section 4.01 with respect to a particular Calendar Quarter shall be due no later than *** following the end of each Calendar Quarter. All payments hereunder shall be payable in United States dollars. All payments owed under this Agreement shall be made by wire transfer to one or more bank accounts (which may each be the account of such Party, any Affiliate thereof, or any Third Party), in such allocation between such accounts, as shall be designated by the Party owed payment from time-to-time upon written notice, unless otherwise specified in writing by such Party, with any such designated account(s) and/or allocation(s) to remain effective with respect to payments owed to such Party until it provides written notice to the other Party setting forth any changes to such account(s) or allocation(s) for payment (in which case any changes specified in such notice shall become effective on the date specified therein).

(c) In the event that any payment due hereunder is not made when due, such payment shall accrue interest from the date due at a rate equal to the greater of (i) ***, or (ii) ***, or, if less, the maximum legally permissible interest rate, calculated based on the number of days such payments are paid after the date such payments are due. The payment of such interest shall not limit a Party from exercising any other rights it may have under this Agreement as a consequence of the lateness of any payment.

(d) During the Term and for a period of *** thereafter, or longer if and as required in order for Collegium to comply with Applicable Law, Collegium shall keep complete and accurate records in sufficient detail to permit BDSI to confirm the completeness and accuracy of (i) the information presented in each Royalty Statement and all payments due hereunder and (ii) the calculation of Net Sales. BDSI and any designee thereof (including but limited to Meda) shall have the right to audit and inspect such Books and Records pursuant to the terms of Section 14.11.

(e) All taxes levied on account of the payments accruing to a Party under this Agreement shall be paid by such Party for its own account, including taxes levied thereon as income to such Party. If provision is made in applicable law or regulation for withholding, such tax shall be deducted from the payment made by a Party (the "*Paying Party*") to the other Party (the "*Paid Party*") hereunder, shall be paid to the proper taxing authority by the Paying Party, and a receipt of payment of such tax shall be secured and promptly delivered to the Paid Party. Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under any double taxation or similar agreement or treaty from time to time in force or in otherwise seeking the return, refund, or credit of any such withheld amount as applicable.

ARTICLE V

COMMERCIALIZATION

Section 5.01 ***Promotion and Marketing Obligations***.

(a) Collegium shall use Commercially Reasonable Efforts to cause the First Commercial Sale of the Current Product to occur within ***, and Collegium shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Territory. As between the Parties, Collegium, at its own expense, will be responsible for all of its Commercialization activities related to the Licensed Products in the Territory.

(b) In the event Collegium sublicenses any of its rights under this Agreement, the activities of Sublicensees may apply to the satisfaction of Collegium's obligations under this Article V, provided, that, subject to the foregoing,

Collegium's obligations under this Agreement shall not be reduced or otherwise affected by any sublicensing by Collegium of its rights under this Agreement.

(c) Upon the request of BDSI, but in no event ***, Collegium shall provide to BDSI in writing its then-current proposed marketing, sales and distribution plan for the Licensed Products, including a high-level summary Collegium's, its Affiliates', and Sublicensees' proposed marketing, sales and distribution strategy and tactics for the sale and distribution of the Licensed Products in the Territory during the following Calendar Year.

Section 5.02 ***Publicity***. BDSI and Collegium will use Commercially Reasonable Efforts to collaborate to create a public relations campaign with respect to the relationship established under this Agreement reasonably intended to maximize shareholder value for both Parties, which may include the issuance of mutually agreeable press releases concerning the following in the Territory (to the extent permitted under Applicable Laws and stock exchange rules): (a) deal closure, (b) data transfer, (c) FDA submissions concerning any Licensed Product, (d) Governmental Approvals of any Licensed Product, (e) First Commercial Sale of each Licensed Product in the Territory, (f) key data from publications of Phase IV Studies concerning any Licensed Product in the Territory, (g) submission and Governmental Approval of additional indications for any Licensed Product in the Territory, (h) payment of any milestone to BDSI hereunder, and (i) other events in the Territory as agreed by both Parties. The Parties shall reasonably cooperate on all of the aforementioned activities which they agree to collaborate on as needed.

ARTICLE VI

REGULATORY COMPLIANCE

Section 6.01 ***Marketing Authorization Holder***. Subject to Collegium's obligations upon termination pursuant to Section 13.06, Collegium shall, upon assignment of the Current Product NDA to Collegium following Supplement Approval, be the holder and owner of all Marketing Authorizations and Governmental Approvals in the Territory concerning Licensed Products and responsible for all associated legal obligations with respect thereto, including but not limited to the performance of all obligations with respect to Licensed Products under the Transmucosal Immediate Release Fentanyl ("*TIRF*") Risk Evaluation and Mitigation Strategy ("*REMS*") program established by FDA. Collegium acknowledges and agrees that such responsibilities under such TIRF REMS program shall include appointing a Collegium representative on the relevant TIRF REMS working group established by the FDA or otherwise associated with such program and paying its portion of all fees, costs, and expenses imposed on, or incurred as, members of such group or otherwise imposed by FDA with respect to such program or group ("*TIRF Fees*"), and Collegium further agrees that it shall promptly reimburse BDSI for the portion of any TIRF Fees paid by BDSI after the Effective Date which correspond to any period of time during which Collegium is the holder of the Current Product NDA.

Section 6.02 ***Maintenance of Marketing Authorizations***. With respect to the Licensed Products, upon assignment of the Current Product NDA to Collegium ("*NDA Assignment*"), Collegium agrees, at its sole cost and expense, to maintain all Marketing Authorizations and Governmental Approvals in the Territory throughout the Term, including submitting any supplemental applications, annual reports, variations or renewals thereof that are required by Applicable Law to be obtained in order to maintain the Marketing Authorizations and Governmental Approvals.

Section 6.03 ***Interaction with Competent Authorities***. After the Effective Date, each Party shall provide to the other Party a copy of any material correspondence or materials that it receives from a Competent Authority regarding any Licensed Product. Such correspondence or summary shall be provided within *** of receipt thereof by the relevant Party. BDSI shall be provided reasonable advance written notice of all material meetings, conferences, or calls with Competent Authorities in the Territory concerning any Licensed Product and BDSI shall be permitted to have one regulatory representative attend all such meetings, conferences, or calls that could reasonably be anticipated to materially concern issues that are related or relevant to BEMA generally or any BEMA-based Products other than Licensed Products. With respect to any Licensed Product, Collegium shall provide BDSI with copies of any materials relating to any material regulatory matter in the Territory and, when reasonably practicable, shall provide copies of any documents to be presented to any Competent Authority in respect of such matters prior to their presentation thereto, so that BDSI, if practicable, shall have an opportunity to review in advance. The materials

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

provided to BDSI under this Article VI with respect to material interactions with any Competent Authority will be considered Collegium's Confidential Information.

Section 6.04 ***ADE Reporting and Phase IV Surveillance***.

(a) ***General.*** Upon NDA Assignment, Collegium shall, at its sole cost and expense, be responsible for all post-Governmental Approval reporting of ADEs and surveillance of Phase IV Studies in the Territory, if and as required by Competent Authorities. All correspondence and communication will be in English. The Party sending the communication will translate as necessary. Collegium shall provide BDSI with (i) a copy of all safety-related correspondence with any Competent Authority within *** of its receipt or submission and (ii) any other information concerning any ADE, AE, or ADR concerning any Licensed Product coming into Collegium's or any of its Affiliates' knowledge or possession that Collegium believes or is informed by BDSI to be reasonably necessary to enable BDSI, any Affiliate thereof, or any licensee or sublicensee of any of the foregoing to comply with any applicable legal or regulatory requirements of any jurisdiction outside the Territory with respect to any BEMA Fentanyl Product, on such time frame as is reasonably sufficient to enable such compliance in a timely manner.

(b) ***Safety Related Regulatory Documents.*** Upon NDA Assignment, Collegium will be responsible for (i) maintaining the company core safety information, as included in the company core data sheet, in the Territory and (ii) maintaining the company core safety information, as included in the package insert/prescribing information, in the Territory. Collegium will also be responsible for submission of any safety-related supplemental applications for changes to any package insert or other labeling.

(c) ***Safety Databases.*** Upon NDA Assignment, Collegium (or its agent) will maintain a pharmacovigilance database for each Licensed Product in the Territory (or each country thereof, if/as applicable). The database(s) will include all ADE reports from spontaneous sources, scientific literature, and PMS reports (serious) and SAE reports from clinical studies coming into the actual knowledge of Collegium, its Affiliates, or any Sublicensee (or any agent of the foregoing). Spontaneous cases will include reports received from both healthcare professionals and consumers. AE data will be coded to the latest version of MedDRA. Report handling and classifying will be carried out in accordance with Collegium's (or its agent's) SOPs (as defined below). All reasonable assistance and access requested by either Party in responding to safety inquiries will be provided upon request. Information in Collegium's safety databases will be used by Collegium to compile PSURs (as defined below) to the FDA (providing a waiver of the requirement to submit postmarketing periodic safety reports in the format described in the regulations has been granted) and other Competent Authorities in the Territory and prepare safety-related supplemental applications for changes in the package insert(s)/labelling for Licensed Products in the Territory.

(d) ***Reporting of Adverse Drug Reactions (ADRs)***

(i) The Parties shall keep each other informed on all safety matters related to the BEMA Fentanyl Products and on any information received from any source concerning any ADR coming to either Party's (or any of its Affiliates') actual knowledge with regard to the BEMA Fentanyl Products.

(ii) Each Party is responsible for fulfilling its reporting obligations to the appropriate Competent Authorities with respect to the BEMA Fentanyl Products in accordance with the applicable national laws and regulations of the different countries.

(iii) Independently of any national reporting requirements, the Parties hereto shall, in relation to the BEMA Fentanyl Products, report to each other all SAEs from clinical trials with a reasonable suspicion of causal relationship to the administered study medication and all serious spontaneously reported suspected ADRs within the ***, but not later than *** after having come to a Party's attention including a case description and medical causality assessment on the International Adverse Event Report Form ("*CIOMS Form*") in English. If required, follow up will be carried out by the Marketing Authorization holder on all SARs (listed and unlisted) and non-serious unlisted ADRs in the Territory according to its own internal procedures, which shall be commercially reasonable and consistent with industry standards. Upon assignment of the Current Product NDA to Collegium, non-serious listed ADRs in the Territory shall be followed up by Collegium if there is a safety concern; and pregnancy and *in utero* reports will be followed up by Collegium at the expected due date. Reasonable attempts shall be made by Collegium to obtain the required minimum information: identifiable patient, reporter, suspect drug, and AE.

