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

FORM 10-Q

☒ **Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended June 30, 2018

OR

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to .

Commission File Number: 001-36375

Corium International, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**38-3230774**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

Corium International, Inc.
235 Constitution Drive
Menlo Park, California 94025
(Address of principal executive offices and zip code)

(650) 298-8255
(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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

As of August 7, 2018, there were approximately 36,250,261 shares of the Registrant's Common Stock outstanding.

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PART I

ITEM 1. FINANCIAL STATEMENTS

CORIUM INTERNATIONAL, INC.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	As of June 30, 2018	As of September 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 82,523	$ 57,466
Accounts receivable	3,556	4,641
Unbilled accounts receivable	228	169
Inventories	1,686	2,300
Prepaid expenses and other current assets	924	982
Total current assets	88,917	65,558
Property and equipment, net	15,810	12,176
Intangible assets, net	7,404	7,117
TOTAL ASSETS	$ 112,131	$ 84,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,519	$ 3,978
Accrued expenses and other current liabilities	6,860	6,411
Long-term debt, current portion	49	13,172
Recall liability, current portion	119	114
Deferred contract revenues, current portion	137	626
Total current liabilities	11,684	24,301
Convertible notes, net	70,021	—
Long-term debt, net of current portion	337	39,027
Recall liability, net of current portion	1,697	1,811
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	87,239	68,639
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 150,000,000 shares authorized; 36,244,074 and 36,004,602 shares issued and outstanding as of June 30, 2018 and September 30, 2017	36	36
Additional paid-in capital	283,826	231,457
Accumulated deficit	(258,970)	(215,281)
Total stockholders' equity	24,892	16,212
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 112,131	$ 84,851

See accompanying notes to condensed financial statements.

CORIUM INTERNATIONAL, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Product revenues	$ 5,901	$ 5,906	$ 18,512	$ 16,301
Contract research and development revenues	1,529	1,936	7,813	5,320
Other revenues	240	267	720	801
Total revenues	7,670	8,109	27,045	22,422
Costs and operating expenses:				
Cost of product revenues	3,507	3,935	10,806	10,892
Cost of contract research and development revenues	2,339	2,977	9,238	7,891
Research and development expenses	8,305	9,122	30,511	22,650
General and administrative expenses	3,325	3,284	10,728	9,288
Amortization of intangible assets	183	159	541	514
Loss on disposal of equipment	4	6	4	6
Total costs and operating expenses	17,663	19,483	61,828	51,241
Loss from operations	(9,993)	(11,374)	(34,783)	(28,819)
Interest income	332	77	617	149
Interest expense	(3,370)	(2,087)	(7,903)	(6,178)
Loss on extinguishment of long-term debt	—	—	(2,258)	—
Other income	640	—	640	—
Loss before income taxes	(12,391)	(13,384)	(43,687)	(34,848)
Income tax expense	—	—	2	2
Net loss and comprehensive loss	$ (12,391)	$ (13,384)	$ (43,689)	$ (34,850)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.43)	$ (1.21)	$ (1.30)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,214,740	31,457,702	36,144,746	26,784,678

See accompanying notes to condensed financial statements

CORIUM INTERNATIONAL, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance - September 30, 2017	36,004,602	$ 36	$ 231,457	$ (215,281)	$ 16,212
Issuance of common stock under Employee Stock Purchase Plan	126,298	—	427	—	427
Issuance of common stock upon exercise of stock options	108,705	—	377	—	377
Issuance of common stock upon net exercise of common stock warrants	4,469	—	—	—	—
Equity component of convertible notes, net of issuance costs of $2.5 million	—	—	46,154	—	46,154
Warrant issued in connection with the convertible note offering	—	—	1,792	—	1,792
Stock-based compensation expense	—	—	3,619	—	3,619
Net loss and comprehensive loss	—	—	—	(43,689)	(43,689)
Balance - June 30, 2018	36,244,074	$ 36	$ 283,826	$ (258,970)	$ 24,892

See accompanying notes to condensed financial statements.

CORIUM INTERNATIONAL, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss and comprehensive loss	$ (43,689)	$ (34,850)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of property and equipment	703	801
Loss on disposal of equipment	4	6
Amortization of intangible assets	541	514
Noncash amortized debt discount and issuance costs on convertible notes	2,379	—
Noncash amortized debt discount and issuance costs on long-term debt and capital leases	172	285
Stock-based compensation expense	3,619	2,711
Issuance of payment-in-kind notes in lieu of cash interest payments	—	1,369
Loss on extinguishment of long-term debt	2,258	—
Other income	(640)	—
Changes in operating assets and liabilities:		
Accounts receivable	1,085	(241)
Unbilled accounts receivable	(59)	86
Inventories	614	(97)
Prepaid expenses and other current assets	58	208
Accounts payable	199	2,530
Accrued expenses and other current liabilities	974	110
Deferred contract revenues	(489)	(234)
Recall liability	(109)	(351)
Net cash used by operating activities	(32,380)	(27,153)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(3,999)	(1,974)
Payments for patents and licensing rights	(828)	(813)
Net cash used by investing activities	(4,827)	(2,787)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of convertible notes	120,000	—
Payments for convertible notes issuance costs	(3,772)	—
Proceeds from issuance of common stock, net of issuance costs	—	56,136
Principal payments on long-term debt	(52,537)	(58)
Payments for long-term debt extinguishment costs	(2,231)	—
Principal payments on capital lease obligations	—	(73)
Proceeds from exercise of stock options	377	229
Proceeds from issuance of common stock under Employee Stock Purchase Plan	427	436
Net cash provided by financing activities	62,264	56,670
NET INCREASE IN CASH AND CASH EQUIVALENTS	25,057	26,730
CASH AND CASH EQUIVALENTS — Beginning of period	57,466	39,833
CASH AND CASH EQUIVALENTS — End of period	$ 82,523	$ 66,563
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 3,434	$ 4,524
Cash paid for income taxes	$ 6	$ 4
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable	$ 372	$ 310
Warrant issued in connection with convertible note offering	$ 1,792	$ —
Unpaid transaction costs associated with issuance of long-term debt	$ —	$ 544

See accompanying notes to condensed financial statements.

CORIUM INTERNATIONAL, INC.
Notes to the Condensed Financial Statements

1. Organization, Description of Business and Summary of Significant Accounting Policies

Organization

Corium International, Inc., a Delaware corporation (the "Company"), is a commercial-stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products that leverage the Company's broad experience with advanced transdermal and transmucosal delivery systems. The Company refers to its Transdermal Delivery Systems as "TDS."

In the normal course of business, the Company enters into collaborative agreements with partners to develop and manufacture products based on the Company's drug delivery technologies and product development expertise. Revenues consist of net sales of products manufactured, royalties and profit-sharing payments based on sales of such products by partners, and product development fees for research and development activities under collaboration agreements with partners. The Company is also engaged in the research and development of its own proprietary transdermal drug delivery products.

