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, 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 October 31, 2016, there were 28,610,551 shares of Common Stock, $0.001 par value per share, outstanding.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

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

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

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

- our ability to obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our plans to commercialize 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 and third-party payor contracts 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, as revised and supplemented by our Quarterly Reports on Form 10-Q filed since the filing of our most recent Annual Report on Form 10-K, 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.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	September 30, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 91,028	$ 95,697
Accounts receivable, net	1,679	—
Inventory	1,576	—
Prepaid expenses and other current assets	1,086	1,186
Total current assets	95,369	96,883
Property and equipment, net	772	738
Intangible assets, net	2,273	—
Restricted cash	97	97
Other long-term assets	214	—
Total assets	$ 98,725	$ 97,718
Liabilities and shareholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 8,970	$ 3,537
Accrued expenses	6,637	2,228
Deferred revenue	3,938	—
Current portion of term loan payable	2,667	2,667
Total current liabilities	22,212	8,432
Lease incentive obligation	42	68
Term loan payable, long-term	2,146	4,146
Total liabilities	24,400	12,646
Commitments and contingencies (see note 11)		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at September 30, 2016 and December 31, 2015; issued and outstanding shares - none at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at September 30, 2016 and December 31, 2015; issued and outstanding shares - 23,588,985 at September 30, 2016 and 20,739,351 at December 31, 2015	24	21
Additional paid-in capital	269,929	214,062
Accumulated deficit	(195,625)	(129,008)
Treasury stock	(3)	(3)
Total shareholders' equity	74,325	85,072
Total liabilities and shareholders' equity	$ 98,725	$ 97,718

See accompanying notes to the condensed consolidated financial statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Product revenues, net	$ 408	$ —	$ 408	$ —
Costs and expenses				
Cost of product revenues	29	—	29	—
Research and development	3,254	3,358	11,617	6,444
Selling, general and administrative	23,567	5,907	55,266	11,027
Total costs and expenses	26,850	9,265	66,912	17,471
Loss from operations	(26,442)	(9,265)	(66,504)	(17,471)
Other expense (income)				
Interest expense, net	2	97	113	350
Gain on extinguishment of debt	—	—	—	(91)
Total other expense, net	2	97	113	259
Net and comprehensive loss	$ (26,444)	$ (9,362)	$ (66,617)	$ (17,730)
Loss per share - basic and diluted	$ (1.13)	$ (0.46)	$ (2.85)	$ (0.94)
Weighted-average shares - basic and diluted	23,460,340	20,531,406	23,334,558	11,179,756

See accompanying notes to the condensed consolidated financial statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine months ended September 30,	
	2016	**2015**
Operating activities		
Net loss	$ (66,617)	$ (17,730)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	360	130
Lease incentive	(25)	(25)
Stock-based compensation expense	4,137	1,217
Non cash interest expense	—	6
Changes in operating assets and liabilities:		
Accounts receivable	(1,679)	—
Inventories	(1,576)	—
Prepaid expenses and other assets	(114)	(338)
Refundable PDUFA fee	—	2,335
Accounts payable	5,401	962
Accrued expenses	4,409	815
Deferred revenue	3,938	—
Net cash used in operating activities	(51,766)	(12,628)
Investing activities		
Purchase of intangible assets	(2,500)	—
Purchases of property and equipment	(136)	(175)
Net cash used in investing activities	(2,636)	(175)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs of $526 and $2,408	51,619	72,029
Proceeds from issuance of Series D convertible redeemable preferred stock, net of issuance costs of $193	—	44,807
Repayment of term note	(2,000)	(619)
Repayment of lease note payable	—	(44)
Restricted cash	—	(16)
Proceeds from the exercise of stock options	114	472
Net cash provided by financing activities	49,733	116,629
Net (decrease) increase in cash and cash equivalents	(4,669)	103,826
Cash and cash equivalents at beginning of period	95,697	1,634
Cash and cash equivalents at end of period	$ 91,028	$ 105,460
Supplemental disclosure of cash flow information		
Cash paid for offering costs	$ 512	$ 1,703
Cash paid for interest	$ 226	$ 260
Supplemental disclosure of non-cash activities		
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 commercializing 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. In April 2016, the U.S. Food and Drug Administration ("FDA") approved the Company's new drug application ("NDA") filing for Xtampza for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, the Company announced the commercial launch of Xtampza.