(iv) Life-threatening or fatal SAEs originating from clinical trials in the Territory with a reasonable suspicion of causal relationship to the BEMA Fentanyl Products shall be reported by a Party to the other Party and, if and as required thereby, by the appropriate Party (as determined by Applicable Law) to appropriate Competent Authorities within ***, but not later than ***. In the case of incomplete or insufficient data available, an initial report has to be issued meeting the time frame, followed by reasonably prompt follow up report(s). Any ADRs originated by either Party are to be reported on CIOMS Form as soon as reasonably possible, but no later than *** days after first receipt. Collegium will report all other ADRs in tabular format ("*CIOMS Line Listings*") in monthly intervals.

(v) In any case where a change in the risk-benefit-ratio of the BEMA Fentanyl Products becomes evident or safety actions due to ADR seem to be necessary (e.g. change of the label, product information, special information/warnings to the medical profession, patients, or authorities, or Product Recall), the Parties hereto will inform each other without delay and use commercially reasonable efforts to harmonize further measures as appropriate. Such exchange of information is realized through direct contacts between the responsible departments. Therefore, both Parties undertake to inform each other on any change in the responsible persons, the address, telephone and fax-numbers in due time. If specific safety measures are to be taken with respect to any Licensed Products in the Territory following NDA Assignment, Collegium will ensure the implementation of such in the Territory within reasonable timeframes or according to regulatory obligations.

(vi) Regulatory inquiries related to safety concerns for the Licensed Products received by either Party will be promptly forwarded to the other Party. The Parties shall work in good faith to develop a mutually agreeable response with respect to any such inquiry in the Territory at least *** before the response is required. The aforementioned information shall be addressed to:

In case of BDSI:

***
BioDelivery Sciences International, Inc.
4131 Parklake Avenue, Suite #225
Raleigh, North Carolina 27612
Tel.: ***
Fax: 919-582-9051
Email: ***

In case of Collegium:

***
COLLEGIUM Pharmaceutical, Inc.
780 Dedham Street, Suite 800
Canton, MA 02021
Tel.: *** | Fax.: 781.828.4697
Mobile: ***
Main Tel.: 781.713.3699
***

(e) ***Literature for marketed products.*** Collegium will have the primary responsibility for reviewing the world-wide relevant scientific literature for any serious and non-serious unlisted ADRs related to the Licensed Products in the Territory according to Applicable Laws.

(f) ***Signal detection / Safety monitoring***. Collegium will perform signal detection concerning the Licensed Products according to its own internal documented practices (as outlined in SOPs/guidelines), which shall be commercially reasonable and consistent with industry standards. Any conclusion raised from the subsequent analysis revealing relevant safety concerns regarding the Licensed Products will be communicated to BDSI in due time or immediately if the conclusions affect the safety profile of the Licensed Products.

(g) ***Periodic reports.*** Upon NDA Assignment, Collegium will be responsible for preparing the periodic reports to be submitted to Competent Authorities in the Territory (Periodic Safety Update Reports ("*PSURs*"), Annual Safety Reports for clinical trials) in accordance with its own standard operating procedures ("*SOPs*"), which shall be commercially reasonable and consistent with industry standards, and Applicable Laws. BDSI will, on Collegium's

reasonable request provide Collegium with all data (e.g. CIOMS Line Listings for SAEs originating from BDSI's clinical trials) in its possession which may reasonably be required for regulatory report compilation in the Territory.

Section 6.05 ***Assistance***. Upon receipt of a written request, each Party shall provide reasonable assistance to the other Party, in connection with such Party's obligations pursuant to this Article VI, subject to prompt reimbursement of all of its pre-approved out-of-pocket costs by the requesting Party.

Section 6.06 ***Compliance***. Collegium and BDSI shall comply with all Applicable Laws in exercising their rights and performing their obligations under this Agreement, including the provision of information by Collegium and BDSI, to the extent in its possession, to each other necessary for BDSI and Collegium to comply with any mandatory reporting requirements. Each Party shall promptly notify the other Party of any comments, responses or notices received from, or inspections by, any applicable Competent Authorities, which relate to or may impact any BEMA Fentanyl Product or the manufacture of any BEMA Fentanyl Product or the sales and marketing of any BEMA Fentanyl Product, and shall promptly inform the other Party of any responses to such comments, responses, notices or inspections and the resolution of any issue raised by any Competent Authorities with respect to any BEMA Fentanyl Product.

Section 6.07 ***Safety/Pharmacoviligance Agreement(s).*** The Parties agree that, upon the written request of any Party or Meda, (i) they shall use Commercially Reasonable Efforts in good faith to negotiate and execute one or more customary and reasonable forms of safety data exchange agreements and/or pharmacovigilance agreements intended to enable the Parties and/or Meda to comply with their respective reporting, monitoring, and related obligations under Applicable Law, or applicable laws, rules, and regulations outside the Territory, with respect to BEMA Fentanyl Products and, if applicable, (ii) BDSI shall use Commercially Reasonable Efforts in good faith to cause Meda to negotiate and execute such agreement(s) pursuant to the terms of any applicable Meda Termination Agreement.

ARTICLE VII

PATENTS AND TRADEMARKS

Section 7.01 ***Maintenance of Licensed Patents and Licensed Marks***. BDSI shall control and, except as explicitly set forth in this Article VII, have full discretion in the preparation, filing, prosecution, maintenance, and defense of the Licensed Patents and Licensed Marks in the Territory, including any *ex parte* reexamination proceedings, *inter partes* review proceeding, post grant review proceeding, derivation proceeding, action for declaratory judgment, interference proceeding or other attack upon the validity, title or enforceability of any Licensed Patents in the Territory. Upon written request by BDSI, Collegium shall provide such assistance as may be necessary to enable BDSI to prosecute and obtain new patents related to any Licensed Improvements Controlled by BDSI, other than Joint Improvements, with the cost and expense of such assistance to be borne by BDSI. BDSI shall keep Collegium advised by forwarding to Collegium copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to the prosecution and maintenance of the Licensed Patents, and shall provide Collegium an opportunity to comment on any proposed responses, voluntary amendments, submissions, or other actions of any kind to be made with respect to Licensed Patents. In the event that BDSI desires to abandon any Licensed Patents and/or the Licensed Marks in the Territory, BDSI shall provide reasonable prior written notice to Collegium of its intention to abandon and a reasonable opportunity to discuss BDSI's rationale supporting such abandonment. In the event that BDSI decides to abandon any Licensed Patent in the Territory that contains Valid Claims that are specific to fentanyl and Cover any Licensed Product, but does not contain any Valid Claims that Cover any BEMA-based products incorporating any API other than fentanyl (such a Licensed Patent, a "*Fentanyl-Specific Patent*"), (a) BDSI shall provide prompt written notice of such decision to Collegium and (b) Collegium may elect by written notice to BDSI, given within *** days of the aforementioned notice from BDSI, continue the maintenance, defense or prosecution of such Fentanyl-Specific Patent at Collegium's expense, and Collegium shall be entitled to undertake such maintenance, defense, or prosecution if BDSI does not, within *** following such written election by Collegium, notify Collegium in writing that BDSI will instead continue the maintenance, defense or prosecution of such Fentanyl-Specific Patent. If BDSI does provide a subsequent notice to Collegium electing to retain control of such maintenance, defense or prosecution of a particular Licensed Patent, BDSI shall retain such control until such time as it later again elects to abandon such Licensed Patent, in which case the rights and

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obligations of the Parties with respect thereto hereunder shall again apply. In the event Collegium does actually assume maintenance, defense, and prosecution of a Fentanyl-Specific Patent pursuant to the foregoing, (i) the ownership of such Fentanyl-Specific Patent shall be retained by BDSI and (ii) Collegium will not be obligated to pay any royalties to BDSI in regards to any Licensed Product that is (A) Covered by Valid Claims of one or more Fentanyl-Specific Patents for which Collegium has assumed responsibility for prosecution, defense or maintenance in accordance with this Section 7.01 and (B) not Covered by any Valid Claim(s) of any other Licensed Patents.

Section 7.02 ***Filing, Prosecution, and Maintenance of Patents Covering Collegium Improvements.*** Collegium shall control and, except as explicitly set forth in this Section 7.02, have full discretion in the preparation, filing, prosecution, maintenance, and defense of any Patents owned or controlled by Collegium or any Affiliate thereof Covering any Collegium Improvement, including any *ex parte* reexamination proceedings, *inter partes* review proceeding, post grant review proceeding, derivation proceeding, action for declaratory judgment, interference proceeding or other attack upon the validity, title or enforceability of any such Patents in the Territory. Collegium shall keep BDSI advised with respect to the foregoing by forwarding to BDSI copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to the prosecution and maintenance of such Patents, and shall provide BDSI a reasonable advance opportunity (to be no less than ***) to review and comment on any proposed patent applications, responses, voluntary amendments, submissions, or other actions of any kind to be made with respect to any such Patents, and Collegium shall reasonably take into consideration any reasonable comments made by BDSI with respect thereto. In the event that Collegium desires to abandon any such Patents Covering Collegium Product-Specific Improvements, Collegium shall provide reasonable prior written notice to BDSI of Collegium's intention to abandon and a reasonable opportunity to discuss Collegium's rationale supporting such abandonment.

Section 7.03 ***Prosecution of Infringement***.

(a) During the Term, each Party shall give prompt written notice to the other Party of any Third Party act in the Territory that (a) concerns any product(s) that contain fentanyl as the sole API but do not contain naloxone and (b) may infringe the Licensed Patents and/or the Licensed Marks in the Territory. BDSI shall, as between the Parties, have the sole and exclusive right with respect to Licensed Marks and Licensed Patents other than Fentanyl-Specific Patents, and the first right with respect to Fentanyl-Specific Patents, but not, in either case, the obligation, to bring and control any action or proceeding (i) concerning any potential or actual infringement of the Licensed Patents or Licensed Marks, (ii) any statutory act of infringement under the Hatch-Waxman Act (including but not limited to on account of any certification provided thereunder (including but not limited to as set forth in Section 7.04)), or (iii) concerning any potential or actual misappropriation of any Licensed Know-How. If BDSI is unable to initiate or to prosecute such action solely in its own name or it is otherwise Commercially Reasonable and reasonably advisable to obtain an effective or interim remedy, Collegium shall, if and as requested by BDSI, join such action and take such other reasonable steps requested by BDSI as are necessary for BDSI to initiate litigation to prosecute and maintain such action, provided, that, under no circumstances will Collegium be obligated to, amend or alter any of the terms of this Agreement in a manner adverse to Collegium's interests in order to enable BDSI to initiate litigation to prosecute and maintain such action. Collegium shall provide, at BDSI's expense, such other assistance and cooperation to BDSI as may be necessary to prosecute any action against such Third Party. Any damages, monetary awards, or other amounts recovered or received in settlement by BDSI shall be ***.