The Company's fiscal year ends on September 30. References to "fiscal" refer to the years ended September 30.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and follow the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. The interim balance sheet as of June 30, 2018, statements of operations and comprehensive loss for the three and nine months ended June 30, 2018 and 2017, statement of stockholders' equity for the nine months ended June 30, 2018, and statements of cash flows for the nine months ended June 30, 2018 and 2017 are all unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's financial position as of June 30, 2018, its results of operations for the three and nine months ended June 30, 2018 and 2017, and its cash flows for the nine months ended June 30, 2018 and 2017. The financial data and the other financial information contained in these notes to the financial statements related to the nine-month periods are also unaudited. The results of operations for the nine months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending September 30, 2018 or for any future annual or interim period. The balance sheet as of September 30, 2017 has been derived from the audited financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements.

The accompanying condensed financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended September 30, 2017 included in the Company's Annual Report on Form 10-K, which was filed with the SEC on December 29, 2017.

There have been no material changes to the significant accounting policies or recent accounting pronouncements previously disclosed in the Company's audited financial statements for the year ended September 30, 2017.

Liquidity

With the exception of fiscal 2013, the Company has incurred losses from operations since fiscal 2006 and has an accumulated deficit of $259.0 million as of June 30, 2018. The Company has financed its operations primarily through the proceeds from the sale of equity securities, and various debt and capital lease financings.

During the nine months ended June 30, 2018, the Company issued $120.0 million aggregate principal amount of convertible notes (the "Convertible Notes") due in 2025 (see Note 4). The Company used the proceeds from the issuance of the Convertible Notes to prepay in full all outstanding borrowings, fees and other amounts due under the earlier term loan agreement with CRG, a structured debt and equity investment management firm. With the addition of the $61.5 million net proceeds arising from the issuance of the Convertible Notes and simultaneous retirement of the CRG indebtedness, the Company believes that its existing cash and cash equivalents will be sufficient to fund operations as currently planned beyond the next 12 months. Consequently, the Company believes there is no longer substantial doubt regarding its ability to continue as a going concern because the Company is no longer required to maintain compliance with covenants related to liquidity or revenues. The unaudited condensed financial statements as of June 30, 2018 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months.

Use of Estimates

Estimates and assumptions are required to be used by management in the preparation of financial statements in conformity with U.S. GAAP that affect the reported amounts of assets, liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of operating revenues and operating expenses during the reporting period. Those estimates and assumptions affect revenue recognition, deferred revenues, impairment of long-lived assets, determination of fair value of stock-based awards and other debt- and equity-related instruments, accounting for clinical trial expenses and accounting for income taxes. As future events and their effects cannot be determined with precision, actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents and accounts receivable. The Company maintains its cash and cash equivalents with a single domestic financial institution that is well capitalized. The Company provides credit, in the normal course of business, to its partners and performs credit evaluations of such partners.

For both the three and nine months ended June 30, 2018, three partners accounted for 100% and 99% of the Company's revenues and three partners accounted for 99% of accounts receivable as of June 30, 2018. For the three and nine months ended June 30, 2017, three partners accounted for 96% and 93% of the Company's revenues. As of September 30, 2017, three partners accounted for 88% of accounts receivable.

Comprehensive Income (Loss)

For the three and nine months ended June 30, 2018 and 2017, the Company did not recognize any other comprehensive income (loss) and, therefore, the net loss and comprehensive loss was the same for all periods presented.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2014-09, "*Revenue from Contracts with Customers, (Topic 606)*" ("ASU 2014-09"). This ASU affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets, unless those contracts are within the scope of other standards. The guidance in this ASU supersedes the revenue recognition requirements in Topic 605, "*Revenue Recognition*" and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance also includes a set of disclosure requirements that will provide users of financial statements with comprehensive information about the nature, amount, timing, and uncertainty of revenue and cash flows arising from a reporting organization's contracts with customers. In August 2015, the Financial Accounting Standards Board issued ASU No. 2015-14, "*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*," which defers the effective date of ASU 2014-09 by one year. These ASUs are effective for annual reporting periods, and interim periods within those years, beginning after December 15, 2017 for public companies and permits the use of either the retrospective or modified retrospective method, with early adoption permitted as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. In April 2016, the FASB issued ASU 2016-10, "*Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*" which further clarifies guidance related to identifying performance obligations and licensing implementation guidance contained in ASU 2014-09. In May 2016, the FASB issued ASU 2016-12, "*Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*" which addresses narrow-scope improvements to the guidance on collectibility, noncash consideration, and completed contracts at transition and provides a practical expedient for contract modifications at transition and an accounting policy election related to the presentation of sales taxes and other similar taxes collected from customers. In December 2016, the FASB issued ASU No. 2016-20, "*Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*," which clarifies areas for correction or improvement in the Accounting Standards Codification.

The Company will adopt the new revenue recognition standard effective October 1, 2018, utilizing the modified retrospective method. The Company is in the process of evaluating the impact the adoption of this standard will have on its financial statements and has performed an initial review of its major contracts with partners. Based on the initial reviews, the Company believes the adoption of the new standard will not have a significant quantitative impact on product revenues, as the timing of revenue recognition for product sales, profit sharing and royalties is not expected to significantly change. For the Company's collaboration and partner arrangements, the consideration the Company is eligible to receive under these arrangements typically consists of nonrefundable upfront payments, reimbursement of research and development costs and milestone payments. The Company believes the adoption of the new standard will not have a significant quantitative impact on the revenue recognition of the reimbursement of research and development costs as the timing of the revenue recognition is not expected to significantly change. The Company continues to review the impact that this new standard will have on the timing of recognition for nonrefundable upfront payments and milestone payments as well as on its financial statement disclosures and has not made a determination on the impact to its financial statements. The Company is also evaluating changes to its accounting processes, internal controls and disclosures required to support the new standard.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*" ("ASU 2016-02"), which supersedes existing guidance on accounting for leases in "*Leases (Topic 840)*" and generally requires separating leases into liability and asset components to be presented in the statement of financial position. Certain qualitative disclosures are also required to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. The provisions of ASU 2016-02 are effective for annual reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of this ASU are to be applied using a modified retrospective approach. The Company is evaluating the effect that this ASU will have on the Company's future financial position, results of operations or cash flows.

In May 2017, the FASB issued ASU No. 2017-09, "*Compensation-Stock Compensation (Topic 718) – Scope of Modification Accounting (Topic 718)*". This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification, and provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. An entity should account for the effects of a modification unless all three of the following conditions are met:

(1) The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.

(2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.

(3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

This ASU is effective for annual periods beginning after December 15, 2017 and the Company will adopt the standard effective October 1, 2018. The adoption of this standard is not expected to have a material impact on the Company's future financial position, results of operations or cash flows.

2. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. Except as noted below, the carrying values of the Company's financial instruments, including cash equivalents, accounts receivable, and accounts payable, approximated their fair values due to the short period of time to maturity or repayment.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset, or an exit price that would be paid to transfer a liability, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level I —Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level II —Inputs that are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level III —Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company did not have any transfers between Levels I, II and III of the fair value hierarchy during the three and nine months ended June 30, 2018. The Company's policy is to determine the need for transfers between levels at the end of the reporting period when circumstances in the underlying valuation criteria are evaluated for changes requiring transfer between levels.

The Company's financial assets that are measured at fair value on a recurring basis by level within the fair value hierarchy are as follows (in thousands):

	As of June 30, 2018			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	$ 83,012	$ —	$ —	$ 83,012

	As of September 30, 2017			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	$ 57,928	$ —	$ —	$ 57,928

The Company did not have any Level III liabilities as of September 30, 2017.

In March 2018, the Company issued $120.0 million aggregate principal amount of Convertible Notes due 2025 with embedded conversion features. The Company estimated the fair value of the liability component at issuance based on a hypothetical non-convertible debt instrument with a seven-year term, but with a fair market value interest rate derived from a Monte Carlo simulation of the coupon and conversion option outcomes of the Convertible Notes. The Company recorded $71.3 million as the gross fair value of the liability at issuance on March 5, 2018, with the balance of $48.7 million recorded to equity as additional paid-in capital, before issuance costs. The fair value of the liability component is based on unobservable inputs and is, therefore, a Level III liability. As of June 30, 2018, the carrying value of the Convertible Notes liability approximates the fair value, net of issuance costs allocated to it.

The carrying value of the Company's long-term debt as of September 30, 2017 reflects the principal amount, adjusted for any unamortized debt issuance costs and discount. The long-term debt liability as of September 30, 2017 includes $51.8 million of adjusted debt principal relating to the then-outstanding term loan with CRG (see Note 4). The fair value of certain debt liabilities have been estimated by the Company based on market quotes for instruments with similar terms and remaining maturities. The following table lists both the carrying and fair values for such liabilities (in thousands):

	As of June 30, 2018		
	Carrying Value	Fair Value	Difference
Long-term debt	$ 386	$ 386	$ —

	As of September 30, 2017		
	Carrying Value	Fair Value	Difference
Long-term debt	$ 52,199	$ 55,888	$ 3,689

3. Inventories

Inventories consist of the following (in thousands):

	As of June 30, 2018	As of September 30, 2017
Raw materials	$ 1,076	$ 1,683
Work in process	386	264
Finished goods	224	353
Total inventories	$ 1,686	$ 2,300

4. Debt

Long-Term Debt

Outstanding long-term debt consists of the following (dollars in thousands):

	As of June 30, 2018	As of September 30, 2017
Term loan agreement expiring June 30, 2019, less unamortized issuance costs of $697 and unamortized discount of $27 as of September 30, 2017. See terms of the agreement below.	$ —	$ 51,779
Notes payable to lessor for tenant improvements. The note calls for monthly payments of principal and interest of $6 at an interest rate of 7% and is due November 2024	386	420
Total	386	52,199
Less current portion	49	13,172
Long-term portion	$ 337	$ 39,027

Term Loan

Since 2012, the Company had borrowed $45.0 million from CRG, a structured debt and equity investment management firm, pursuant to a term loan agreement and subsequent amendments to such agreement. The amended agreement provided for a maximum borrowing of $45.0 million, excluding payment-in-kind ("PIK") notes. The amended agreement required interest to be paid quarterly at a simple annual rate of 15%, and that all outstanding principal be repaid in four equal quarterly payments beginning on September 30, 2018, with interest continuing to accrue on the unpaid principal at a simple annual rate of 15%. In addition, the amended agreement contained a provision whereby the Company could, at each quarterly payment due date prior to June 30, 2018, choose to convert that portion of each quarterly interest obligation equal to 3.5% of the then-outstanding principal into PIK notes. Since inception of the amended agreement, the Company converted $7.5 million of interest into PIK notes, each of which were added to the then-outstanding principal. Amounts outstanding under the term loan agreement were collateralized by all of the Company's assets.

The amended agreement also provided for a prepayment premium, the amount of which varied with the date on which prepayment was made if the Company chose to repay principal prior to December 31, 2018, or upon other specified events, including a change of control. For the period January 1, 2018 through December 31, 2018, the prepayment premium was equal to 3.25% of the aggregate value of the principal and PIK notes outstanding at the time of prepayment. An additional fee of 1.0% of the aggregate value of the principal and PIK notes outstanding was due at the time of repayment of the loan, whether paid early or upon the maturity date.

On March 5, 2018, the Company terminated the term loan agreement with CRG, as amended, and prepaid in full all outstanding borrowings, fees and other amounts due thereunder, in an aggregate amount of approximately $54.8 million plus accrued interest. This amount included total prepayment fees equal to 4.25% of the principal amount then outstanding. The loss on extinguishment of the debt was $2.3 million and is included in the Statement of Operations and Comprehensive Loss for the nine months ended June 30, 2018. The Company was in continuous compliance with the financial covenants from inception through termination of the loan.

Convertible Notes

In March 2018, the Company issued $120.0 million aggregate principal amount of Convertible Notes due 2025, which aggregate principal amount included the exercise in full by the initial purchaser of the Convertible Notes of an option to purchase $20.0 million of such Convertible Notes. The Convertible Notes are senior, unsecured obligations and accrue interest at an interest rate of 5.00% per year, payable in cash semi-annually in arrears on March 15 and September 15 of each year, beginning on September 15, 2018. The Convertible Notes have a maturity date of March 15, 2025, unless earlier converted or repurchased in accordance with their terms. The Company received $116.2 million in net proceeds from the sale of the Convertible Notes, after deducting payments for offering fees and expenses of $3.8 million.

The Convertible Notes were issued pursuant to an indenture, dated as of March 5, 2018, by and between the Company and U.S. Bank National Association, as trustee (the "Indenture"). Pursuant to their terms, the Convertible Notes will be convertible into cash, shares of the Company's common stock, or a combination of cash and shares of the Company's common stock, at the Company's election, as discussed in more detail below. The Convertible Notes have an initial conversion rate of 58.0552 shares of common stock per $1,000 principal amount, which is equivalent to an initial conversion price of approximately $17.22 per share of common stock. The conversion rate and the corresponding conversion price will be subject to adjustment upon the occurrence of certain events, including, but not limited to, stock splits and dividends, rights offerings, cash dividends, or a make-whole fundamental change (as described in the Indenture).

The Company may not redeem the Convertible Notes prior to March 15, 2022. The Company may redeem for cash all or any portion of the Convertible Notes, at its option, on or after March 15, 2022 if certain conditions are met, including, but not limited to, if the last reported sales price per share of the Company's common stock has exceeded 130% of the conversion price for each of at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter.

