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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

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 October 31, 2015 there were 20,688,914 shares of Common Stock, $0.001 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report 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,” “will,” “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 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;
- the size and growth potential of the markets for our product candidates, and our ability to service those markets;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the rate and degree of market acceptance of our 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 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 success of competing products that are or become available;
- 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, future 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 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.

See (i) the section entitled “Risk Factors” in our Current Report on Form 8-K, filed with the United States Securities and Exchange Commission (the “SEC”), on June 19, 2015, (ii) Part II, Item 1A in our Quarterly Report on Form 10-Q for the Quarterly period ended June 30, 2015, filed with the SEC on August 12, 2015 and (iii) those risks described from time to time in other reports which we file with the SEC, for a more complete discussion of these risks and uncertainties and for other risks and uncertainties. Those factors and the other risk factors described therein are not necessarily all of the important factors that could cause actual results or developments to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. Consequently, there can be no assurance that actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited).

Collegium Pharmaceutical, Inc.

CONDENSED BALANCE SHEETS

(unaudited)

(in thousands, except share and per share amounts)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 105,460	$ 1,634
Refundable PDUFA fee	—	2,335
Prepaid expenses and other current assets	866	527
Total current assets	106,326	4,496
Property and equipment, net	627	514
Restricted cash	97	80
Total assets	$ 107,050	$ 5,090
Liabilities, convertible redeemable preferred stock and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,237	$ 2,208
Accrued expenses	2,681	1,956
Current portion of deferred rent and lease note payable	15	59
Current portion of term loan payable	2,667	1,194
Convertible bridge notes with related parties	—	5,000
Total current liabilities	8,600	10,417
Lease incentive obligation	76	101
Term loan payable, long-term	4,813	6,813
Total liabilities	13,489	17,331
Commitments and contingencies (See Note 9)		
Series A convertible redeemable preferred stock, $0.001 par value; authorized shares — none at September 30, 2015 and 18,498,419 at December 31, 2014; issued and outstanding shares — none at September 30, 2015 and 9,232,334 at December 31, 2014; liquidation preference of none at September 30, 2015 and $12,781 at December 31, 2014	—	12,781
Series B convertible redeemable preferred stock, $0.001 par value; authorized shares - none at September 30, 2015 and 27,324,237 at December 31, 2014; issued and outstanding shares - none at September 30, 2015 and 27,324,237 at December 31, 2014; liquidation preference of none at September 30, 2015 and $51,212 at December 31, 2014	—	51,212
Series C convertible redeemable preferred stock, $0.001 par value; authorized shares - none at September 30, 2015 and 8,658,344 at December 31, 2014; issued and outstanding shares - none at September 30, 2015 and 8,658,008 at December 31, 2014; liquidation preference of none at September 30, 2015 and $13,114 at December 31, 2014	—	13,114
Series D convertible redeemable preferred stock, $0.001 par value; authorized shares - none at September 30, 2015 and December 31, 2014; issued and outstanding shares - none at September 30, 2015 and December 31, 2014; liquidation preference of none at September 30, 2015 and December 31, 2014	—	—
Shareholders' equity (deficit):		
Common stock, $0.001 par value; authorized shares - 100,000,000 at September 30, 2015 and 72,000,000 at December 31, 2014; issued and outstanding shares - 20,687,829 at September 30, 2015 and 1,006,219 at December 31, 2014	20	1
Additional paid-in capital	213,027	12,407
Accumulated deficit	(119,483)	(101,753)
Treasury stock	(3)	(3)
Total shareholders' equity (deficit)	93,561	(89,348)
Total liabilities, convertible redeemable preferred stock and shareholders' equity (deficit)	$ 107,050	$ 5,090

See accompanying notes to the unaudited condensed financial statements.

Collegium Pharmaceutical, Inc.

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 3,358	$ 5,818	$ 6,444	$ 12,652
General and administrative	5,907	687	11,027	1,686
Total operating expenses	9,265	6,505	17,471	14,338
Loss from operations	(9,265)	(6,505)	(17,471)	(14,338)
Other expense:				
Interest expense, net	97	51	350	110
Gain on extinguishment	-	-	(91)	-
Total other expense, net	97	51	259	110
Net loss	$ (9,362)	$ (6,556)	$ (17,730)	$ (14,448)
Net loss per share - basic and diluted	$ (0.46)	$ (7.85)	$ (0.94)	$ (18.26)
Weighted-average number of common shares used in net loss per share-basic and diluted	20,531,406	940,627	11,179,756	926,597

See accompanying notes to the unaudited condensed financial statements.