The Company's operations are subject to certain risks and uncertainties. The principal risks include inability to successfully commercialize products, changing market conditions for products and product candidates (including development of competing products), changing regulatory environment and reimbursement landscape, negative outcome of clinical trials, inability or delay in completing clinical trials or obtaining regulatory approvals, 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 $195,625 at September 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, a follow-on offering completed in January 2016 and an additional follow-on offering completed in October 2016. The Company anticipates that it will continue to incur losses in the near future as it commercializes Xtampza and continues the development of, and seeks regulatory approvals for, other product candidates. The Company believes that its cash and cash equivalents at September 30, 2016, together with expected cash inflows from the commercialization of Xtampza, as well as the proceeds of its follow-on offering completed in October 2016 (see note 2), will enable the Company to fund its operating expenses, debt service and capital expenditure requirements into 2019.

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 September 30, 2016, the results of operations for the three and nine months ended September 30, 2016 and 2015, and cash flows for the nine months ended September 30, 2016 and 2015. The results of operations for the three and nine month periods ended September 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. The Company received proceeds from this public offering of approximately $51,174, after deduction of underwriting discounts and commissions and expenses payable by the Company.

The significant increase in common stock outstanding over the past 12 months 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 before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through the date of issuance of these financial statements.

In October 2016, the Company issued and sold in a public offering an aggregate of 5,000,000 shares of its common stock at $16.00 per share. The Company received net proceeds from this public offering of approximately $74,800 (or approximately $86,100 if the underwriters exercise their option to purchase 750,000 additional shares from the Company in full), after deduction of underwriting discounts and commissions and estimated expenses payable by the Company.

Significant Accounting Policies

Inventory

Inventories are stated at the lower of cost or net realizable value. 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 commercial manufacturing of Xtampza.

Prior to the approval of Xtampza by the FDA in April 2016, the Company recorded all costs incurred related to the manufacturing of Xtampza as research and development expense. Subsequent to approval, the Company began capitalizing these costs as inventory as they are incurred.

The Company has capitalized $1,576 of inventory as of September 30, 2016. The Company expects sales of the capitalized units to occur during the next twelve months. The Company expects costs of product revenues to increase due

to the expected increases in net product sales of Xtampza and the fact that the Company had expensed all manufacturing costs as research and development expense in periods prior to FDA approval of Xtampza. The impact on cost of product revenues as a result of inventory not capitalized prior to FDA approval is immaterial.

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 sells Xtampza in the United States principally to distributors and retailers ("customers"), which in turn sell the product to healthcare providers for the treatment of patients. The Company provides the right of return to its customers for unopened product for a limited time before and after its expiration date. Given the Company's limited sales history for Xtampza and the inherent uncertainties in estimating product returns, the Company has determined that the shipments of Xtampza made to its customers thus far do not meet the criteria for revenue recognition at the time of shipment. Accordingly, the Company recognizes revenue when the product is sold-through by its customers, provided all other revenue recognition criteria are met. The Company invoices its customers upon shipment of Xtampza and records accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price, less any realized adjustments to the gross invoice price. The Company then recognizes revenue when Xtampza is sold-through, or when product is prescribed directly to the patient. Healthcare providers to whom distributors sell Xtampza hold limited inventory that is designated for patients, thereby limiting the risk of return.

Advertising and Product Promotion Costs

Advertising and product promotion costs are included in selling, general and administrative expenses and were $3,486 and $10,492 in the three and nine months ended September 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 its financial statements as of and for the three and nine months ended September 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. Loss per Common Share

Diluted loss per share is computed using the more dilutive of (a) the two-class method, or (b) the if-converted method. The Company allocates loss 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 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 loss per share if their effect is antidilutive.

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Net loss	$ (26,444)	$ (9,362)	$ (66,617)	$ (17,730)
Extinguishment of preferred stock - see note 9	—	—	—	31,806
Accretion of prior preferred stock	—	—	—	(23,327)
Accretion and dividends of Series D preferred stock	—	—	—	(1,245)
Loss attributable to common shareholders — basic and diluted	$ (26,444)	$ (9,362)	$ (66,617)	$ (10,496)
Weighted-average number of common shares used in net loss per share - basic and diluted	23,460,340	20,531,406	23,334,558	11,179,756
Loss per share - basic and diluted	$ (1.13)	$ (0.46)	$ (2.85)	$ (0.94)

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,	
	2016	2015	2016	2015
Outstanding stock options	2,258,775	1,356,246	2,258,775	1,356,246
Warrants	2,445	2,445	2,445	2,445
Redeemable convertible preferred stock	—	—	—	—
Unvested restricted stock	95,159	153,589	95,159	153,589

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 (unadjusted) 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, 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)
September 30, 2016				
Money market funds, included in cash equivalents	$ 80,445	$ 80,445	$ —	$ —
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 September 30, 2016 and December 31, 2015, the carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, deferred revenue and loan payable approximated their estimated fair values because of the short-term nature of these financial instruments.