Noteholders may convert their Convertible Notes at their option only in the following circumstances:

- at any time during a calendar quarter after June 30, 2018, if the last reported sales price per share of the Company's common stock exceeds 130% of the conversion price for each of at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
- during the five consecutive business days immediately after any five consecutive trading day period (such five consecutive trading day period, referred to as the measurement period) in which the trading price per $1,000 principal amount of Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate on such trading day;
- upon the occurrence of certain corporate events or distributions on the Company's common stock;
- the Company calls the Convertible Notes for redemption; and
- at any time from, and including, September 15, 2024 until the close of business on the scheduled trading day immediately before the maturity date.

The Convertible Notes are considered convertible debt with a cash conversion feature. The Company has separated the carrying value of the convertible debt into liability and equity components. The $71.3 million initial carrying amount of the liability component is based on the calculated fair value of a hypothetical non-convertible debt instrument with a seven-year term, but with a fair market value interest rate derived from a Monte Carlo simulation of the coupon and conversion option outcomes of the Convertible Notes. The $48.7 million gross carrying value of the equity component, which amount is also recorded as the initial debt discount, represents the standalone value of the conversion option, and was determined by Monte Carlo simulation. The carrying value of the Convertible Notes equals the aggregate par value of the Convertible Notes less the unamortized debt discount and unamortized debt issuance costs. The debt discount and debt issuance costs are being amortized to interest expense over the seven-year term of the Convertible Notes, using the effective interest rate method. The equity component will not be re-measured as long as it continues to meet the conditions for equity classification. The $46.2 million equity component of the Convertible Notes, which is net of $2.5 million in issuance costs allocated to it, is included in additional paid-in capital.

In connection with the issuance of the Convertible Notes, the Company incurred $6.2 million of total debt issuance costs, primarily consisting of underwriting, legal and other professional fees, including a $2.4 million estimate of the fair value of a warrant issued to the initial purchaser (see Note 6), and allocated these costs to the liability and equity components in proportion to their respective carrying values. Of the total debt issuance costs, $3.7 million was allocated to the liability component and is recorded as a reduction of the Convertible Notes carrying value in the balance sheet, while the remaining $2.5 million was allocated to the equity component.

Debt discount and issuance costs totaling $52.4 million are being amortized to interest expense over the seven-year life of the Convertible Notes using the effective interest rate method. As of June 30, 2018, the interest rate was 5.00%, and the effective interest rate was 11.21%. Interest expense related to the Convertible Notes for the three and nine months ended June 30, 2018 was $3.4 million and $4.3 million, including $1.9 million and $2.4 million related to the amortization of the debt discount and issuance costs.

The table below summarizes the carrying value of the Convertible Notes as of June 30, 2018 (in thousands):

Gross proceeds	$ 120,000
Portion of proceeds allocated to equity component (additional paid-in capital)	(48,671)
Debt issuance costs	(6,204)
Portion of issuance costs allocated to equity component (additional paid-in capital)	2,517
Amortization of debt discount and debt issuance costs	2,379
Carrying value of Convertible Notes	$ 70,021

5. Collaboration and Partner Arrangements

The Company has recognized the following revenues from its collaboration and partner agreements (in thousands):

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Mayne	$ 1,572	$ 2,207	$ 6,261	$ 4,411
Par	—	—	—	363
P&G	5,149	4,406	14,942	12,519
Agile	949	1,154	5,605	4,014
Other	—	342	237	1,115
Total revenues	$ 7,670	$ 8,109	$ 27,045	$ 22,422

Included in revenues from Mayne is profit sharing, which totaled $0.2 million and $0.6 million for the three and nine months ended June 30, 2018, compared to $0.1 million and $0.7 million for the corresponding periods in fiscal 2017.

6. Warrants

The Company issued warrants to purchase shares of the Company's capital stock as part of several transactions occurring from fiscal 2008 through fiscal 2018. The warrants were recorded as equity instruments at the date of their issuances based on the terms of the warrants.

On May 14, 2018 (the "Warrant Issuance Date"), the Company issued a warrant to purchase 350,000 shares of the Company's common stock to Cantor Fitzgerald (the "Cantor Warrant") in connection with its role as the initial purchaser of the Company's offering of the Convertible Notes. The Cantor Warrant has a term of 7 years and a strike price of $17.22 per share. The Company estimated the value of the warrant to be $2.4 million as of a measurement date of March 31, 2018, and recorded that value as an adjustment to equity, and then further adjusted this estimate to the actual fair value of the warrant at issuance, which was $1.8 million as of the Warrant Issuance Date. The change in the value of the warrant from March 31, 2018 to the Warrant Issuance Date was recorded as other income in the Statements of Operations and Comprehensive Loss for the three and nine months ended June 30, 2018. The warrant was treated as an equity instrument, with its initial estimated value of $2.4 million recorded as an additional issuance cost associated with the offering of the Convertible Notes. The total Convertible Notes issuance costs of $6.2 million includes the warrant's initial estimated value of $2.4 million. The Company estimated the fair value of this warrant as of May 14, 2018 using the Black-Scholes option pricing model with the following key assumptions:

Expected term (in years)	7.0
Risk-free interest rate	2.96 %
Expected volatility	70 %
Expected dividend rate	0 %

As of June 30, 2018 and September 30, 2017, warrants to purchase 382,380 and 51,386 shares of common stock were outstanding, with a weighted average exercise price of $16.55 and $9.26 per share. These common stock warrants have terms ranging from seven to ten years and are exercisable at any time within the terms. These warrants expire at various dates between December 2020 and May 2025. The fair value of these warrants was recorded in stockholders' equity upon issuance.

During the nine months ended June 30, 2018, warrants to purchase 19,006 shares of common stock were net exercised, resulting in the issuance of 4,469 shares of common stock.

7. Convertible Preferred Stock, Common Stock and Stockholders' Equity

Convertible Preferred Stock

The Company was authorized to issue up to 5.0 million shares of preferred stock as of June 30, 2018 and September 30, 2017 with a par value of $0.001 per share. No preferred stock was outstanding as of those dates.

Common Stock

The Company was authorized to issue up to 150.0 million shares of common stock as of June 30, 2018 and September 30, 2017 with a par value of $0.001 per share. As of June 30, 2018, there were 36,244,074 shares of common stock outstanding and as of September 30, 2017, there were 36,004,602 shares of common stock outstanding.

Controlled Equity Offering

In December 2015, the Company entered into a Controlled Equity Offering℠ Sales Agreement with Cantor Fitzgerald & Co., as agent ("Cantor Fitzgerald"), pursuant to which the Company may offer and sell, from time to time through Cantor Fitzgerald, shares of its common stock, par value $0.001 per share, with aggregate proceeds of up to $20.0 million. The Company will pay Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from any shares of common stock sold by Cantor Fitzgerald. The Company has not sold any shares of common stock under this sales agreement. The offer and sale of these shares will require the filing of a new registration statement, or an amendment to an existing one, because the registration statement on Form S-3 that was filed by the Company with the SEC on May 8, 2015 (File No. 333-204025), including the related prospectus that covered the offer and sale of shares pursuant to the agreement with Cantor Fitzgerald, has expired.