(b) In the event that BDSI decides not to enforce, or to abandon or discontinue the enforcement of, any Fentanyl-Specific Patent against any Third Party infringer thereof, BDSI will notify Collegium and the Parties will use Commercially Reasonable Efforts in good faith to agree within *** (or, in the case of any statutory act of infringement under the Hatch-Waxman Act, within ***) after Collegium's receipt of such notice on an approach to address such infringement in a way that is designed to preserve both the validity and enforceability of the infringed Fentanyl-Specific Patent and the commercial value of the Licensed Products in the Territory, which approach may include (without limitation) giving Collegium the right to initiate litigation to prosecute or maintain such action against any Third Party infringer. In the event the Parties are unable to agree upon a reasonable course of action within such ***, as applicable, then BDSI shall authorize Collegium to enforce the applicable Fentanyl-Specific Patent against the Third Party infringer thereof. Without limiting the foregoing, if BDSI has authorized an infringement action by Collegium pursuant to this Section 7.03, but Collegium is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then at Collegium's written request, Collegium shall be entitled to join BDSI as a necessary party to such action and BDSI shall reasonably

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cooperate with Collegium, at Collegium's expense. Collegium shall not enter into a settlement, consent judgment, or other voluntary disposition of any such infringement action by Collegium without BDSI's prior written approval. Any damages, monetary awards, or other amounts recovered or received in settlement by Collegium shall be ***. Notwithstanding the foregoing, BDSI, at its expense, shall have the right to be represented by counsel of its choice in any proceeding governed by this Section 7.03(b).

Section 7.04 ***Hatch-Waxman Act Litigation.*** Notwithstanding anything herein to the contrary, should a Party receive a certification for a Licensed Product pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended (the "*Hatch-Waxman Act*"), including any notice under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) or a similar notice with respect to, in either case, any Licensed Product or any Competing Product in the Territory, then such Party shall immediately (and in any event no later than within *** after such receipt) provide the other Party with a copy of such certification.

Section 7.05 ***Infringement Claimed by Third Parties***. In the event a Third Party commences a judicial or administrative proceeding against a Party and such proceeding, other than a proceeding to which Section 7.01 applies, pertains to the manufacture, use, sale, marketing, or import of a Licensed Product in the Territory by or on behalf of Collegium, an Affiliate thereof, or a Sublicensee (the "*Third Party Claim*"), or threatens to commence such a Third Party Claim, the Party against whom such proceeding is threatened or commenced shall give prompt notice to the other Party.

Section 7.06 ***Payment of Costs and Expenses***. Upon its receipt of a reasonably detailed invoice setting forth a Party's reasonable, documented costs and expenses incurred pursuant to any provision of this Article VII relating to the Territory, for which the other Party shall be liable in accordance with this Article VII, such other Party shall pay such costs and expenses within *** of receipt of an invoice therefor.

ARTICLE VIII

CONFIDENTIALITY

Section 8.01 ***Confidentiality***. The Parties agree that, for the Term and for *** thereafter, each Party will keep completely confidential and will not publish, submit for publication or otherwise disclose, and will not use for any purpose except for the purposes contemplated by this Agreement (including but not limited to the exercise or enforcement of rights or performance of obligations under this Agreement), any Confidential Information of the other Party.

Section 8.02 ***Authorized Disclosure***. Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction; provided, however, that in each case such disclosing Party will, to the extent reasonably practicable, (i) first have given written notice to the other Party and given such other Party a reasonable opportunity to take appropriate action and (ii) cooperate with such other Party as necessary to obtain an appropriate protective order or other protective remedy or treatment; provided, further, that in each case, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order, as determined in good faith by the Party that is obligated to disclose Confidential Information pursuant to such order;

(b) otherwise required to be disclosed by any applicable law, rule, or regulation (including, without limitation, the U.S. federal securities laws and the rules and regulations promulgated thereunder) or the requirements of any stock exchange to which a Party or any Affiliate thereof is subject; provided, however, that the Party that is so required will provide such other Party with written notice of such disclosure reasonably in advance thereof to the extent reasonably practicable and reasonable measures will be taken to assure confidential treatment of such information, including such measures as may be reasonably requested by the disclosing Party with respect to such Confidential Information;

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(c) made by such Party, in connection with the performance of this Agreement, to such Party's Affiliates, licensees, sublicensees, contractors, directors, officers, employees, consultants, representatives or agents, or to other Third Parties, in each case on a need to know basis and solely to use such information for business purposes relevant to and permitted or required by this Agreement, and provided that (i) each such party to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations substantially as protective as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations; or

(d) made by (x) such Party to existing or potential acquirers, existing or potential collaborators, licensees, licensors, sublicensees, investment bankers, accountants, attorneys, existing or potential investors, merger or acquisition targets, partners, venture capital firms or other financial institutions or investors for use of such information for business purposes relevant to this Agreement or for due diligence in connection with the financing, licensing or acquisition of such Party or an Affiliate thereof (or such Party's or its Affiliate's acquisition of, or merger with, a Third Party) or (y) BDSI to Meda in performance of its obligations under, or with respect to any agreement entered into between BDSI and Meda concerning the termination, prior to the effectiveness of this Agreement, of that certain previous agreement between Meda and BDSI pursuant to which Meda enjoyed certain rights to BEMA Fentanyl Products in the Territory (such previous agreement, the "*Meda License*"; any such termination-related agreement, a "*Meda Termination Agreement*"), and provided that (i) each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations (or in the case of attorneys or accountants, an equivalent professional duty of confidentiality) substantially as protective as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations.

Section 8.03 ***Publications.*** Subject to Sections 8.01 and 8.02 and this Section 8.03, each Party shall have the right to publish, present or otherwise disclose, including in scientific journals or promotional literature, information in its possession or control pertaining to any BEMA Fentanyl Product developed or commercialized by or for it or any Affiliate thereof, or, in the case of BDSI, pertaining directly to any Licensed Technology; provided, however, that if Collegium or any Affiliate thereof desires to publish or present any such information in regards to any of their respective BEMA Fentanyl Products, then the following procedure shall apply: (a) Collegium shall first provide a copy of the proposed publication or presentation to BDSI for review and comment *** in advance of any submission for publication or presentation (or, in the case of any presentation, *** in advance of such submission) (such ***, the "*Review Period*"); (b) if during the Review Period Collegium receives written notice from BDSI identifying specific Confidential Information of BDSI in such a proposed publication or presentation, then, at the reasonable request of BDSI in such notice and at BDSI's option, Collegium shall, and Collegium shall ensure that its Affiliates, delete such Confidential Information from the proposed publication and/or delay such publication or presentation for up to an additional thirty *** in order to permit BDSI to file a patent application covering such Confidential Information.

Section 8.04 ***Disclosure of Agreement***. Neither Party shall release to any Third Party or publish in any way any non-public information with respect to the terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, (x) a Party may disclose the terms of this Agreement to actual or potential investors, lenders, investment bankers, and other financial institutions of its choice solely for purposes of financing the business operations of such Party or an Affiliate thereof, or, to any prospective or actual licensee, sublicensee, licensor, manufacturer, marketing or other corporate partner, acquirer, or merger or acquisition target and (y) BDSI shall be entitled to disclose the terms of this Agreement to Meda pursuant to any Meda Termination Agreement; provided such disclosing Party only discloses such information under conditions of confidentiality on terms substantially as protective as those contained in this Article VIII. Nothing contained in this paragraph shall prohibit either Party from filing this Agreement as required by the rules and regulations of the Securities and Exchange Commission, national securities exchanges (including those located in countries outside of the United States) or the Nasdaq Stock Market; provided the disclosing Party discloses only such information required to be disclosed in order to comply with such requirements, as reasonably determined by such Party, including requesting confidential treatment of this Agreement (after providing a reasonable opportunity for consultation by the other Party) and filing this Agreement in redacted form. The Parties agree to cooperate with respect to requests for confidential treatment to be submitted to the Securities and Exchange Commission or any similar foreign authority with respect to certain portions of this Agreement and any redactions thereof for such purposes.

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ARTICLE IX

REPRESENTATIONS AND WARRANTIES

Section 9.01 ***Corporate Power***. As of the Effective Date, each Party hereby represents and warrants that such Party is duly organized and validly existing under the laws of the jurisdiction of its organization and has full corporate power and authority to enter into this Agreement and the transactions contemplated hereby and to carry out the provisions hereof.

Section 9.02 ***Due Authorization***. As of the Effective Date, each Party hereby represents and warrants that such Party is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder.

Section 9.03 ***Binding Obligation***. As of the Effective Date, each Party hereby represents and warrants that this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms, except that the enforcement of the rights and remedies created hereby is subject to bankruptcy, insolvency, reorganization and similar laws of general application affecting the rights and remedies of creditors and that the availability of the remedy of specific performance or of injunctive relief is subject to the discretion of the court before which any proceeding therefor may be brought. As of the Effective Date, each Party represents and warrants that the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over it.

Section 9.04 ***Legal Proceedings***. As of the Effective Date, each Party hereby represents and warrants to the other Party that, except, with respect to BDSI, for those proceedings described on Exhibit F with respect to a BEMA-based Product other than a BEMA Fentanyl Product (the "*Actavis Litigation*"), there is no action, suit or proceeding pending against or affecting, or, to the Knowledge of either Party, threatened against or affecting that Party, or any of its assets, before any court or arbitrator or any governmental body, agency or official that would, if decided against either Party, have a material adverse impact on the business, properties, assets, liabilities or financial condition of that Party (that are not already reflected in that Party's respective financial statements as filed with the Securities and Exchange Commission (or foreign equivalent thereof) or otherwise made public or provided to the other Party) and which would have a material adverse effect on that Party's ability to consummate the transactions and perform the obligations contemplated by this Agreement.

Section 9.05 ***Limitation on Warranties***. Except as expressly set forth in this Agreement, nothing herein shall be construed as a representation or warranty by BDSI to Collegium that the Licensed Technology is not infringed by any Third Party, or that the practice of such rights does not infringe any intellectual property rights of any Third Party.

Section 9.06 ***No Guarantee of Success.*** Collegium and BDSI acknowledge and agree that nothing in this Agreement will be construed as representing any estimate or projection of (i) the successful Development or Commercialization of any Licensed Product under this Agreement, (ii) the number of Licensed Products that will or may be successfully Developed or Commercialized under this Agreement, (iii) anticipated sales or the actual value of any Licensed Products that may be successfully Developed or Commercialized under this Agreement or (iv) the damages, if any, that may be payable if this Agreement is terminated for any reason. Neither Party makes any warranties, express or implied, or covenants concerning the success of the Development or Commercialization of any Licensed Products or the commercial utility, merchantability, or fitness for a particular purpose of any Licensed Product. In addition, Collegium makes no representation, warranty or covenant, either express or implied, that (A) it will successfully Develop or Commercialize or continue to Develop or Commercialize any Licensed Product in the Territory, (B) if Commercialized, that any Licensed Product will achieve any particular sales level in the Territory or (C) it will devote, or cause to be devoted, any level of diligence or resources to Developing or Commercializing any Licensed Product in the Territory, other than is expressly required under Sections 2.02 and 5.01(a) and Article VI.