Collegium Pharmaceutical, Inc.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine months ended September 30,	
	2015	**2014**
Operating activities		
Net loss	$ (17,730)	$ (14,448)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	130	141
Lease incentive	(25)	(25)
Stock-based compensation expense	1,217	16
Non cash interest expense	6	6
Accrual of back end fees related to note payable	-	(12)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(338)	(139)
Refundable PDUFA fee	2,335	—
Accounts payable	962	1,563
Accrued expenses	815	2,518
Net cash used in operating activities	(12,628)	(10,380)
Investing activities		
Purchases of property and equipment	(175)	—
Net cash used in investing activities	(175)	—
Financing activities		
Proceeds from issuance of common stock, net of issuance costs of $2,408	72,029	—
Proceeds from issuance of Series D convertible redeemable preferred stock, net of issuance costs of $193	44,807	—
(Repayment of) borrowing from term note	(619)	7,044
Repayment of lease note payable	(44)	(46)
Restricted cash	(16)	—
Proceeds from the exercise of stock options	472	9
Net cash provided by financing activities	116,629	7,007
Net increase (decrease) in cash and cash equivalents	103,826	(3,373)
Cash and cash equivalents at beginning of period	1,634	7,551
Cash and cash equivalents at end of period	$ 105,460	$ 4,178
Supplemental disclosure of non-cash activities		
Preferred stock conversion to common stock	$ 120,302	$ —
Accruals of dividends and accretion to redemption value	$ 24,572	$ 2,469
Conversion of bridge note to preferred stock	$ 5,000	$ —
Cash paid for interest	$ 260	$ 46
Cash paid for taxes	$ 4	$ —
Repayment of term note with proceeds of notes payable	$ —	$ 944

See accompanying notes to the unaudited condensed financial statements.

Collegium Pharmaceutical, Inc.

NOTES TO CONDENSED 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 planning to commercialize next-generation abuse-deterrent products that incorporate the Company’s patented DETERx® platform technology for the treatment of chronic pain and other diseases. The Company’s lead product candidate, Xtampza ER™, or Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. Xtampza has received Fast Track status from the U.S. Food and Drug Administration (‘‘FDA’’). The Company’s new drug application (‘‘NDA’’) filing for Xtampza was accepted by the FDA on February 10, 2015. On February 25, 2015, the FDA set a Prescription Drug User Fee Act, or PDUFA, goal date of October 12, 2015 for completion of its review of the Xtampza NDA. On November 6, 2015, the FDA granted tentative approval to the Xtampza NDA 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. With a tentative approval, the FDA has determined that Xtampza meets the required quality, safety and efficacy standards for approval but that it is subject to an automatic stay of up to 30 months as a result of patent litigation filed by Purdue Pharma, L.P (Purdue) in March 2015.

The Company’s operations are subject to certain risks and uncertainties. The principal risks include negative outcome of clinical trials, inability or delay in completing clinical trials or obtaining regulatory approvals, changing market conditions for products being developed by the Company, 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.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited condensed 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 management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. 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. Additionally, operating results for the interim periods ended September 30, 2015 and 2014 are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The condensed interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Prospectus dated May 6, 2015 (“Prospectus”) filed pursuant to Rule 424 (b) (4) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission (“SEC”) on May 7, 2015 in conjunction with the Company’s initial public offering of common stock.

Initial Public Offering

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 condensed 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. The significant increase in common stock outstanding in May 2015 is expected to impact the year-over-year comparability of the Company's net loss per share calculations in future periods.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Through the date of the filing of this Form 10-Q, the Company has concluded that no subsequent events have occurred that require disclosure, except as described in Note 9.

Critical Accounting Policies

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 stock 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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB"), issued Accounting Standards Update ("ASU"), No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC"), Topic 605, Revenue Recognition, and creates a new Topic 606, Revenue from Contracts with Customers. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. On August 12, 2015, the FASB issued ASU No. 2015-14, which defers the effective date of ASU No. 2014-09 by one year to December 15, 2017 for annual reporting periods beginning after that date, including interim periods within those periods. The FASB also approved permitting early adoption of the standard, but not before the original effective date of December 15, 2016. The Company has not yet determined which adoption method it will utilize or the effect that the adoption of this guidance will have on its financial statements.