5. Inventory

Upon FDA approval of Xtampza in April 2016, the Company began capitalizing inventory costs for Xtampza in preparation for the product launch. Prior to April 2016, the Company expensed costs associated with Xtampza, including raw materials, work in process and finished goods, as research and development expense. 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 September 30, 2016:

	September 30, 2016
Raw materials	$ 437
Work in process	—
Finished goods	1,139
Total inventory	$ 1,576

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), or Onsolis, in the United States. Onsolis is a Transmucosal Immediate-Release Fentanyl ("TIRF") film indicated for the management of breakthrough pain in certain cancer patients. 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 $21,000 may become payable by the Company subject to the satisfaction of certain commercialization, intellectual property, and net sales milestones, including $4,000 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 $2,500 and is contractually committed to reimburse BDSI up to a maximum of $2,000 for its out-of-pocket expenses incurred in connection with the manufacturing transfer. The Company recorded the upfront payment as an intangible asset on the Condensed Consolidated Balance Sheet and will amortize it on a straight-line basis over the remaining patent life, a period of approximately 3.7 years. During the three and nine months ended September 30, 2016, the Company recognized amortization of expense of $227 related to the Onsolis intangible asset. As of September 30, 2016, the remaining amortization period is approximately 3.3 years and

estimated remaining amortization for 2016, 2017, 2018, 2019 and 2020 is expected to be $170, $682, $682, $682 and $57.

7. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2016	December 31, 2015
Accrued bonuses and incentive compensation	$ 2,887	$ 1,474
Accrued payroll and related benefits	1,383	93
Accrued development costs	980	80
Accrued other operating costs	585	186
Accrued sales & marketing	515	157
Accrued audit and legal	267	209
Accrued interest	20	29
Total accrued expenses	$ 6,637	$ 2,228

8. Convertible Bridge Note with Related Party

In November and December 2014, the Company entered into a Note Purchase Agreement providing for the issuance of $5,000 of convertible promissory notes (the "Bridge Notes") to a group of investors (the "Holders") bearing interest at a rate per annum of 6.0%. The Holders were related parties of the Company. In connection with the Series D convertible preferred stock financing (see note 9), 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 Bridge 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 loss 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 nine months ended September 30, 2016 were as follows:

	Common Stock		Additional Paid- In	Treasury Stock,		Total Shareholders'
	Shares	Amount	Capital	at cost	Accumulated Deficit	Equity (Deficit)
Balance, December 31, 2015	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	—	—	4,137	—	—	4,137
Exercise of common stock options	56,716	—	114	—	—	114
Issuance for employee stock purchase plan	42,918	—	445	—	—	445
Net loss	—	—	—	—	(66,617)	(66,617)
Balance, September 30, 2016	23,588,985	$ 24	$ 269,929	$ (3)	$ (195,625)	$ 74,325

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 on the first day of each fiscal year until the expiration of the Plan equal to 4% of the total number of outstanding shares of common stock on December 31st of the immediately preceding calendar year (or a lower amount as otherwise determined by the board of directors prior to January 1st). As of September 30, 2016, there were 1,114,652 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 activity for the nine months ended September 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	(24,336)	5.73
Unvested at September 30, 2016 (1)	51,382	$ 5.73

(1) Excludes 43,777 shares of unvested restricted stock remaining from the early exercise of stock options as of September 30, 2016.

A summary of the Company's restricted stock units activity for the nine months ended September 30, 2016 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2015	—	$ —
Granted	41,739	16.15
Settled	—	—
Forfeited	—	—
Outstanding at September 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 (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	1,452,149	$ 10.37	10.4	$ 24,887
Granted	970,481	16.50		
Exercised	(56,716)	2.01		
Cancelled	(107,139)	16.06		
Outstanding at September 30, 2016	2,258,775	$ 12.94	8.9	$ 14,340
Exercisable at September 30, 2016	483,752	$ 8.93	8.2	$ 5,011
Vested and expected to vest at September 30, 2016	2,229,823	$ 13.00	8.9	$ 14,616

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,	
	2016	2015
Risk-free interest rate	1.5 %	1.7 %
Volatility	77 %	77 %
Expected term (years)	6.02	6.21
Expected dividend yield	-	-

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Research and development expenses	$ 171	$ 73	$ 474	$ 150
Selling, general and administrative expenses	1,470	430	3,663	1,067
Total stock-based compensation expense	$ 1,641	$ 503	$ 4,137	$ 1,217