Section 9.07 ***Sufficient Rights***. BDSI represents and warrants that (a) it has and shall maintain during the Term of this Agreement (i) an exclusive license to or ownership of, as applicable, the Licensed Technology, the Licensed Marks and any other intellectual property rights which are the subject of Collegium's licenses under this Agreement and (ii) the right to grant the licenses described in this Agreement, and (b) the grant of such licenses by BDSI will

not conflict with or violate any of the terms of any agreement of BDSI concerning the Licensed Technology or the Licensed Marks.

Section 9.08 ***No Infringement***. BDSI represents and warrants that, to BDSI's Knowledge as of the Effective Date, BDSI is not aware of any Third Party intellectual property rights which would be infringed by the Development or Commercialization, including the manufacture, use, or sale, of the Current Product in the Territory.

Section 9.09 ***Intellectual Property***. BDSI represents and warrants that (i) to BDSI's Knowledge as of the Effective Date, the Licensed Technology, Licensed Marks and other intellectual property rights which are the subject of the licenses granted to Collegium hereunder comprise, all intellectual property rights reasonably necessary for Collegium to Develop and Commercialize the Current Product and (ii) there are no other intellectual property rights owned or Controlled by BDSI or any of its Affiliates as of the Effective Date, other than the rights in the Licensed Technology, which cover the Current Product or would otherwise prevent Collegium from Developing and/or Commercializing the Current Product in the Territory as set forth herein.

Section 9.10 ***Documents***. BDSI represents and warrants that, to its Knowledge as of the Effective Date, all documents provided to Collegium by or on behalf of BDSI prior to the Effective Date are materially true and correct and no document provided to Collegium by or on behalf of BDSI, contains any untrue statement of a relevant material fact or omits to state a relevant material fact necessary not to make the statements contained in the document materially misleading.

Section 9.11 ***HSR Determination.*** Collegium represents and warrants that it has determined in good faith, prior to the Effective Date, that it is not required to make any filing with respect to this Agreement or the transactions contemplated hereby in order to comply with any obligations under the HSR Act.

Section 9.12 ***Collegium Affiliates.*** Collegium represents and warrants that, as of the Effective Date, there are no Affiliates of Collegium.

Section 9.13 ***Termination of CDC Agreement and Survival.*** BDSI covenants to make all payments and to provide all reports, notices and materials to CDC when due under the CDC Agreement and to exercise its rights and perform its obligations thereunder to the extent necessary to maintain such rights under the CDC Agreement in a manner consistent with the license rights granted to Collegium pursuant to this Agreement. Without limiting the foregoing, BDSI shall not (a) knowingly commit any act or omission that would reasonably be expected to give rise to any right of CDC to terminate the CDC Agreement or CDC Consent or (b) exercise any right it may have to terminate the CDC Agreement or CDC Consent, or otherwise amend the CDC Agreement or CDC Consent, in a way that adversely affects Collegium's rights hereunder with respect to any of the Licensed Technology, without the prior written consent of an officer of Collegium, provided that such covenant shall not be construed to require BDSI to (i) pay any amounts to CDC in excess of the amounts properly due such parties under the CDC Agreement or (ii) agree to become subject to any obligations in excess of those currently provided under the CDC Agreement. If BDSI does not make any payment or take any required action under the CDC Agreement when due, Collegium may, but shall not be obligated to and without prejudicing any of its other rights or remedies, make such payment or take such action for BDSI's account with the right to credit such payment or costs against any amounts payable from Collegium to BDSI under this Agreement. BDSI represents and warrants that, subject to Section 13.06(e), any licenses granted to Collegium under this Agreement will, as described in CDC Consent, (A) survive any exclusive licensing and assignment to CDC, upon termination of the CDC Agreement by CDC pursuant to Section 10.2 or 10.3 thereof, of BDSI's rights under the Licensed Technology, Licensed Marks, and other intellectual property rights which are the subject of Collegium's licenses under this Agreement and (B) be assigned to CDC, subject to Collegium's continued compliance with the terms of this Agreement, provided that such termination of the CDC Agreement does not result from and is not related to any uncured material breach of this Agreement by Collegium.

Section 9.14 ***Debarment***. Each Party represents and warrants to the other that, as of the Effective Date, it has never been and is not currently debarred by the FDA pursuant to 21 U.S.C. §335(a) or (b) ("*Debarred Entity*"), and each Party agrees that it will not obtain advice or assistance from any individual debarred pursuant to 21 U.S.C. §335(a) or (b). Each Party represents and warrants to the other that it has no Knowledge, as of the Effective Date, of any circumstances that may affect the accuracy of the foregoing warranties and representations, including, but not limited to, FDA investigations of, or debarment proceedings against, it or any person or entity with which it is

associated or that provides services to such Party, and such Party will immediately notify the other in writing if it becomes aware of any such circumstances during the term of this Agreement.

Section 9.15 ***CDC Acknowledgement.*** Collegium hereby expressly acknowledges to CDC that, to the extent (a) provided in this Agreement or the CDC Consent and (b) provisions of the CDC Agreement, as modified by the CDC Consent, expressly apply to sublicensees of BDSI thereunder, this Agreement shall be subject to the rights of CDC under the CDC Agreement.

ARTICLE X

INDEMNIFICATION; INSURANCE; LIMITATION OF LIABILITY

Section 10.01 ***Indemnification by BDSI.*** Subject to Section 10.03, BDSI hereby agrees to defend, indemnify and hold harmless Collegium, its Affiliates, and its and their respective directors, officers, employees, agents, other representatives, and successors and assigns ("*Collegium Indemnitees*") from and against all suits, claims, proceedings or causes of action brought by Third Parties ("*Claims*"), and all associated damages, liabilities, expenses and/or loss, including reasonable legal expenses and reasonable attorneys' fees (collectively, "*Losses*"), arising out of BDSI's, its Affiliates', or BDSI's or its Affiliates' officers', directors', employees', agents', or other representatives' (i) negligence or willful misconduct with respect to the subject matter of this Agreement, (ii) breach of this Agreement, (iii) failure to comply with any Applicable Law with respect to the subject matter of this Agreement, or (iv) manufacture, use, sale, offer for sale, development, commercialization, import, or export of any BEMA Fentanyl Product(s) within or outside the Territory; provided, that BDSI shall not have any such obligation if and to the extent any such Claims or Losses result from any Collegium Indemnitees' (A) negligence or willful misconduct, (B) breach of this Agreement, (C) failure to comply with Applicable Laws with respect to the subject matter of this Agreement, or (D) manufacture, use, sale, offer for sale, Development, Commercialization, import, or export of any Licensed Product(s) not in accordance with this Agreement.

Section 10.02 ***Indemnification by Collegium.*** Subject to Section 10.03, Collegium hereby agrees to indemnify, defend and hold BDSI, its Affiliates, CDC, NB Athyrium LLC, and BDSI's, its Affiliates', CDC's, and NB Athyrium LLC's officers, directors, employees, contractors, agents, other representatives, and successors and assigns(collectively, "*BDSI Indemnitees*") harmless from and against any Losses resulting from Claims brought against any BDSI Indemnitee(s) resulting from (I) Collegium's, its Affiliates', Sublicensees', or any of Collegium's, its Affiliates', or Sublicensees' directors', officers', employees', agents', or other representatives' (a) negligence or willful misconduct with respect to the subject matter of this Agreement, (b) failure to comply with Applicable Laws with respect to the subject matter of this Agreement, (c) manufacture, use, sale, offer for sale, Development, Commercialization, import, or export of any Licensed Product(s) or other exercise of the rights granted to Collegium under this Agreement, or (d) alleged or actual infringement or misappropriation of any Third Party's Patents or other intellectual property rights in the manufacture, use, sale, offer for sale, Development, Commercialization, import, or export of any Licensed Product(s) in the Territory or (II) Collegium's, its Affiliates', or any of Collegium's, its Affiliates', or its or their directors', officers', employees', agents', or other representatives' breach of this Agreement, except if and to the extent such Claims or Losses result from any BDSI Indemnitee's (i) negligence or willful misconduct, (ii) breach of this Agreement, or (iii) failure to comply with any Applicable Laws with respect to the subject matter of this Agreement.

Section 10.03 ***Indemnification Procedures***. Each Party's agreement to indemnify, defend, and hold harmless under Section 10.01 or 10.02, as applicable, is conditioned upon the indemnified party (a) providing written notice to the indemnifying Party of any Claim or Loss arising out of the indemnified matter as soon as reasonably possible, and in any event no later than within *** after the indemnified Party has actual Knowledge of such Claim or Loss, (b) permitting the indemnifying Party to assume control over the investigation of, preparation and defense against, and settlement or voluntary disposition of any Claim, (c) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation, preparation, defense, and settlement or voluntary disposition of any such Claim or Loss, and (d) not compromising, settling, or entering into any voluntary disposition of any such Claim without the indemnifying Party's prior written consent, which consent shall not be unreasonably withheld; provided, however, that, if the party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (a), the indemnifying Party will only be relieved of its indemnification obligation under this Article

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X to the extent materially prejudiced by such failure. In no event may the indemnifying Party compromise, settle, or enter into any voluntary disposition of any claim, demand or action in any manner that explicitly admits material fault or wrongdoing on the part of the indemnified party or incurs non-indemnified liability (including any payment obligation) on the part of the indemnified party without the prior written consent of the indemnified party, and in no event may the indemnifying Party settle, compromise, or agree to any voluntary disposition of any matter subject to indemnification hereunder in any manner which would, in the case of any settlement, compromise or voluntary disposition effected by Collegium pursuant to its obligations under Section 10.02, reasonably be anticipated to have a material likelihood of adversely affecting any portion of the Licensed Technology or the Licensed Marks, or BDSI's, its Affiliates', or any of their respective Third Party licensees' or Third Party sublicensees' ability to manufacture, Develop, or Commercialize BEMA Fentanyl Products outside the Territory, or any other then-current BEMA-based products anywhere in the world, without BDSI's prior written consent or, in the case of any settlement, compromise or voluntary disposition effected by BDSI pursuant to its obligations under Section 10.01, negatively affect the scope of the licenses granted to Collegium in Section 3.02 or Section 3.03 or that would reasonably be anticipated to have a material likelihood of negatively affecting Collegium's ability to Commercialize and Develop the Licensed Products in the Territory, without Collegium's prior written consent.

Section 10.04 ***Insurance***.