In July 2015, the FASB issued ASU No. 2015-11, which amends existing guidance for measurement of inventory. Current inventory guidance requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost. An entity should measure all inventory to which the amendments apply at the lower of cost and net realizable value.

Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in the ASU No. 2015-11 more closely align the measurement of inventory pursuant to GAAP with the measurement of inventory pursuant to International Financial Reporting Standards. The amendments are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not expect the adoption of this guidance to have a material impact on its condensed financial statements.

3. Net Loss per Common Share

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Net loss	$ (9,362)	$ (6,556)	$ (17,730)	$ (14,448)
Extinguishment of preferred stock - see note 7	—	—	31,806	—
Accretion of prior preferred stock - see note 7	—	(832)	(23,327)	(2,469)
Accretion and dividends of Series D preferred stock	—	—	(1,245)	—
Loss attributable to common shareholders — basic and diluted	$ (9,362)	$ (7,388)	$ (10,496)	$ (16,917)
Weighted-average number of common shares used in net loss per share—basic and diluted	20,531,406	940,627	11,179,756	926,597
Net loss per share—basic and diluted	$ (0.46)	$ (7.85)	$ (0.94)	$ (18.26)

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Outstanding stock options	1,356,246	311,365	1,356,246	311,365
Warrants	2,445	18,810	2,445	18,810
Redeemable convertible preferred stock	-	6,552,820	-	6,552,820
Unvested restricted stock	153,589	28,536	153,589	28,536

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

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at September 30, 2015 and December 31, 2014.

Description	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2015				
Money market funds, included in cash equivalents	$104,911	$ 104,911	$ —	$ —
December 31, 2014				
Money market funds, included in cash equivalents	$ 457	$ 457	$ —	$ —

The Company's cash equivalents are comprised of money market funds that are measured on a recurring basis based on quoted market prices.

5. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2015	December 31, 2014
Accrued compensation	$ 1,169	$ 635
Accrued development costs	597	970
Accrued marketing	685	—
Accrued audit and legal	109	249
Accrued interest	31	71
Accrued other	90	31
Total accrued expenses	$ 2,681	$ 1,956

6. 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 7), the Bridge Notes converted into Series D convertible preferred stock. Upon the conversion, the Company recognized a gain on extinguishment of $91.

7. Convertible Preferred Stock

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 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. During the nine months and three months ended September 30, 2015, total accrued dividends and accretion for preferred stock was $24,572 and none, respectively.

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.

8. Stock-based Compensation

In July 2014, the Company adopted the 2014 Stock Incentive Plan (the "Plan"), under which 525,700 shares of common stock are authorized for issuance to employees, officers, directors, consultants and advisors of the Company. In connection with the Company's reincorporation into Virginia in July 2014, each outstanding option to purchase shares of common stock under the Company’s 2012 Stock Incentive Plan and 2002 Stock Plan, was automatically terminated and replaced with an option to purchase shares of common stock under the Plan having the same vesting terms and exercise price as the option that was replaced. 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 contain 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.

In April 2015, the Plan was amended to increase the maximum number of shares of common stock that may be issued to 2,700,000 shares. In addition, an “evergreen provision” was added to the Plan that allows for an annual increase in the number of shares of common stock available for issuance under the Plan. The annual increase will be added on the first day of each fiscal year beginning with the fiscal year ending December 31, 2016, and on each anniversary thereof until the expiration of the Plan equal to 4% of the outstanding shares of our common stock on December 31st of the immediately preceding fiscal year (or such lesser number of shares of common stock as determined by the board of directors).

Restricted common stock

A summary of the Company’s restricted stock activity for the nine months ended September 30, 2015 and related information is as follows:

	Shares	Weighted average purchase price per share
Unvested at December 31, 2014	15,387	$ 0.69
Granted	194,694	5.73
Vested	(128,955)	5.13
Unvested at September 30, 2015 (1)	81,126	$ 5.73

(1) Excludes 72,463 shares of unvested restricted stock remaining from the early exercise of stock options as of September 30, 2015.