8. Stock-Based Compensation

Equity Incentive Plans

As of June 30, 2018 and September 30, 2017, the Company had three equity incentive plans, all of which are sponsored by the Company. On March 19, 2014, the Company's board of directors approved the adoption of the 2014 Equity Incentive Plan (the "2014 Plan"), which is the only plan under which the Company can grant new awards. Under the 2014 Plan, the Company had initially reserved a total of 1.0 million shares of common stock plus the remaining unissued shares under the Company's 2012 Equity Incentive Plan (the "2012 Plan"), which was adopted in November 2012 and was replaced by the 2014 Plan. The 2014 Plan provides for the grant of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, stock bonus awards, performance-based stock awards, and other forms of equity compensation, all of which may be granted to employees (including officers), non-employee directors and consultants of the Company. The Company also sponsored the 2002 Stock Option Plan that expired in 2012. The term "Corium Plans" refers to the 2014 Plan, the 2012 Plan and the 2002 Stock Option Plan.

On January 1 of each year during the ten-year term of the 2014 Plan, the number of shares of common stock issuable under the 2014 Plan will be automatically increased by 4% of the number of shares of common stock outstanding as of the preceding December 31, unless a lesser number of shares is agreed to by the Company's board of directors. On January 16, 2018 and January 10, 2017, the Company's board of directors authorized an increase of 1,444,716 and 902,298 shares to be added to the total number of shares of common stock issuable under the 2014 Plan. As of June 30, 2018 and September 30, 2017, the Company had reserved 6,396,840 and 5,060,829 shares of common stock for issuance pursuant to the 2014 Plan. As of June 30, 2018 and September 30, 2017, the Company had 1,714,127 and 1,129,232 shares of common stock available for issuance pursuant to the 2014 Plan.

Stock Options

The exercise price of each stock option granted under the Corium Plans is required to be no less than the fair market value of the Company's common stock on the date of the grant. The maximum term of stock options granted under the Corium Plans is ten years and the vesting period is typically four years.

A summary of stock option activity under the Corium Plans during the nine months ended June 30, 2018 is as follows:

	Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands)
Balance - September 30, 2017	3,787,222	$ 4.85	6.84	$ 23,819
Options granted	811,050	$ 11.59		
Options exercised	(108,705)	$ 3.47		
Options forfeited / cancelled	(20,784)	$ 7.48		
Options expired	(445)	$ 2.22		
Balance - June 30, 2018	4,468,338	$ 6.10	6.77	$ 11,990
Options exercisable - June 30, 2018	3,085,519	$ 5.01	5.92	$ 10,193
Options vested and expected to vest - June 30, 2018	4,328,101	$ 6.02	6.71	$ 11,835

All outstanding stock options under the Corium Plans as of June 30, 2018 have an exercise price between $2.12 and $14.12 per share.

The weighted-average fair value of the stock options granted for the nine months ended June 30, 2018 were estimated using the Black-Scholes option-pricing model with the following assumptions:

	Nine Months Ended June 30, 2018
Expected term (in years)	5.27 - 6.57
Risk-free interest rate	2.08 % - 2.72 %
Expected volatility	67 % - 73 %
Expected dividend rate	0 %

Expected Term — The expected term represents the period that the stock-based awards are expected to be outstanding before exercise or cancellation. As the Company's historical share exercise experience has not yet provided a reasonable basis upon which to estimate expected term because of a lack of sufficient data points, the Company estimated the expected term by using the midpoint between the vesting commencement date and the contractual expiration period of the stock-based awards.

Risk-Free Interest Rate — The risk-free interest rate is based on the constant maturity yields of U.S. Treasury notes with remaining maturities similar to the expected term.

Expected Volatility — Because the Company has insufficient information on the volatility of its common stock due to limited historical data regarding the volatility of its common stock, the expected volatility used is based on the volatility of a group of comparable publicly-traded companies. In evaluating comparability, the Company considered factors such as industry, stage of life cycle and size. The Company will continue to analyze the historical stock price volatility and term assumptions as more historical data for the Company's common stock becomes available.

Expected Dividend Rate — The Company has never paid any dividends, does not plan to pay dividends in the foreseeable future, and, therefore, uses an expected dividend rate of zero in the valuation model.

Restricted Stock Unit Awards

The fair value of restricted stock unit awards is determined on the grant date based on the fair market value of the Company’s common stock on the date of the grant. The restricted stock unit awards granted under the 2014 Plan have a maximum term of ten years and typically vest over a four-year period.

A summary of restricted stock unit award activity under the Corium Plans during the nine months ended June 30, 2018 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested - September 30, 2017	144,375	$ 6.44
Granted	70,000	$ 11.59
Vested	(27,502)	$ 5.50
Forfeited	—	$ —
Nonvested - June 30, 2018	186,873	$ 8.51

As of June 30, 2018 and September 30, 2017, the Company had 214,375 and 144,375 restricted stock unit awards outstanding.

2014 Employee Stock Purchase Plan

On March 19, 2014, the Company's board of directors approved the adoption of the 2014 Employee Stock Purchase Plan (the "2014 ESPP"), with 310,000 shares initially reserved for issuance. The 2014 ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code of 1986 with the purpose of providing employees with an opportunity to purchase the Company's common stock through accumulated payroll deductions.

On January 1 of each year during the ten-year term of the plan, the number of shares issuable under the 2014 ESPP will be automatically increased by 1% of the number of shares of common stock and common stock equivalents outstanding as of the preceding December 31, unless a lesser number of shares is agreed to by the Company's board of directors. On January 16, 2018 and January 10, 2017, the Company's board of directors reserved an additional 409,224 and 267,565 shares of common stock for issuance pursuant to the 2014 ESPP. No more than 4.0 million shares may be issued over the ten-year term of the 2014 ESPP without the consent of the Company's stockholders. Shares subject to purchase rights granted under the Company's 2014 ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the Company's 2014 ESPP. As of June 30, 2018 and September 30, 2017, there were 919,325 and 636,399 shares of common stock available for issuance pursuant to the 2014 ESPP.

For the three and nine months ended June 30, 2018, the Company recorded stock-based compensation expense related to the 2014 ESPP of $73,000 and $146,000 compared to $60,000 and $224,000 for the corresponding periods in fiscal 2017. For the nine months ended June 30, 2018 and 2017, the Company issued 126,298 and 134,855 shares of common stock to employees pursuant to the 2014 ESPP.

The fair value of the purchase rights granted under the 2014 ESPP for the current offering periods were estimated by applying the Black-Scholes option-pricing model to each of the four purchase periods in the offering period using the following assumptions**:**

	As of June 30, 2018		
Fair value of common stock	$ 4.82	–	$ 8.51
Grant price	$ 4.10	–	$ 7.23
Expected term (in years)	0.5	–	2.0
Expected volatility	46 %	–	84 %
Risk-free interest rate	1.08 %	–	2.58 %
Expected dividend rate	0 %		

Fair Value of Common Stock — The fair market value of the Company's common stock on the first day of each offering period.