(a) Except as otherwise provided below, BDSI shall maintain insurance, including commercial general liability, product liability and, for clinical trials it sponsors, clinical trials liability insurance, workers compensation and employer's liability and errors and omissions liability insurance, with respect to its activities under this Agreement regarding Licensed Products in such amount as it customarily maintains with respect to similar activities for its other products, but not less than (i) $*** each occurrence and $*** aggregate for commercial general liability, (ii) $*** each occurrence and aggregate for product liability, and (iii) such amount as is reasonable and customary in the U.S. pharmaceutical industry for errors and omissions liability insurance, workers compensation, and employer's liability. Such coverage shall be maintained for not less than *** following expiration or termination of this Agreement or if such coverage is of the "claims made" type, for *** following expiration or termination of this Agreement. Upon written request, BDSI shall provide Collegium with written evidence of the required coverage. Coverage may be in the form of primary insurance or a combination of primary and excess insurance.

(b) Except as otherwise provided below, Collegium shall maintain insurance, including commercial general liability, product liability and, for clinical trials it sponsors, clinical trials liability insurance, workers compensation and employer's liability and errors and omissions liability insurance, with respect to its activities under this Agreement regarding Licensed Products in such amount as it customarily maintains with respect to similar activities for its other products, but not less than the greater of (i) $*** each occurrence and aggregate for commercial general liability, (ii) $*** each occurrence and aggregate for product liability at all times prior to the first commercial sale of a Licensed Product by Collegium or any Affiliate thereof or first sale of a Licensed Product by any Sublicensee, and $*** each occurrence and aggregate for product liability at all times thereafter, (iii) $*** each occurrence and aggregate for clinical trials liability in connection with any clinical trials conducted by or on behalf of Collegium or any Affiliate thereof hereunder prior to the first commercial sale of a Licensed Product by Collegium or any Affiliate thereof, and $*** each occurrence and aggregate for clinical trials liability in connection with any clinical trials conducted by or on behalf of Collegium or any Affiliate thereof at all times thereafter, and (iv) such amount as is reasonable and customary in the U.S. pharmaceutical industry for errors and omissions liability insurance, workers compensation and employer's liability. Such coverage shall be maintained for not less than *** following expiration or termination of this Agreement or if such coverage is of the "claims made" type, for *** following expiration or termination of this Agreement. Upon written request, Collegium shall provide BDSI with written evidence of the required coverage. Coverage may be in the form of primary insurance or a combination of primary and excess insurance.

(c) Each Party shall provide the other Party *** notice of any material change, cancellation or non-renewal of any required insurance under this Agreement. In the event of a material change, cancellation, or non-renewal in coverage, each Party shall replace such coverage to comply with this Agreement so that there is no lapse of coverage for any time period. It is understood that the above-required insurance shall not be construed to create a limit of either Party's liability, with respect to its indemnification obligations or otherwise, under this Agreement.

Section 10.05 ***Limitation of Liability***. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR TO ANY AFFILIATE THEREOF OR TO ANY THIRD PARTY CLAIMING UNDER OR

THROUGH SUCH PARTY OR ANY OF ITS AFFILIATES FOR LOST PROFITS, LOST REVENUE, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR FOR ANY SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY (WHETHER BREACH OF CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE) AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING UNDER ANY CAUSE OF ACTION AND ARISING IN ANY WAY OUT OF THIS AGREEMENT, PROVIDED THAT, NOTWITHSTANDING THE FOREGOING, THE FOREGOING LIMITATION WILL NOT LIMIT EITHER PARTY'S (A) INDEMNIFICATION OBLIGATIONS FOR CLAIMS OR LOSSES UNDER ARTICLE 10.01 OR 10.02 OR (B) LIABILITY FOR WILLFUL PATENT INFRINGEMENT, PATENT INFRINGEMENT OUTSIDE OF THE TERRITORY, PATENT INFRINGEMENT OCCURRING FOLLOWING ANY TERMINATION OF THIS AGREEMENT, PATENT INFRINGEMENT IN THE TERRITORY WITH RESPECT TO ANY SUBJECT MATTER OTHER THAN A BEMA FENTANYL PRODUCT (OR THE MANUFACTURE OR USE THEREOF), OR ANY BREACH OF ARTICLE VIII.

ARTICLE XI

COVENANTS

Section 11.01 ***Access to Books and Records***. Each Party covenants and agrees that it shall permit the other Party (or any Third Party allowed to be granted such rights by the other Party under this Agreement) to exercise such inspection rights with regards to such Party's Books and Records as expressly set forth in Section 14.11 of this Agreement.

Section 11.02 ***Marketing Expenses***. Collegium covenants and agrees that, as between Collegium and BDSI, Collegium shall be solely responsible for the cost and implementation of all of its own marketing, sales, promotional and related activities concerning the marketing, sale and promotion of the Licensed Products in the Territory.

Section 11.03 ***Affiliates.*** Without limitation of Section 3.02(c), each of Collegium and BDSI shall cause its respective Affiliates who engage in the performance of any activities, exercise any rights, assume any obligations hereunder, or have access to, or know or use, the other Party's Confidential Information, to comply with all obligations applicable to such Affiliates in connection therewith under this Agreement. Each Party shall be responsible and liable for any performance of its obligations hereunder by any of its Affiliates and their compliance with the terms of this Agreement in connection therewith, and any breach of the terms of this Agreement by any Affiliate of a Party shall be deemed a breach of this Agreement by such Party. In addition, Parent shall be jointly and severally liable with Arius for any breach by Arius of any of the terms of this Agreement, as a primary obligor and not merely as a surety, and Collegium shall not be required to pursue any right or remedy it may have against Arius as a condition to enforcement against Parent arising from any such breach.

Section 11.04 ***Compliance***. Collegium covenants and agrees that it shall comply in all material respects with all Applicable Laws affecting the use, possession, distribution, advertising and all forms of promotion in connection with its sale and distribution of the Licensed Products and Demonstration Samples in the Territory following the NDA Assignment. Notwithstanding anything to the contrary, any failure of Collegium, any Affiliate thereof, or any Sublicensee to adhere to any Applicable Laws in the Territory concerning the handling of narcotics which materially adversely affects BDSI's, its Affiliates', or any of its or their licensees' or sublicensees' future manufacture, use, shipment, handling, sale, marketing, or distribution of fentanyl (or any product incorporating fentanyl) in connection with the Licensed Technology shall be deemed a material breach of this Agreement entitling BDSI, subject to prior notice and, with respect solely to the first *** failures, a right to cure in the same manner as provided in Section 13.02(b), to terminate this Agreement immediately pursuant to Section 13.02(b). For the avoidance of doubt, the foregoing covenant does and shall not apply to, and BDSI acknowledges and agrees that Collegium is not assuming any responsibility or liability under any circumstances for, the use, possession, distribution, advertising or promotion of any Licensed Products or Demonstration Samples or any failure to comply with Applicable Laws concerning the handling of any narcotics, including fentanyl, by or on behalf of BDSI, any of its Affiliates or any Third Party on its or their behalf or for its or their benefit prior to the NDA Assignment.

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

Section 11.05 ***Reports***. Collegium covenants and agrees that, except as otherwise specified in this Agreement, Collegium shall, following NDA Assignment, have the obligation and responsibility for and shall make any and all necessary reports to each Competent Authority with respect to the Licensed Product and shall provide BDSI with a complete copy of any such report simultaneously with its submission of the report to each Competent Authority. Collegium covenants and agrees that, except as otherwise specified in this Agreement, Collegium shall, following NDA Assignment, have the obligation and responsibility for and shall make any and all necessary reports in respect of the safe and lawful handling of the Licensed Products as a narcotic substance to each Competent Authority, and shall provide BDSI with a complete copy of any such report simultaneously with the submission of the report to each Competent Authority.

Section 11.06 ***Further Actions***. Upon the terms and subject to the conditions hereof, each of the Parties hereto shall use its Commercially Reasonable Efforts to (a) take, or cause to be taken, all appropriate action and do, or cause to be done, all things necessary, proper or advisable under Applicable Law or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from Competent Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made by the Parties in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (c) make all necessary filings, and thereafter make any other required submissions, with respect to this transaction under (i) the United States' Securities Exchange Act of 1934, as amended and the United States' Securities Act of 1933, as amended, and the rules and regulations thereunder and any other applicable securities laws and (ii) any other Applicable Law. The Parties hereto shall cooperate with each other in connection with the making of all such filings, including by providing copies of all such documents to the other Party's counsel (subject to appropriate confidentiality restrictions) prior to filing and, if requested, by accepting all reasonable additions, deletions or changes suggested in connection therewith.

Section 11.07 ***Protection of the Licensed Marks***. Collegium covenants and agrees that neither it nor its Affiliates shall publish, employ, or cooperate in the publication of any advertising material with regard to the Licensed Technology, the Licensed Marks, or any other trademarks of BDSI which Collegium knows are misleading or deceptive and both Parties covenant and agree that neither it nor any of its Affiliates shall publish, employ, or cooperate in the publication of any advertising materials with regard to the Parties or any BEMA Fentanyl Products which it knows are misleading or deceptive.

Section 11.08 ***Equitable Relief***. The Parties understand and agree that because of the difficulty of measuring economic losses to the non-breaching Party as a result of a breach of (i) the covenants set forth in Article VIII or this Article XI or (ii) the licenses granted under this Agreement (taking into account any expressly reserved or retained rights thereunder), and because of the immediate and irreparable damage that may be caused to the non-breaching Party for which monetary damages may not be a sufficient remedy, the Parties agree that the non-breaching Party may be entitled to seek specific performance, temporary and permanent injunctive relief, and such other equitable remedies to which it may then be entitled against the breaching Party. This Section 11.08 shall not limit any other legal or equitable remedies that the non-breaching Party may have against the breaching Party for violation of (1) the covenants set forth in Article VIII or this Article XI or (2) the licenses granted under this Agreement (taking into account any expressly reserved or retained rights thereunder). The Parties agree that the non-breaching Party shall have the right to seek relief for any violation or threatened violation of Article VIII, this Article XI, or the licenses granted under this Agreement (taking into account any expressly reserved or retained rights thereunder) by the breaching Party from any court of competent jurisdiction in any jurisdiction authorized to grant the relief necessary to prohibit the violation or threatened violation of Article VIII, this Article XI, or the licenses granted under this Agreement (taking into account any expressly reserved or retained rights thereunder). This Section 11.08 shall apply with equal force to the breaching Party's Affiliates.

Section 11.09 ***Competing Products***. During the Term, neither BDSI, any Affiliate thereof, Collegium, nor any Collegium Affiliate shall, directly or indirectly (through Third Parties or, in the case of Collegium or a Collegium Affiliate, Affiliates of Collegium that are not Collegium Affiliates), knowingly or recklessly enable or contract with any Third Party or, in the case of Collegium or a Collegium Affiliate, Affiliates thereof other than Collegium Affiliates, to develop, manufacture, market, sell or distribute any Competing Product in the Territory for the Territory or itself develop, manufacture, market, sell or distribute any Competing Product in the Territory for the Territory, provided that, notwithstanding anything to the contrary, (X) neither the foregoing nor any other provision of this Agreement (other than Section 3.02(a)) shall be construed to limit BDSI's, its Affiliates', or any of its or their

Third Party licensees', sublicensees', or contractors' rights to (a) develop, manufacture, have manufactured, or use, in the Territory any products (including BEMA Fentanyl Products or Competing Products) which are intended solely for commercial sale to Third Parties located outside the Territory, (b) develop, manufacture, have manufactured, use, sell, or offer for sale in the Territory any products other than BEMA Fentanyl Products or Competing Products, or (c) otherwise exercise BDSI's reserved rights under Section 3.02(a) and (Y) this Section 11.09 shall not apply to any Affiliate of BDSI that is not controlled by Parent or Arius (with "controlled" having, for purposes of this clause (Y), the meaning set forth in the definition of Affiliate established under Article I) or any Affiliate of Collegium that is not a Collegium Affiliate.