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, 2014	281,029	$ 0.69		
Granted	1,197,452	10.47		
Exercised	(121,729)	3.89		
Cancelled	(506)	2.06		
Outstanding at September 30, 2015	1,356,246	$ 9.04	9.2	$ 17,722
Exercisable at September 30, 2015	208,438	$ 2.65	7.9	$ 4,056
Vested and expected to vest at September 30, 2015	1,341,543	$ 9.13	9.2	$ 18,595

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

	Nine months ended September 30,	
	2015	2014
Risk-free interest rate	1.7 %	1.8 %
Dividend yield	-	-
Volatility	77 %	77 %
Expected term (years)	6.21	6.25

9. Commitments and Contingencies

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 can elect to sue the Company for infringement, and if they do, receive a stay of up to 30 months before the FDA can issue a final approval for Xtampza, unless the stay is earlier terminated. On March 24, 2015, Purdue sued the Company in the District of Delaware asserting infringement of four patents. On March 26, 2015, Purdue filed a second suit against the Company in the District of Massachusetts asserting infringement of the same four patents. On July 23, 2015, Purdue voluntarily dismissed the Massachusetts suit. On August 6, 2015, the Delaware court dismissed the suit in Delaware and issued a memorandum opinion finding the Delaware court lacks personal jurisdiction over the Company Following the dismissal in Delaware, on August 6, 2015, the Company filed a complaint in the Southern District of New York asserting an action to obtain patent certainty, and requesting that the New York court find that Xtampza will not infringe any valid patent claim of the patents asserted by Purdue in the Delaware action. Also on August 6, 2015, Purdue sued the Company in the District of Massachusetts asserting the same claims as the prior suit. On August 7, 2015, Purdue filed a motion in the Delaware court requesting reconsideration of the August 6, 2015 order that dismissed the case. In the motion requesting reconsideration, Purdue asked that the Delaware court find that it does have personal jurisdiction over the Company and then transfer the case to the District of Massachusetts. On October 7, 2015, the Delaware court transferred the case to the District of Massachusetts. On November 9, 2015, the Company filed a motion for summary judgment, for which it requested expedited hearing in Massachusetts. 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.

In March 2015, the Company amended its lease to include an additional 9,660 square feet of space for a total of 19,335 square feet. In addition, the lease term was extended and now terminates on the date that is 5 years following August 2015 which is the date that the landlord delivered the expansion space with certain improvements substantially completed. At the Company's election, the lease term may be extended for an additional 5-year term.

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 Current Report on Form 8-K filed with the SEC on June 19, 2015 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 planning to commercialize next-generation abuse-deterrent products that incorporate our patented DETERx platform technology for the treatment of chronic pain and other diseases. Our lead product candidate, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. Xtampza has received Fast Track status from the U.S. Food and Drug Administration, or FDA. Our new drug application, or NDA, filing for Xtampza was accepted by the FDA on February 10, 2015. On February 25, 2015, the FDA set a Prescription Drug User Fee Act, or PDUFA, goal date of October 12, 2015 for completion of its review of the Xtampza NDA. On November 6, 2015, the FDA granted tentative approval to the Xtampza NDA 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. With a tentative approval, the FDA has determined that Xtampza meets the required quality, safety and efficacy standards for approval but it is subject to an automatic stay of up to 30 months as a result of patent litigation filed by Purdue Pharma, L.P (Purdue) in March 2015.

As part of receipt of Tentative Approval for our NDA for Xtampza, we have agreed upon a product label, product packaging, and REMS program, among other things, with the FDA, subject to change should new information become available prior to FDA granting final approval. Certain human abuse potential studies are included in the agreed-upon label, as well as data supporting the administration of the product as a sprinkle or administered via an NG/G Tube.

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, 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, if approved, 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.

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 as we currently have no approved products, 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.

Outlook

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $17.7 million and $14.4 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of $119.5 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur net losses in the foreseeable future as we seek regulatory approval for, and, if approved, 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:

- 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.

If we obtain regulatory approval for Xtampza, we expect to incur significant commercialization expenses related to marketing, manufacturing, distribution, product sales and reimbursement functions. Initially we plan to detail Xtampza to approximately 10,000 physicians who write more than 50% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 100 sales representatives. In addition, we plan to deploy 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 our product candidates.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

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

The critical accounting policies we identified in the Prospectus related to accrued expenses, impairment of long-lived assets, convertible redeemable preferred stock, stock-based compensation and income taxes. There were no changes to these critical accounting policies in the quarter ended September 30, 2015. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in the Prospectus.