At September 30, 2016, there was approximately $15,792 of unrecognized compensation expense related to unvested options, restricted stock units and restricted stock awards, which is expected to be recognized as expense over a weighted average period of approximately 3.0 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, as revised and supplemented by our Quarterly Reports on Form 10-Q filed since the filing of our most recent 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 commercializing 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. In April 2016, the U.S. Food and Drug Administration, or FDA, approved our new drug application, or NDA, filing for Xtampza for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Certain human abuse potential studies are included in the approved label, as well as data supporting the administration of the product as a sprinkle or administered through feeding tubes. In June 2016, we announced the commercial launch of Xtampza, and in October 2016, we announced the submission of a New Drug Submission to Health Canada seeking marketing approval of Xtampza for the same indication for which we obtained approval from the FDA.

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 $2.3 billion in U.S. sales in 2015. 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 head-to-head clinical trials 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 October 2016, we announced the submission of a Supplemental New Drug Application to the FDA for Xtampza to include comparative oral pharmacokinetic data from a recently completed clinical study evaluating the effect of physical manipulation by crushing Xtampza compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release).

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. 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, pre-commercialization activities and the creation and protection of related intellectual property. Since 2011, we have not generated any significant 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 proceeds of public offerings and sale of our equity securities.

Outlook

We expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities. Initially, we plan to detail Xtampza to approximately 11,500 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.

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $66.6 million and $17.7 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $195.6 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 may increase 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 commercial stage public company.

We believe that our cash and cash equivalents at September 30, 2016, together with expected cash inflows from the commercialization of Xtampza, as well as the proceeds of our follow-on offering completed in October 2016, will enable us to fund our operating expenses, debt service and capital expenditure requirements into 2019. Accordingly, we will seek in the future to fund our operations through additional 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.

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 interim periods ended September 30, 2016. Estimates include revenue recognition, including the estimates of discounts and allowances related

to commercial sales of Xtampza, estimates utilized in the valuation of inventory, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, intangible assets, tax valuation reserves and accrued expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in the Annual Report.

Inventory

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

We have capitalized $1.6 million of inventory as of September 30, 2016. We expect sales of the capitalized units to occur during the next twelve months. We expect costs of product revenues to increase due to the expected increases in net product sales of Xtampza and the fact that we had expensed all manufacturing costs as research and development expense in periods prior to FDA approval of Xtampza. The impact on cost of product revenues as a result of inventory not capitalized prior to FDA approval is immaterial

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 sell Xtampza in the United States principally to customers, which in turn sell the product to healthcare providers for the treatment of patients. We provide the right of return to our customers for unopened product for a limited time before and after its expiration date. Given our limited sales history for Xtampza and the inherent uncertainties in estimating product returns, we have determined that the shipments of Xtampza made to our customers thus far do not meet the criteria for revenue recognition at the time of shipment. Accordingly, we recognize revenue when the product is sold-through by our customers, provided all other revenue recognition criteria are met. We invoice customers upon shipment of Xtampza to them and record accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price, less any realized adjustments to the gross invoice price. We then recognize revenue when Xtampza is sold-through, or when product is prescribed directly to the patient. Healthcare providers to whom distributors sell Xtampza hold limited inventory that is designated for patients, thereby limiting the risk of return.

RESULTS OF OPERATIONS
(in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Product revenues, net	$ 408	$ —	$ 408	$ —
Cost of product revenues	29	—	29	—
Research and development	3,254	3,358	11,617	6,444
Selling, general and administrative	23,567	5,907	55,266	11,027
Other expense, net	2	97	113	259
Net loss	$ (26,444)	$ (9,362)	$ (66,617)	$ (17,730)

Comparison of the nine months ended September 30, 2016 and September 30, 2015

Product revenues, net were zero for the nine months ended September 30, 2015, or the 2015 Period, compared to $408,000 for the nine months ended September 30, 2016, or the 2016 Period. The $408,000 increase was due to the launch of Xtampza in June 2016.

Cost of product revenues were zero for the 2015 Period, compared to $29,000 the 2016 Period. The $29,000 increase was due to the launch of Xtampza in June 2016.

Research and development expenses were $6.4 million for the 2015 Period, compared to $11.6 million for the 2016 Period. The $5.2 million increase was primarily related to:

- an increase in clinical trial costs of $4.0 million due to the commencement of clinical trials with Xtampza and our second product candidate;
- an increase in salaries, wages and benefits of $1.2 million primarily due to increased headcount and stock-based compensation expense;
- an increase in manufacturing transfer costs of $499,000 related to Onsolis partially offset by;
- a decrease in consulting costs of $1.1 million primarily due to the completion of FDA advisory committee preparation in 2015.