Section 11.10 ***.

Section 11.11 ***No Encumbrances.*** Except to the extent Collegium may assign this Agreement under Section 14.01, Collegium shall not, without the prior written consent of BDSI, such consent not to be unreasonably withheld, sell, license or sublicense (except as permitted by Section 3.02(a)), encumber or otherwise transfer to a Third Party any of Collegium's rights in Governmental Approvals, Marketing Authorizations, or Regulatory Filings in respect to any Licensed Product. Except to the extent BDSI may assign this Agreement under Section 14.01, BDSI shall not sell, assign, license, sublicense, encumber or otherwise transfer to a Third Party any of BDSI's rights in any Licensed Technology, or otherwise take any action, that would diminish the rights under the Licensed Technology granted to Collegium under this Agreement.

Section 11.12 ***.

Section 11.13 ***Arius Two Agreement and Consent.*** BDSI shall not (a) knowingly commit any act or omission that would reasonably be expected to give rise to any right of Arius Two, Inc. to terminate that certain BEMA License Agreement between Arius Two, Inc. ("*Arius Two*") and Arius, dated September 5, 2007, as amended (the "*Arius Two Agreement*") or that certain Sublicensing Consent between Arius and Arius Two, dated on or about the Effective Date of this Agreement (the "*Arius Two Consent*"), or (b) exercise any right it may have to terminate the Arius Two Agreement or Arius Two Consent, or otherwise amend the Arius Two Agreement or Arius Two Consent, in a way that adversely affects Collegium's rights hereunder with respect to any of the Licensed Technology without the prior written consent of an officer of Collegium.

ARTICLE XII

PRODUCT RECALL

Section 12.01 ***Product Recall Determination***. If at any time or from time to time, a Competent Authority requests Collegium to conduct a Product Recall of any Licensed Product Developed or Commercialized by or for Collegium, any Affiliate thereof, or any Sublicensee in the Territory or if a voluntary Product Recall of any such Licensed Product in the Territory is contemplated by Collegium, any Affiliate thereof, or any Sublicensee, Collegium shall immediately notify BDSI in writing, and except as otherwise set forth in this Article XII, Collegium will, at its sole cost and expense, conduct such Product Recall in as reasonable, prudent, and expeditious a manner as possible to preserve the goodwill and reputation of such Licensed Products and the goodwill and reputation of the Parties, provided that:

(a) Collegium shall not, and shall ensure that its Affiliates and Sublicensees do not, carry out a voluntary Product Recall in the Territory with respect to such Licensed Product without the prior written approval of BDSI, such approval not to be unreasonably withheld, conditioned or delayed (for the avoidance of doubt, any Product Recall that is reasonably deemed necessary in order to avoid serious personal injury shall not be considered as a voluntary Product Recall, provided that Collegium shall provide BDSI the opportunity to advise and comment with respect to any such Product Recall prior to its execution); and

(b) the Parties shall reasonably cooperate, at Collegium's expense, in the conduct of any Product Recall for such Licensed Product in the Territory.

Notwithstanding the foregoing, Collegium, any Affiliate thereof, or any Sublicensee may, without BDSI's prior consent, immediately effect any Product Recall (i) resulting from any death or life-threatening Adverse Event

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

associated with any Licensed Product or (ii) required to comply with any Applicable Law with respect to any Licensed Product. In the event Collegium notifies BDSI, or BDSI otherwise becomes aware, that Collegium, any Affiliate thereof, or any Sublicensee does not intend to undertake a Product Recall of the type described in clauses (i) or (ii) above, BDSI shall be entitled to do so upon notice to Collegium without Collegium's prior written consent.

Section 12.02 ***Product Recall Management.*** Collegium shall have the right to control and/or conduct any Product Recall of any Licensed Product Developed or Commercialized by or for it, any Affiliate thereof, or any Sublicensee in the Territory, subject to Section 12.01. The Product Recall shall be the sole responsibility of Collegium, its Affiliates, or Sublicensees, as applicable, and shall be carried out by Collegium, its Affiliates, or Sublicensees in as reasonable, prudent, and expeditious a manner as possible to preserve the goodwill and reputation of the affected Licensed Products and the goodwill and reputation of the Parties. Collegium, its Affiliates or Sublicensees, as applicable, shall maintain records of all sales and distribution of Licensed Products and customers in the Territory sufficient to reasonably adequately administer a Product Recall, for the period required by Applicable Law, and make such records available to BDSI or any designee thereof immediately upon request.

Section 12.03 ***Product Recall Costs***. Notwithstanding Section 12.02, Collegium shall bear all costs and expenses related to the conduct of any Product Recall of any Licensed Product Developed or Commercialized by or for it, its Affiliates or Sublicensees in the Territory.

Section 12.04 ***Notification of Threatened Action***. Throughout the duration of this Agreement and with respect to all Licensed Products, the Parties shall immediately notify each other of any information a Party receives regarding any threatened or pending action, inspection or communication by or from a concerned Competent Authority which may affect the safety or efficacy claims of the Licensed Products or the continued marketing of the Licensed Products.

ARTICLE XIII

TERM AND TERMINATION

Section 13.01 ***Term***. This Agreement shall commence as of the Effective Date and expire on the expiration of the last-to-expire Royalty Term ("*Term*"). Upon expiration of the Term of this Agreement, (a) the rights granted to Collegium in the Territory under Section 3.02 shall survive and become perpetual, irrevocable, royalty-free, and fully-paid, and nonexclusive and (b) the rights granted to Collegium in the Territory under Section 3.03 shall survive, provided that BDSI shall retain the right to terminate such rights granted under Section 3.03 as set forth therein or, in a manner substantially similar to that set forth in Section 13.02(b), for Collegium's material, uncured breach of Section 3.03.

Section 13.02 ***Termination by Either Party for Cause***. Subject to Section 13.07, either Party may terminate this Agreement prior to the expiration of this Agreement upon the occurrence of any of the following:

(a) upon or after the permanent cessation of operations of the other Party without a successor, or the bankruptcy or judicially declared insolvency of such Party, or the dissolution or winding up of the other Party (other than dissolution or winding up for the purposes or reconstruction or amalgamation) without a successor; or

(b) upon or after the material breach of this Agreement by the other Party (other than a failure to pay by Collegium, which is addressed in Section 13.03(c)), if the breaching Party has not cured such breach, if capable of being cured within such time period, within *** after written notice thereof by the non-breaching Party, provided that, notwithstanding the foregoing, BDSI shall be entitled to terminate this Agreement pursuant to Section 13.03(c) without providing the aforementioned opportunity to cure.

Section 13.03 ***Termination by BDSI***. Subject to Section 13.07, BDSI may, by written notice to Collegium, terminate this Agreement:

(a) upon the failure by Collegium to pay the license fee pursuant to Section 3.01 within the time period set forth therein;

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

(b) (i) upon the loss, revocation, suspension, termination, or expiration of Collegium's (or any Collegium Affiliates' or Sublicensees') license to sell narcotics in the Territory, if (A) as a result of such loss, revocation, suspension, termination or expiration none of the foregoing entities would be legally permitted to sell Licensed Products in the Territory and (B) Collegium (or the applicable Collegium Affiliate or Sublicensee) fails to take all actions necessary to reinstate such license within *** of such loss, revocation, suspension, termination, or expiration, or (ii) any material breach of the second sentence of Section 11.04 which is not remedied within *** thereof;

(c) upon the failure by Collegium on *** to pay any amount overdue under this Agreement within *** from receipt of a written notice (as given pursuant to Section 14.06 hereof) thereof to Collegium from BDSI (with respect to any amounts due under this Agreement pursuant to an invoice to be sent by BDSI, the first such invoice shall not be deemed "notice" for purposes of this paragraph);

(d) upon the occurrence of any material misrepresentation or omission in any Royalty Statement, which misrepresentation or omission is caused by Collegium's willful misconduct, gross negligence or bad faith; or

(e) in the event the First Commercial Sale of a Licensed Product hereunder does not occur by the date ***, provided that, to the extent that Collegium can reasonably demonstrate that manufacturing or supply delays outside of Collegium's, its Affiliates', and Sublicensees' reasonable control prevented the First Commercial Sale from occurring by such date, such date shall be automatically by an amount equal to the extent of such manufacturing or supply delays.

Section 13.04 ***Termination by Collegium.*** Collegium shall have the right, following the Effective Date and in its sole discretion, to terminate this Agreement upon *** written notice to BDSI.

Section 13.05 ***Remedies***. All of a non-breaching Party's remedies with respect to a breach of this Agreement shall be cumulative, and the exercise of one remedy under this Agreement by the non-breaching Party shall not be deemed to be an election of remedies. These remedies shall include the non-breaching Party's right to sue for damages for such breach without terminating this Agreement and to seek such other remedies as may be available to such Party at law or in equity.

Section 13.06 ***Effect of Termination.***

(a) Upon any termination of this Agreement by either Party, and subject to Section 13.06(b) and the exercise of the rights granted thereunder, (i) the rights granted under Sections 3.02 and 3.03 with respect to the Licensed Marks and the Licensed Technology, and any sublicenses granted thereunder, shall terminate, (ii) Collegium and its Affiliates shall immediately transfer to BDSI all information in Collegium's and its Affiliates' possession concerning the following: Licensed Products, Licensed Product inventory, Collegium Know-How, Collegium Patents, Collegium Marks, Collegium Documentation, Product-Related Materials, Regulatory Filings, Marketing Authorizations, and Governmental Approvals, and, if and as subsequently requested by BDSI in writing, transfer and assign to BDSI all right, title, and interest in all Demonstration Samples and Licensed Product inventory, Regulatory Filings, Marketing Authorizations, and Governmental Approvals, and Product-Related Materials (other than Collegiums' right, title or interest in or to any Collegium Know-How, Collegium Patents, Collegium Marks or any other Collegium intellectual property rights embodied in any of the foregoing), (iii) Collegium hereby grants BDSI and its Affiliates the perpetual, irrevocable, royalty-free, fully-paid, transferable, exclusive right and license, with rights of sublicense, under the Collegium Know-How and Collegium Patents, and a perpetual, irrevocable, royalty-free, fully-paid, transferable, non-exclusive license, with rights of sublicense, under the Collegium Marks, to develop, make, have made, use, sell, offer for sale, import, and export, market and promote BEMA Fentanyl Products and Demonstration Samples in the Territory (including but not limited to all Licensed Products Commercialized or under Developed by Collegium or any of its Affiliates or Sublicensees as of the effective date of termination), and (iv) Collegium shall provide BDSI all information requested by BDSI concerning any manufacturing, supplier, distributor, research, development, clinical study, or other contracts concerning the Development, manufacture, or Commercialization of Licensed Products or Demonstration Samples entered into by Collegium or its Affiliates with Third Parties ("*Product-Related Contracts*") and, if and as subsequently requested by BDSI, assign such Product-Related Contracts to BDSI or otherwise reasonably facilitate BDSI's establishment of similar relationships with such Third Parties.