RESULTS OF OPERATIONS

Comparison of the Nine Months ended September 30, 2015 and September 30, 2014

Research and development expenses were $12.7 million for the nine months ended September 30, 2014 (the “2014 Period”), compared to $6.4 million for the nine months ended September 30, 2015 (the “2015 Period”). The $6.2 million decrease was primarily related to:

- a decrease in clinical trial costs of $8.1 million due to the completion of clinical trials for Xtampza during 2014;
- an increase in consulting costs of $1.2 million mainly due to costs associated with the FDA Advisory Committee meeting held in September 2015; and

- an increase in manufacturing costs of $1.0 million related to Xtampza.

General and administrative expenses were $1.7 million for the 2014 Period compared to $11.0 million for the 2015 Period. The $9.3 million increase was primarily related to:

- an increase in commercial costs of $3.4 million primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza;
- an increase in salaries, wages and benefits of $3.4 million primarily due to headcount, bonuses and stock compensation expense;
- an increase in legal and consulting fees of $760,000 primarily due to costs related to litigation;
- an increase in insurance costs of $491,000 due to directors' and officers' insurance; and
- an increase in professional fees of $401,000 primarily due to audit, accounting and recruitment fees.

Comparison of the Three Months ended September 30, 2015 and September 30, 2014

Research and development expenses were $5.8 million for the quarter ended September 30, 2014 (the "2014 Quarter"), compared to $3.4 million for the quarter ended September 30, 2015 (the "2015 Quarter"). The $2.4 million decrease was primarily related to:

- a decrease in clinical trial costs of $4.4 million due to the completion of clinical trials with Xtampza during 2014 partially offset by;
- an increase in consulting costs of $1.1 million mainly due to costs associated with the FDA Advisory Committee meeting;
- an increase in manufacturing costs of $588,000 related to Xtampza; and
- an increase in salaries, wages and benefits of $251,000 primarily due to headcount and stock compensation expense.

General and administrative expenses were $687,000 for the 2014 Quarter compared to $5.9 million for the 2015 Quarter. The $5.2 million increase was primarily related to:

- an increase in commercial costs of $2.9 million primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza;
- an increase in salaries and wages of $1.6 million primarily due to increases in headcount, bonuses and stock compensation expense;
- an increase in insurance costs of $297,000 due to directors' and officers' insurance;
- an increase in legal and consulting fees of $266,000 primarily due to costs related to litigation; and
- an increase in professional fees of $214,000 primarily due to recruitment fees.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

We have incurred net losses and negative cash flows from operations since inception. Since inception, we have funded our operations primarily through the private placements of our preferred stock, our IPO, convertible notes and commercial bank debt. As of September 30, 2015, we had $105.5 million in cash and cash equivalents.

In March 2015, we issued 41,666,667 shares of Series D convertible preferred stock in exchange for aggregate consideration of $50.0 million, including $45.0 million in cash. In connection with this financing, convertible notes with related parties in the aggregate principal amount of $5.0 million automatically converted to an aggregate of 4,166,667 shares of Series D convertible preferred stock.

In May 2015, we closed our IPO, which resulted in the sale of 6,670,000 shares of our 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. We received net proceeds from the IPO of approximately $72.0 million, after deducting underwriting discounts, commission 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 mid-2017, including the commercialization of Xtampza, if approved, and the

continuation of our development of our other 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 on a recurring basis.

Cash flows

Operating activities. Cash used was $12.6 million in the 2015 Period and $10.4 million in the 2014 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 seek regulatory approval for, and, prepare to commercialize Xtampza by establishing sales, marketing, manufacturing and distribution capabilities and fund research, development and clinical activities for additional product candidates.

Investing activities. The cash used in the 2015 Period was related to the purchase of property and equipment. There was no cash used for investing activities in the 2014 Period.

Financing activities. The cash provided by financing activities for the 2015 Period primarily represent net proceeds from the IPO and from the sale of Series D convertible preferred stock of $72.0 million and $44.8 million, respectively. The cash provided by financing activities for the 2014 Period primarily reflects the $7.0 million drawdown of a term note payable.

Funding requirements

Since 2011, we have not generated any product revenue. We do not know when, or if, we will generate any revenue as we seek regulatory approval for, and potentially begin to commercialize, Xtampza. We anticipate that we will continue to incur losses for the next several years, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, Xtampza and our other product candidates, and begin to commercialize any approved products. We are subject to all of the risks common to the 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 public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from our pharmaceutical 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 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 other product candidates for clinical trials, preclinical studies 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 other product candidates, which may be expensive to defend and delay the commercialization of Xtampza or our other 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;
- the effect of competing technological and market developments; and
- the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval.

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 the Prospectus.