Grant Price — 85% of the fair market value of the Company's common stock on the first day of the offering period.

Expected Term — The expected term is based on the end dates of the four purchase periods of each two year offering period, which are six, twelve, eighteen or twenty-four months from the commencement of each new offering period.

Expected Volatility — The expected volatility is based on the historical volatility of the Company's common stock over each of the expected terms.

Risk-Free Interest Rate — The risk-free interest rate is based on the constant maturity yields of U.S. Treasury notes with remaining maturities similar to each expected term.

Expected Dividend Rate — The Company has never paid any dividends, does not plan to pay dividends in the foreseeable future, and, therefore, uses an expected dividend rate of zero in the valuation model.

Stock-Based Compensation Expense

Employee stock-based compensation expense for the three and nine months ended June 30, 2018 and 2017 is classified in the condensed statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Cost of product revenues	$ 127	$ 93	$ 348	$ 300
Cost of contract research and development revenues	96	61	266	169
Research and development	269	174	750	501
General and administrative	743	592	2,255	1,741
Total stock-based compensation	$ 1,235	$ 920	$ 3,619	$ 2,711

As of June 30, 2018, there was a total of $7.7 million of unrecognized employee stock-based compensation expense, net of estimated forfeitures, related to unvested stock-based awards under the Corium Plans, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 2.6 years.

9. Product Recall Liability

In fiscal 2008 and fiscal 2010, Actavis, Inc. ("Actavis") issued two voluntary recalls of certain lots and strengths of Fentanyl TDS manufactured by the Company and sold and distributed at that time by Actavis in the United States. The Company and Actavis negotiated financial settlements for these two recalls, and the Company accrued amounts related to these settlements in fiscal 2009 and 2011. These recall liabilities were subsequently reduced through various mechanisms per the terms of the settlement agreements.

In October 2012, the Company reached a revised settlement related to the two recalls, which provided for a total and combined remaining liability of $5.0 million as of the settlement date. The revised liability will be repaid through quarterly payments in arrears based on a percentage of the average of the total net revenues recorded by the Company in those prior periods related to Fentanyl TDS, and may be pre-paid by the Company in its discretion. These quarterly payments have been paid to Actavis since July 1, 2013. In April 2017, the Company and Actavis mutually agreed to extend the provision for quarterly payments through April 1, 2019, and agreed that, to the extent that the revised settlement liability has not been fully repaid as of April 30, 2019, the remaining liability, if any, will be converted into the most recent form of capital stock issued by the Company in connection with a financing, at the price per share of that financing. The revised liability does not accrue interest.

During the three and nine months ended June 30, 2018, the Company made an immaterial amount of settlement payments to Actavis compared to $0.1 million and $0.3 million for the corresponding periods in fiscal 2017. The outstanding balance of the recall liability was $1.8 million and $1.9 million as of June 30, 2018 and September 30, 2017.

10. Net Loss and Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of the Company's basic and diluted net loss per share attributable to common stockholders during the three and nine months ended June 30, 2018 and 2017 (in thousands, except share and per share data):

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Basic and diluted net loss per share				
Net loss attributable to common stockholders, basic and diluted	$ (12,391)	$ (13,384)	$ (43,689)	$ (34,850)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,214,740	31,457,702	36,144,746	26,784,678
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.43)	$ (1.21)	$ (1.30)

The following outstanding shares of common stock equivalents were excluded from the computation of the diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Convertible notes	6,968,641	—	6,968,641	—
Stock options to purchase common stock	4,468,338	4,058,134	4,468,338	4,058,134
Unvested restricted stock unit awards	186,873	102,500	186,873	102,500
Shares authorized under the 2014 ESPP	919,325	636,399	919,325	636,399
Common stock warrants	382,380	51,386	382,380	51,386

11. Income Taxes

The Company did not record a provision for Federal income taxes for the nine months ended June 30, 2018 because it expects to generate a net operating loss for the year ending September 30, 2018. The income tax expense of $2,000 for both the nine month periods ended June 30, 2018 and 2017 represents minimum statutory payments due in the states in which the Company is subject to taxation. The Company's deferred tax assets continue to be fully offset by a valuation allowance.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "2017 Tax Act"). The 2017 Tax Act makes broad and complex changes to the U.S. tax code and will affect the Company's fiscal year ending September 30, 2018, including, but not limited to reducing the U.S. federal corporate tax rate from 35 percent to 21 percent and creating limitations on net operating losses ("NOLs") generated after December 31, 2017. Because the Company's fiscal years do not coincide with the federal tax year, Section 15 of the Internal Revenue Code requires that the Company's fiscal year ending September 30, 2018 will have a blended corporate tax rate of 24.53 percent, which is based on the applicable tax rates in effect before and after December 31, 2017 weighted by the number of days in the Company's 2018 fiscal year before and after December 31, 2017.

The SEC staff issued Staff Accounting Bulletin 118 ("SAB 118"), which provides guidance on accounting for the tax effects of the 2017 Tax Act. SAB 118 provides a measurement period that should not extend beyond December 22, 2018 for companies to complete the accounting under ASC 740, "*Income Taxes.*" In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the 2017 Tax Act for which the accounting under ASC 740 is complete. To the extent that a company's accounting for certain income tax effects of the 2017 Tax Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in the financial statements. If a company is unable to determine such a provisional estimate, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the 2017 Tax Act.

Although the Company's analysis of the 2017 Tax Act is incomplete, it does not currently have the necessary information available, prepared, or analyzed in sufficient detail to make reasonable estimates of the impact of the 2017 Tax Act on the Company's financial statements, the Company expects there will be no impact on the Company's financial statements due to the full valuation allowance applied to the Company's deferred tax assets.

The 2017 Tax Act also limits the use of Net Operating Loss carryforwards (or "NOLs") generated after December 31, 2017 to 80% of taxable income. The Company does not expect profitability in the near term, nor has it conducted an analysis on its NOLs generated to date, so the future impact of such NOL limitations is not yet known.

12. Segment and Enterprise-Wide Information

The Company's chief operating decision maker is its President and Chief Executive Officer. The President and Chief Executive Officer reviews the Company's operating results on an aggregate basis for purposes of allocating resources and evaluating financial performance. The Company has one business activity and there are no segment managers who are held accountable for operations or operating results for levels or components. Accordingly, the Company has a single reporting segment and operating unit structure.

All of the Company's revenues are derived from partners conducting their business involving the Company's products and services primarily in North America and all long-lived assets are located in the United States.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the (1) unaudited condensed financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and (2) the audited financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the fiscal year ended September 30, 2017 included in the Annual Report on Form 10-K filed with SEC on December 29, 2017. This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "seek" and similar expressions or variations. Such forward-looking statements may include, but are not limited to, our plans and strategy for our business, and are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors", set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q and in our other SEC filings. We disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements. Our fiscal year ends September 30. Throughout this discussion and analysis, references to "fiscal," "fiscal year" or "fiscal years" refer to years ended September 30.