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

(b) Upon termination of this Agreement other than by BDSI pursuant to Section 13.02 or 13.03, or as permitted in writing by BDSI in the event of any termination by BDSI pursuant to Section 13.02 or 13.03, Collegium (and/or its Affiliates and Sublicensees, if and as applicable) shall have the right, for a period of *** from the date of termination to distribute and sell existing inventory of Licensed Products subject to the terms of this Agreement (including Article IV hereof), provided that such Licensed Products shall be sold at a Commercially Reasonable price, and Collegium shall, in the event post-termination sales of Licensed Products are permitted pursuant to the foregoing, not be required to comply with its obligations under Section 13.06(a) to assign any assets to BDSI (including Regulatory Filings, Marketing Authorizations, and Governmental Approvals) that are reasonably necessary to exercise such post-termination right, until the expiration of the above-referenced *** period.

(c) Except as otherwise provided in this Agreement, expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under Sections 2.03 (Regulatory Submissions) (with respect to Collegium's obligations thereunder), 3.02(b) (Licensed Technology), 3.02(c) (Licensed Technology) (with respect to the surviving terms of this Agreement), 3.03(b) (Use of Licensed Marks) (with respect to expiration, but not termination), 3.03(c) (Additional Terms) (with respect to expiration, but not termination), 3.03(d) (Termination of License) (with respect to expiration, but not termination), 3.05 (Ownership of Improvements), 3.06 (Licenses to BDSI), 4.03 (Reports and Payments) (for Net Sales of Licensed Products sold during the Term or pursuant to Section 13.06(b)), 6.01 (Marketing Authorization Holder) (with respect to expiration, but not termination), 6.03 (Interaction with Competent Authorities) (with respect to expiration, but not termination), 6.04 (a) (General) (with respect to expiration, but not termination), 6.04(b) (Safety Related Regulatory Documents) (with respect to expiration, but not termination), 6.04(c) (Safety Databases) (with respect to expiration, but not termination), 6.04(d) (Reporting of Adverse Drug Reactions), 6.04(e) (Literature for marketed products) (with respect to expiration, but not termination), 6.04(f) (Signal detection/Safety Monitoring) (with respect to expiration, but not termination), 6.04(g) (Periodic reports) (with respect to expiration, but not termination), 6.05 (Assistance) (with respect to the applicable surviving terms of this Agreement), 6.06 (Compliance) (with respect to expiration, but not termination), 7.02 (Filing, Prosecution, and Maintenance of Patents Covering Collegium Improvements), 7.03 (Prosecution of Infringement) (for infringements that occurred during the Term), 7.05 (Infringement Claimed by Third Parties), 7.06 (Payment of Costs and Expenses) (with respect to the applicable surviving terms of Article VII), 11.01 (Access to Books and Records), 11.03 (Affiliates) (with respect to the applicable surviving terms of this Agreement), 11.04 (Compliance) (with respect to expiration, but not termination), 11.05 (Reports) (with respect to expiration, but not termination), 11.07 (Protection of the Licensed Marks) (with respect to expiration, but not termination), 11.08 (Equitable Relief) and 11.10 (Right of First Negotiation; Right of First Refusal) (for any ROFN Product for which an ROFN Notice was or should have been given during the Term) and Articles I (Definitions), VIII (Confidentiality), IX (Representations and Warranties) (except Section 9.13 with respect to termination), X (Indemnification; Insurance; Limitation of Liability), XII (Product Recall), XIII (Term and Termination) and XIV (Miscellaneous) shall survive expiration or termination of this Agreement.

(d) Subject to the provisions of this Section 13.06, and except as necessary to enable the exercise of any rights granted under this Agreement or perform any obligations under this Agreement following its termination, within *** following the termination of this Agreement by either Party, each Party shall return to the other Party, or destroy, upon the written request of the other Party, any and all Confidential Information of the other Party in its possession and upon a Party's request, such destruction (or delivery) shall be confirmed in writing to such Party by a responsible officer of the other Party.

(e) In the event BDSI's rights with respect to Licensed Products under the Licensed Technology, Licensed Marks, and any other intellectual property rights which are the subject of Collegium's licenses under this Agreement are, in the case of a termination of the CDC Agreement by CDC pursuant to Section 10.2 or 10.3 thereof, exclusively licensed and assigned to CDC then the rights and benefits of BDSI under this Agreement, to the extent (i) not imposing obligations in excess of those imposed on CDC under the CDC Agreement (any such excess cost or obligation, an "Excess Requirement") and (ii) relating to the rights of BDSI subject to the above referenced termination by CDC, shall be automatically assigned to CDC, as described in the CDC Consent to provide for Collegium's continued quiet enjoyment of the rights granted to it under this Agreement in accordance with its terms. If Collegium asks CDC to satisfy any Excess Requirement, CDC declines to satisfy such Excess Requirement, Collegium asks BDSI to satisfy such Excess Requirement, and BDSI declines to satisfy such Excess Requirement, then BDSI represents and warrants that CDC and BDSI shall have agreed in the CDC Consent that, at

Collegium's own expense, Collegium may (but shall not be obligated to) undertake, perform or satisfy such Excess Requirement, in whole or in part, or take such other actions as it reasonably determines in good faith are reasonably consistent with maintaining the benefits intended for Collegium under this Agreement.

Section 13.07 ***Suspension of Cure Period Pending Dispute Resolution.*** If a Party gives notice of breach under Section 13.02 or Section 13.03 and the other Party, acting in good faith, disputes in writing prior to the end of the applicable cure period whether such notice was proper, then the issue of whether a material breach has occurred shall be resolved in accordance with Section 14.03. If as a result of such dispute resolution process it is determined that the notice of breach was proper, then such notice shall be deemed to have been effective if the breaching Party fails thereafter to cure such breach in accordance with the determination made in the resolution process within the applicable cure period following such determination. If as a result of such dispute resolution process it is determined that the notice of breach was improper, then no such notice shall be deemed to have been effective and this Agreement shall remain in effect. All of the terms and conditions of this Agreement, including all of the licenses granted hereunder, shall remain in full force and effect during the pendency of such dispute resolution process.

ARTICLE XIV

MISCELLANEOUS

Section 14.01 ***Assignment***. Except as explicitly contemplated by this Agreement, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided*, however, that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent (a) in connection with the transfer or sale of all or substantially all of the business of such assigning Party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise, or (b) to any of its Affiliates. Notwithstanding the foregoing, any such assignment to an Affiliate shall not relieve the assigning Party of its responsibilities for performance of its obligations under this Agreement, so long as such Affiliate remains an Affiliate of the assigning Party. Each Party shall promptly notify the other Party of any purported assignment of this Agreement. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any purported assignment not in accordance with this Agreement shall be void.

Section 14.02 ***Force Majeure***. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including, but not limited to, fire, floods, embargoes, terrorism, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any Governmental Authority or the other Party, or for any other reason which is completely beyond the reasonable control of the Party (collectively a "*Force Majeure*"); provided that the Party whose performance is delayed or prevented shall continue to use good faith diligent efforts to mitigate, avoid or end such delay or failure in performance as soon as practicable.

Section 14.03 ***Governing Law; Jurisdiction; Dispute Resolution***.

(a) This Agreement shall be governed by and construed under the state laws of the State of New York, without reference to its conflicts of laws principles.

(b) In the event that any controversy or claim shall arise between the Parties under, out of, in connection with, or relating to this Agreement or the breach thereof, the Party initiating such controversy or making such claim shall provide to the other Party written notice containing a brief and concise statement of the initiating Party's claims, together with relevant facts supporting them. During a period of ***, or such longer period as may be mutually agreed upon in writing by the Parties, following the date of said notice, the Parties shall make good faith efforts to settle the dispute. Such efforts may include, but shall not be limited to, full presentation of both Parties' claims and responses, with or without the assistance of counsel, before the chief executive officers (or their designees) of the Parties. If for whatever reason the Parties are unable to resolve the dispute within *** after the issuance of a notice

of dispute, then either Party may, by written notice to the other Party, submit the dispute to binding arbitration in accordance with the provisions of Section 14.03(c).

(c) In the event that the Parties have been unable to reach accord using the procedures set forth in Section 14.03(b), either Party may seek final resolution of the matter through binding arbitration upon written notice to the other Party. The failure of a Party to comply with the provisions of Section 14.03(b) with respect to any controversy or claim shall, except as set forth in Section 14.03(d), constitute an absolute bar to the institution of any proceedings, by arbitration or otherwise, by such Party with respect to such controversy or claim. Any such arbitration shall be held in a location that is mutually agreed upon by the Parties, which provides neither party an advantage (or, if the Parties are unable to agree on a location within *** of the initiation of arbitration hereunder, such location shall be New York, New York), in the English language before a single independent, neutral arbitrator, who shall be selected by agreement of the Parties, or, if the Parties cannot agree within *** after commencement of arbitration, then by the American Arbitration Association ("*AAA*") in accordance with the then existing Commercial Arbitration Rules of the AAA (the "*Rules*") and judgment upon the award rendered by the arbitrator may be entered or enforced in any court having jurisdiction thereof. The arbitrator shall have at least twenty (20) years' experience in pharmaceutical patent licensing. The arbitrator shall permit the Parties to have discovery to the extent permitted by the Rules. The decision of the arbitrator shall be final and binding on the Parties and shall be accompanied by a written opinion of the arbitrator explaining the arbitrator's rationale for its decision. Except as may otherwise be determined by the arbitrator in its award to be just and appropriate in light of the particular circumstances and outcome of the arbitration, the Party losing the arbitration shall pay all fees and costs of the arbitrator and the AAA and reimburse the prevailing Party for its reasonable attorneys' fees, costs, expenses, and disbursements (including, for example, expert witness fees and expenses, photocopy charges and travel expenses). The intent of the Parties is that, except for the entering of an arbitration order in a court of competent jurisdiction or as set forth in Section 14.03(d), disputes shall be resolved finally in arbitration as provided above, without appeal, and without recourse to litigation in the courts.