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 September 30, 2015, we had cash and cash equivalents consisting of cash and money market funds of $105.5 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 September 30, 2015. 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 (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2015, 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 September 30, 2015 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, unless the stay is earlier terminated. On March 26, 2015, Purdue filed a second suit against us in the District of Massachusetts asserting infringement of the four patents.

We have engaged experienced litigation counsel who worked carefully with us to construct a strategy to prevail in such litigation as expeditiously as possible. On April 6, 2015, in the District of Delaware case, we filed a motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York where three of the patents have already been invalidated. On July 23, 2015, Purdue voluntarily dismissed the Massachusetts suit. On August 6, 2015, the Delaware court dismissed the suit in Delaware and issued a memorandum opinion finding the Delaware court lacks personal jurisdiction over the Company. Following the dismissal in Delaware, on August 6, 2015, the Company filed a complaint in the Southern District of New York asserting an action to obtain patent certainty, and requesting that the New York court find that Xtampza will not infringe any valid patent claim of the patents asserted by Purdue in the Delaware action. Also on August 6, 2015, Purdue sued the Company in the District of Massachusetts asserting the same claims as the prior suit. On August 7, 2015, Purdue filed a motion in the Delaware court requesting reconsideration of the August 6, 2015 order that dismissed the case. In the motion requesting reconsideration, Purdue asked that the Delaware court find that it does have personal jurisdiction over the Company but transfer the case to the District of Massachusetts. On October 7, 2015, the Delaware court transferred the case to the District of Massachusetts. We plan to continue to take all steps necessary to vigorously defend ourselves against these claims. On November 9, 2015, the Company filed a motion for summary judgment, for which it requested expedited hearing, in Massachusetts. At this time we are unable to provide meaningful quantification of how this litigation may impact our business or future financial condition, results of operations, or cash flows.

Item 1A. Risk Factors.

There are no material changes from the risk factors previously disclosed under the heading "Risk Factors" in our Current Report on Form 8-K filed with the SEC on June 19, 2015, or the Form 8-K, and in Item 1A "Risk Factors" in Part II of our quarterly report on Form 10-Q for the quarterly period ended June 30, 2015 filed on August 12, 2015, or the Second Quarter 2015 Form 10-Q. In addition to the other information set forth in this Form 10-Q, you should carefully consider the factors discussed in the Form 8-K and the Second Quarter 2015 Form 10-Q. The risks described in the Form 8-K and the Second Quarter 2015 Form 10-Q are not the only risks that we face. Additional risks not presently known to us or that we do not currently consider significant may also have an adverse effect on us. If any of the risks actually occur, our business, results of operations, cash flows or financial condition could suffer. We cannot assure you that any of the events discussed in the risk factors in the Form 8-K and the Second Quarter 2015 Form 10-Q will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows and if so our future prospects would likely be materially and adversely affected. If any of such events were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. You should understand that it is not possible to predict or identify all such risks. Consequently, you should not consider the risk factors in the Form 8-K and the Second Quarter 2015 Form 10-Q to be a complete discussion of all potential risks or uncertainties.

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

RECENT SALES OF UNREGISTERED SECURITIES

From May 12, 2015 to September 30, 2015, 6,170 shares of common stock were acquired through the exercise of outstanding stock option awards under our equity incentive plan by certain employees, prior to the effectiveness of the Company's Registration Statement on Form S-8 filed on November 2, 2015. The exercise price for the options ranged from $0.90 to $3.38, and the gross proceeds from the exercises was approximately $13,000. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Rule 701 promulgated under the Securities Act.

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, $11.3 million of which have been utilized for the development of our commercial infrastructure, research and development of our other 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 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: November 12, 2015

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

Date: November 12, 2015

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

EXHIBIT INDEX

10.1	Employment Agreement, dated August 4, 2015, by and between Michael Heffernan and Collegium Pharmaceutical, Inc., incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed on August 10, 2015.
10.2	Employment Agreement, dated August 4, 2015, by and between Paul Brannelly and Collegium Pharmaceutical, Inc., incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed on August 10, 2015.
10.3	Employment Agreement, dated August 4, 2015 by and between Barry S. Duke and Collegium Pharmaceutical, Inc., incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, filed on August 12, 2015.
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

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: November 12, 2015

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: November 12, 2015

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended September 30, 2015 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: November 12, 2015

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended September 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Brannelly, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

/s/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: November 12, 2015