Company Overview

We are a commercial-stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products that leverage our broad experience with advanced transdermal and transmucosal delivery systems, or TDS. We have multiple proprietary programs in preclinical and clinical development focusing primarily on the treatment of neurological disorders, with two lead programs in Alzheimer's disease. We have developed and are the sole commercial manufacturer of seven prescription drug and consumer products for our marketing partners. We have two proprietary transdermal platforms: Corplex™ for small molecules and MicroCor®, a biodegradable microstructure technology for small molecules and biologics, including vaccines, peptides and proteins.

We have built significant know-how and experience in the development, scale-up and manufacture of complex specialty products, and have formed relationships with our partners that include both the development of new product formulations and our manufacture of the resulting products. Our partners include Mayne Pharma Inc., or Mayne, The Procter & Gamble Company, or P&G, Agile Therapeutics, or Agile, and Aequus Pharmaceuticals, Inc., or Aequus, as well as other pharmaceutical companies. All of our current commercial products are distributed, promoted and marketed by our partners.

The following table identifies: (1) products we have developed that are marketed by our partners, (2) products we have developed with our partners that are in clinical trials and that our partners have permitted us to disclose, (3) publicly disclosed clinical stage Central Nervous System, or CNS, products in our proprietary pipeline, including those in Bioequivalence, or BE trials, and (4) products currently awaiting Food and Drug Administration, or FDA, approval as part of a pending New Drug Application, or NDA, or an Abbreviated New Drug Application, or ANDA.

Partner	Product/Candidate	Application	Status
Mayne	Clonidine TDS	Hypertension	Marketed
Mayne	Fentanyl TDS	Pain	Marketed
P&G	Crest Whitestrips (5 Products)	Teeth Whitening	Marketed
Agile	Twirla	Contraception	NDA Filed
Self-funded	Donepezil TDS	Alzheimer's	BE Complete
Self-funded	Memantine TDS	Alzheimer's	Phase 1
Aequus	Aripiprazole TDS	Psychiatric Disorders	Phase 1
Mayne	ANDA	Motion Sickness	ANDA Filed

In August 2016, Mayne acquired the commercial rights to the Clonidine Transdermal Delivery System, or Clonidine TDS, and the product-related agreements from Teva Pharmaceuticals USA, Inc., or Teva, as a result of a Federal Trade Commission, or FTC, consent order in which Teva agreed to divest the product in connection with Teva's acquisition of the generic business of Allergan, plc, or Allergan. Mayne currently sells Clonidine TDS throughout the United States. Development of the product commenced in 2004, and it was commercially launched in 2010.

In March 2017, Mayne acquired the commercial rights to the Fentanyl TDS from Par Pharmaceuticals, or Par. Par had originally acquired the product as a result of an FTC-mandated divestiture of Fentanyl TDS from Actavis Inc., or Actavis, in connection with the merger of Actavis with Watson Pharmaceuticals, Inc. Mayne currently sells Fentanyl TDS throughout the United States. We began the development of Fentanyl TDS in May 2002, and the product was commercially launched in 2007.

Our partnership with P&G began in 2005 with the development of the various products under the Crest® Whitestrips label, the first of which was commercially launched in 2009. P&G currently sells Crest Whitestrips products globally.

In addition to commercialized products, we have a number of partner-funded and self-funded product candidates in various stages of development. One of these products is Twirla®, which is an investigational combination hormonal contraceptive transdermal patch designed to deliver two hormones, ethinyl estradiol and levonorgestrel, at levels comparable to low-dose oral contraceptives over seven days. Twirla incorporates the proprietary SkinFusion® adhesive technology designed by Agile. We are the exclusive manufacturer of this product for Agile.

In June 2017, Agile resubmitted its NDA with the results of an additional Phase 3 clinical trial that had been recommended by the FDA in 2013. On December 22, 2017, Agile disclosed that the FDA had issued a Complete Response Letter, or CRL, in response to the resubmission of its NDA, which stated that the FDA could not approve Agile's NDA in its current form. Agile further disclosed that it met with the FDA in April 2018 to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla, and that the FDA informed Agile that it continued to have significant concerns regarding the adhesion properties of Twirla in Agile's clinical trials, and that Agile needed to address the Twirla *in vivo* adhesion properties by reformulating the transdermal system and conducting a formal adhesion study with the new formulation. In June 2018, Agile submitted a formal dispute resolution request to the FDA. The dispute pertains to the determination from the FDA's reviewing Division of Bone, Reproductive and Urologic Products, or DBRUP, that concerns surrounding the *in vivo* adhesion properties of Twirla prevent its approval and cannot be addressed through Agile's proposed patient compliance programs. In July 2018, Agile reported that the Office Director of the FDA's Office of Drug Evaluation III, or ODEIII, has affirmed the position of DBRUP and denied their appeal of the CRL. In addition, Agile disclosed that it intends to appeal the ODEIII decision to the Office of New Drugs. We continue to work with Agile as it pursues the dispute resolution process for Twirla.

In addition to our partnered products, we are developing products utilizing our Corplex technology, some of which we advanced into human clinical trials during 2015 and 2016. Our two lead central nervous system product candidates are for the transdermal treatment of Alzheimer's disease and incorporate the two most commonly-prescribed drugs already approved by the FDA for this disease: donepezil and memantine.

Our donepezil and memantine product candidates first entered into Phase 1 clinical trials in fiscal 2015, and we announced positive results for several donepezil and memantine clinical trials in fiscal 2016. In April 2016, we received positive feedback from the FDA on our pre-Investigational New Drug, or pre-IND, submission that outlined our proposed 505(b)(2) regulatory pathway for Corplex Donepezil based on a demonstration of bioequivalence, or BE. Specifically, the FDA advised us that if we can adequately demonstrate bioequivalence between Corplex Donepezil and oral Aricept in our planned bioequivalence studies, additional clinical efficacy studies would not be required. Bioequivalence clinical studies are designed to assess the biological equivalence of pharmaceutical products based on their pharmacokinetic, or PK, profiles, and are generally performed in healthy subjects. These studies are relatively short in duration and provide a development path that is generally less costly and more streamlined than typical clinical development programs, which require studies demonstrating safety and efficacy in patients with the disease.

Additionally, in August 2016, after review of our pre-IND submission of Corplex Memantine, the FDA concurred with our development plans for this product, including our proposal for a pivotal study based on the demonstration of bioequivalence between the Corplex Memantine and oral Namenda XR® extended release capsules.