(d) Notwithstanding the foregoing provisions of this Section 14.03, (i) each Party shall be entitled to seek injunctive or equitable relief to enforce the respective covenants and agreements of the Parties in this Agreement (including with respect to any breach or threatened breach of confidentiality or to enforce provisions of this Agreement relating to ownership rights in intellectual property or the assignment of assets) and (ii) either Party may initiate an action before any court having competent jurisdiction in order to obtain interim or conservatory relief, such as an order to preserve the status quo and to avoid incurring irreparable harm pending the resolution of any dispute that is submitted to arbitration, to prevent or enjoin, without in either case complying with the procedures set forth in Section 14.03(b) or 14.03(c).

Section 14.04 ***Waiver***. No waiver of any term or condition of this Agreement shall be effective unless set forth in a written instrument duly executed by or on behalf of the waiving Party. Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

Section 14.05 ***Severability***. In case any provision of this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. Any provision of this Agreement held invalid or unenforceable in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

Section 14.06 ***Notices***. All notices and other communications provided for herein shall be dated and in writing and shall be deemed to have been duly given (a) on the date of delivery, if delivered personally, by e-mail or by facsimile machine, receipt confirmed, (b) on the following business day, if delivered by a nationally recognized overnight courier service, with receipt acknowledgement requested, or (c) three (3) business days after mailing, if sent by registered or certified mail, return receipt requested, postage prepaid, in each case, to the Party to whom it is directed at the following address (or at such other address as any Party hereto shall hereafter specify by notice in writing to the other Parties hereto):

If to BDSI: BioDelivery Sciences International, Inc.

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

4131 Parklake Avenue, Suite #225
Raleigh, North Carolina 27612
Attn: Mark Sirgo, Chief Executive Officer
Telephone: 919-582-9050
Facsimile: 919-582-9051

Copies (which shall not constitute notice) to: Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, North Carolina 27607 USA
Attn: Jason S. Wood
Telephone: (919) 781-4000
Facsimile: (919) 781-4865

If to Collegium: Collegium Pharmaceutical, Inc.
780 Dedham Street, Suite 800
Canton, MA 02021
Attn: Paul Brannelly, Chief Financial Officer
Telephone: 781-713-3734
Facsimile: 781-828-4697

Copies (which shall not constitute notice) to: Gunderson Dettmer LLP
One Marina Park Drive, Suite 900
Boston, Massachusetts, 02210 USA
Attn: Timothy H. Ehrlich
Telephone: (617) 648-9119
Facsimile: (617) 648-9120

Section 14.07 ***Independent Contractors***. It is expressly agreed that BDSI and Collegium shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership or agency of any kind. Neither BDSI nor Collegium shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

Section 14.08 ***Rules of Construction***. The Parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the Party drafting such agreement or document. Whenever the context hereof shall so require, the singular shall include the plural, the male gender shall include the female gender and neuter, and vice versa.

Section 14.09 ***Publicity***. Collegium and BDSI shall consult with each other before issuing any press release with respect to this Agreement or the transactions contemplated hereby and neither shall issue any such press release or make any such public statement without the prior consent of the other, which consent shall not be unreasonably withheld; provided, however, that a Party may, without the prior consent of the other Party, issue such press release

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

or make such public statement as may upon the advice of counsel be required by law or the rules and regulations of the Nasdaq or any other stock exchange. No such consent of the other Party shall be required to release information which has previously been made public.

Section 14.10 ***Entire Agreement; Amendment***. This Agreement (including the Exhibits attached hereto) sets forth all of the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations conditions or understandings, either oral or written, between the Parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

Section 14.11 ***Audit and Inspection Rights***. Upon *** prior written notice from either Party (the "*Requesting Party*"), the Party receiving such notice (the "*Audited Party*") shall permit an independent certified public accountant selected by the Requesting Party (or any designee thereof, including with respect to BDSI, Meda) and reasonably acceptable to the Audited Party (with respect to inspections or audits directly concerning financial matters) or any designee selected by the Requesting Party and reasonably acceptable to the Audited Party (with respect to inspections or audits not directly concerning financial matters) to audit and/or inspect only those Books and Records (including but not limited to financial records) as may be necessary pursuant to the terms of the applicable Section of this Agreement granting the applicable audit and/or inspection rights to the Requesting Party pursuant to this Section 14.11; provided, however, that in no event may any audit and/or inspection right granted under any Section of this Agreement be conducted more than once in any Calendar Year, unless otherwise agreed by the Audited Party. Any such independent accounting firm or designee shall be subject to the confidentiality provisions of this Agreement. In the case of any audit and/or inspection directly concerning financial matters, a copy of any report provided to a Party by the accountant shall be given concurrently to the other Party and shall be considered the Audited Party's Confidential Information. Subject to the terms of this paragraph, any such inspection or audit shall be conducted (a) at the sole cost of the Requesting Party and (b) during the Audited Party's normal business hours. If the applicable audit involves payments made and/or to be made by one Party to the other Party and such accounting firm concludes that there was an overpayment or underpayment by one Party to the other Party with respect thereto, within *** of the date of delivery of such accounting firm's report concluding that an overpayment or underpayment occurred, the amount overpaid shall be promptly repaid by the overpaid Party or the amount underpaid shall be promptly augmented by the underpaying Party as necessary to correct the underpayment, and if there was an underpayment, the underpaying Party shall pay interest on the unpaid amount at the rate set forth in Section 4.03(c). If the amount of such underpayment for any particular Calendar Quarter was equal to or greater than *** of the proper amount payable with respect to such Calendar Quarter, the Audited Party shall promptly reimburse the Requesting Party for the reasonable, documented costs associated with the audit. The Parties agree that the rights granted to BDSI under this Section 14.11 may be exercised by CDC in a manner consistent with similar rights established with respect to CDC in the CDC Agreement.

Section 14.12 ***Headings***. The captions contained in this Agreement are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles hereof.

Section 14.13 ***Counterparts***. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures to this Agreement may be transmitted via facsimile and such signatures shall be deemed to be originals.

Section 14.14 ***Third Party Beneficiary***. CDC shall be an intended third party beneficiary to this Agreement for the sole purpose of enforcing Sections 7.01, 10.02, 11.01, 11.11, and 13.06(e) and enforcing BDSI's rights under Sections 2.03, 2.04, 2.05, 3.02(a), 4.03, 6.03, 6.04, and 11.05.

Section 14.15 ***CREATE Act***. This Agreement includes a joint research agreement as defined in 35 U.S.C. § 103(c)(3).

[Signature page to follow.]

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorized officers as of the Effective Date.

ARIUS PHARMACEUTICALS, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and Chief Executive Officer

BIODELIVERY SCIENCES
INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and Chief Executive Officer

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Michael Heffernan
Name: Michael Heffernan
Title: Chief Executive Officer

EXHIBIT A

LICENSED MARKS

Mark	Class	Registration Number	Registration Date	Register
ONSOLIS	5	3723904	December 8, 2009	PRINCIPAL

EXHIBIT B

LICENSED PATENTS

Title	*Patent or Application No.*	*Expiration Date*	*Owner*
Bioerodable Film For Delivery Of Pharmaceutical Compounds Of Mucosal Surfaces	*6,159,498*	October 18, 2016	ARIUS TWO, INC.
Pharmaceutical Carrier Device Suitable For Delivery Of Pharmaceutical Compounds To Mucosal Surfaces	*7,579,019*	January 22, 2020	ARIUS TWO, INC.
Transmucosal Delivery Devices With Enhanced Uptake	*14/746,168*	July 23, 2027	BIODELIVERY SCIENCES INTERNATIONAL, INC.
Mucoadhesive Devices For Treatment Of Pain And Opioid Dependence	*14/875,107*	August 20, 2032 or March 7, 2034, if issued, depending on the priority claim	BIODELIVERY SCIENCES INTERNATIONAL, INC

EXHIBIT C

PERMITTED COLLEGIUM DEVELOPMENT/MANUFACTURING ACTIVITIES

- Investigator initiated studies involving ONSOLIS® with academic, government, and private institutions.

EXHIBIT D

MFG TRANSFER PLAN

***

Additional Terms & Conditions

- Changes in raw material prices will impact the quoted pricing
- Charges may be incurred if order is cancelled or postponed after placement of purchase order.
- Warehousing and/or disposal fees may be incurred for material stored at *** longer than 90 days without production activity.

EXHIBIT E

LICENSED MARK GUIDELINES

Collegium shall indicate on any product package insert therefor, or promotional material that bears or displays a Licensed Trademark that "The trademark ONSOLIS is used under license." Collegium shall comply with any additional reasonable guidelines for usage of the Licensed Marks that BDSI may provide and that BDSI may modify from time to time.

Guidelines for Use of Domain Names. Collegium shall post on all websites associated with the ONSOLIS related domain names (a) a privacy policy that complies with all applicable law; (b) a Terms of Use policy that complies with all applicable laws, and contains commercially reasonable provisions that BDSI may request from time to time; and (c) statements on the home page that (i) the website and its content are intended for USA audiences; and (ii) "The trademark ONSOLIS is used under license." Collegium shall adopt and implement commercially reasonable measures to protect and preserve the security of personal information collected through websites associated with the ONSOLIS related domain names. Collegium shall comply with any additional guidelines for usage of the ONSOLIS related domain names that BDSI may provide and that BDSI may modify from time to time.

Collegium shall not adopt, use, register or apply for registrations anywhere in the world for the Licensed Marks and ONSOLIS related domain names or any other Trademarks or domain names that (i) are likely to cause confusion with the Licensed Marks or ONSOLIS related domain names; (ii) are variations of the Licensed Marks or ONSOLIS related domain names; or (iii) incorporate the Licensed Marks or ONSOLIS related domain names. In using the Licensed Marks and ONSOLIS related domain names pursuant to this Agreement, Collegium shall in no way represent that it has any rights, title or interest in the Licensed Marks and ONSOLIS related domain names other than those expressly granted under this Agreement.

EXHIBIT F

BDSI LEGAL PROCEEDINGS

BioDelivery Sciences International, Inc. and Arius Two, Inc., v. Actavis Laboratories UT, Inc., and Actavis, Inc., Civil Action No. 16-cv-175, United States District Court for the District of Delaware

*** Confidential Information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

Exhibit 31.1

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

I, Michael T. Heffernan, 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)) 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 is made known to us by others within the registrant, particularly during the period in which this report is being prepared;

b) 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

c) 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/ MICHAEL T. HEFFERNAN

Michael Heffernan
President and Chief Executive Officer

Date: August 11, 2016

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)) 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 is made known to us by others within the registrant, particularly during the period in which this report is being prepared;

b) 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

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

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

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

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

/s/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: August 11, 2016

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Michael T. Heffernan, 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/ MICHAEL T. HEFFERNAN

Michael Heffernan
President and Chief Executive Officer

Date: August 11, 2016

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Brannelly, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

/s/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: August 11, 2016