Selling, general and administrative expenses were $11.0 million for the 2015 Period compared to $55.3 million for the 2016 Period. The $44.3 million increase was primarily related to:

- an increase in salaries, wages and benefits of $20.3 million primarily due to an increase from 12 to 201 employees and an increase in stock-based compensation expense;
- an increase in sales and marketing costs of $14.4 million primarily due to preparation for and support of the commercial launch of Xtampza;
- an increase in Post Marketing Requirement ("PMR") costs required with FDA approval of Xtampza of $4.8 million; and
- an increase in commercial costs of $3.5 million primarily due to consultant costs related to analytics and strategies for the commercialization of Xtampza.

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

Product revenues, net were zero for the three months ended September 30, 2015, or the 2015 Quarter, compared to $408,000 for the three months ended September 30, 2016, or the 2016 Quarter. The $408,000 increase was due to the launch of Xtampza in June 2016.

Cost of product revenues were zero for the 2015 Quarter, compared to $29,000 for the 2016 Quarter. The $29,000 increase was due to the launch of Xtampza in June 2016.

Research and development expenses were $3.4 million for the 2015 Quarter, compared to $3.3 million for the 2016 Quarter. The $104,000 decrease was primarily related to:

- an increase in clinical trial costs of $533,000 due to the commencement of clinical trials with Xtampza and our second product candidate;
- an increase in manufacturing transfer costs of $499,000 related to Onsolis;
- an increase in salaries, wages and benefits of $369,000 primarily due to increased headcount and stock-based compensation expense offset by;
- a decrease in consulting costs of $956,000 primarily due to the completion of FDA advisory committee preparation in 2015; and
- a decrease in manufacturing costs of $657,000 mainly due to a decrease in the cost of validation batches of Xtampza.

Selling, general and administrative expenses were $5.9 million for the 2015 Quarter compared to $23.6 million for the 2016 Quarter. The $17.7 million increase was primarily related to:

- an increase in salaries and wages of $8.8 million primarily due to an increase from 12 to 201 employees and an increase in bonuses and stock-based compensation expense;
- an increase in PMR costs required with FDA approval of Xtampza of $4.8 million;
- an increase in sales and marketing costs of $2.3 million primarily due to support for the commercial launch of Xtampza; and
- an increase in commercial costs of $1.2 million 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 September 30, 2016, we had $91.0 million in cash and cash equivalents.

In January 2016, we issued and sold in a public offering an aggregate of 2,750,000 shares of our common stock at $20.00 per share. We received proceeds from this public offering of approximately $51.2 million, after deducting underwriting discounts and commissions and expenses payable by us.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash, together with the net proceeds of approximately $74.8 million from our October 2016 offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, and expected gross profit contributions from Xtampza, will provide us with adequate cash resources to fund our operations into 2019. We have based this estimate on assumptions (including assumptions regarding the outcomes of our negotiations with payors and pharmacy benefit managers, including UnitedHealth and Cigna) 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 $51.8 million in the 2016 Period and $12.6 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 in investing activities was $2.6 million in the 2016 Period and $175,000 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 $51.6 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 significant revenue from product sales and we continue to incur significant research, development and other expenses related to our ongoing operations. We are in the early stages of commercialization of Xtampza. We anticipate that we will continue to incur losses in the near future as we 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 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 cash flow from the sale of our products, if ever, we expect to finance future cash needs through public or private equity or debt financings or other sources. 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 our 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 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;
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

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

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 September 30, 2016, we had cash and cash equivalents consisting of cash and money market funds of $91.0 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, 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 September 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 September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

There are no material changes from the legal proceedings previously disclosed in our Quarterly Report on Form 10-Q for the period ended June 30, 2016 filed with the SEC on August 11, 2016.

Item 1A. Risk Factors.

There are no material changes from the risk factors previously disclosed under the heading "Risk Factors" in our Annual Report, as revised and supplemented by our Quarterly Reports on Form 10-Q filed since the filing of our Annual Report and those risks described from time to time in other reports which we file with the SEC. In addition to the other information set forth in this Form10-Q, you should carefully consider the factors discussed in the Annual Report. The risks described in the Annual Report 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 Annual Report 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 Annual Report 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

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, all 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 our 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: November 10. 2016

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

Date: November 10. 2016

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

EXHIBIT INDEX

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 10, 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: November 10, 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 September 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: November 10, 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 September 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: November 10, 2016