In fiscal 2016, we initiated our first bioequivalence study, which we previously referred to as our pilot BE study, for Corplex Donepezil, and we completed the study in April 2017. The first bioequivalence study was a six-month, three-period, randomized crossover study comparing the steady-state pharmacokinetic profiles of once-daily oral Aricept with two Corplex Donepezil transdermal patches that differed only in size. Based on the results of our earlier one-week Phase 1 PK study comparing Corplex Donepezil with oral Aricept, we projected that the maximum plasma concentration, or Cmax, and the area under the curve, or AUC, of plasma concentration of donepezil with the Corplex patch over the course of a week, at steady state, would be similar to the same measurements of oral Aricept. Data from the first BE study demonstrated that the smaller of the two Corplex Donepezil product candidates successfully met the statistical criteria for bioequivalence to oral Aricept based on the primary PK parameters of Cmax at steady state and AUC at steady state that had been previously established with the FDA. Both Corplex transdermal treatments were well tolerated, with favorable adhesion, skin safety and gastrointestinal side effect profiles after application of over 500 patches in the course of the study. For example, the incidence of treatment-related nausea in subjects on the smaller patch was more than six-fold lower than the incidence of nausea with oral Aricept.

In August 2017, we held an end of Phase 2 meeting with the FDA in which we reviewed the results from the first BE study. The FDA confirmed the choice of PK parameters and statistical testing approaches for the BE study and also confirmed our design of the planned supportive studies and other requirements for product registration. The FDA also indicated that it would consider whether the data from the first BE study could be sufficient for an NDA submission, and we provided additional data requested by the FDA during its review. However, due to uncertainty at that time as to the length or outcome of that review, we initiated dosing of our second BE study for Corplex Donepezil, which we have previously referred to as our pivotal BE study, in October 2017. The design of the second BE study was similar to the first BE study and was a single center, randomized, multiple dose, two-way crossover study in healthy volunteers, conducted at the same site as the first BE study. Dosing for this second BE study was completed in mid-February 2018. Following its review, the FDA provided positive feedback in mid-February, and we subsequently announced our intention to rely on the data from our successful first BE study for the planned NDA submission for Corplex Donepezil. We have completed treatments in all the ancillary studies required for the NDA filing and are planning to submit a Section 505(b)(2) NDA for this product candidate in the first quarter of calendar 2019.

We are currently focusing our resources and clinical development efforts on Corplex Donepezil, the highest priority of our proprietary programs. We are also pursuing development of several pipeline product candidates, including Corplex Memantine. We anticipate following the same bioequivalence-based development pathway for Corplex Memantine that we are following for Corplex Donepezil. In addition, we continue to perform preclinical development work on other proprietary pipeline products with a primary focus on developing innovative products for treatment of central nervous system diseases, and have identified several product candidates that have met our initial technical and commercial criteria for further development, including fingolimod for the treatment of relapsing and remitting multiple sclerosis and lidocaine for the non-opioid management of acute pain.

In April 2015, we entered into an agreement with Aequus to develop new transdermal products with an initial focus on neurological and psychiatric disorders. The first project under this collaboration is a multi-day transdermal formulation of aripiprazole, a drug already approved by the FDA for the treatment of a variety of psychiatric conditions. Aequus reported positive results from a single dose Phase 1 bioavailability clinical trial in the first calendar quarter of 2016 and, in April 2017, announced positive results from a follow-up repeat dose 28-day study to evaluate the bioavailability and safety of this product candidate. In addition, we have recently expanded our relationship with Aequus to include formulation and manufacturing of Aequus' long-acting transdermal patch for nausea and vomiting in pregnancy.

We routinely enter into other feasibility and development agreements with pharmaceutical and biotechnology companies involving our transdermal technologies.

Components of Statements of Operations

Revenues

During the nine months ended June 30, 2018 and 2017, we recognized revenues in three categories: product revenues, contract research and development revenues, and other revenues.

Product Revenues—Product revenues consisted of product sales to our partners and profit sharing from products that have been sold by our partners. Clonidine TDS, Fentanyl TDS and Crest Whitestrips provided all of our product revenues during the nine months ended June 30, 2018 and 2017.

Our product revenues from Clonidine TDS consisted of revenues from the sale of products we manufactured and shipped to Mayne, along with profit sharing from the net profits earned by Mayne on its sales of the product. For the nine months ended June 30, 2018, product revenues related to Clonidine TDS were similar to those for the same period in fiscal 2017. Although product revenues from Clonidine TDS in fiscal 2018 may be higher than fiscal 2017 revenues, product revenues beyond 2018 are expected to be adversely impacted by the longer term trend of increasing competition among generic drug marketers.

Our product revenues from Fentanyl TDS consisted of revenues from the sale of products we manufactured and shipped to Mayne following Mayne's March 2017 acquisition of the product from Par, along with profit sharing from the net profits earned by Mayne on its sales of the product. Product revenues related to Fentanyl TDS increased for the nine months ended June 30, 2018, compared to the same period in fiscal 2017, as a result of an increase in the number of units shipped. There have been, and will likely continue to be, material variations in quantities of Fentanyl TDS ordered from quarter to quarter, and we expect that our product revenues from Fentanyl TDS in fiscal 2018 and beyond will be lower than fiscal 2017 as a result of continued pressure on market pricing and the timing of orders from Mayne.

Product revenues from Crest Whitestrips consisted of revenues from the sale of products manufactured and shipped to P&G. Revenues increased for the nine months ended June 30, 2018, compared to the same period in fiscal 2017, as a result of increased global demand for the current products. We expect product revenues from P&G to be higher in fiscal 2018, compared to fiscal 2017, as demand is expected to continue to increase. We have completed the expansion of our commercial manufacturing capacity and expect to be able to meet this increased demand during the fourth quarter of fiscal 2018 and beyond.

Contract Research and Development Revenues —We also generated revenues from agreements with our partners for the research, development and scale-up activities of new products. The terms of our agreements with these partners may include nonrefundable upfront payments, partial or complete reimbursement of research and development costs, and milestone payments. Contract research and development revenues increased for the nine months ended June 30, 2018, compared to the same period in fiscal 2017, due to increased development activities for Agile and P&G. We currently expect our revenues from contract research and development in fiscal 2018 to be roughly flat compared to fiscal 2017.

Other Revenues —Other revenues consisted primarily of income derived from certain aspects of our arrangements with our partners, whereby a portion of the revenues received under these agreements is treated for accounting purposes as rental income from embedded leases associated with these relationships. Other revenues have not been, and are not expected to be, a significant portion of our revenues.

Costs and Expenses

Cost of Product Revenues —The primary components of our cost of product revenues are materials, personnel costs, depreciation, facilities costs, other overhead costs, and infrastructure expenses associated with the manufacturing of our products. Our manufacturing overhead costs are significant, and are allocated proportionately among our products at levels consistent with then-current unit production volumes. As the number of units we manufacture increases, our overhead costs should increase less rapidly due to economies of scale, resulting in lower per-unit costs associated with higher unit production volumes. Conversely, if total unit production volumes decrease, the cost of product revenues, measured as a percentage of product revenues, may increase as we lose economies of scale, unless offset by other savings. In addition, cost of product revenues varies with the mix of products sold.

Cost of Contract Research and Development Revenues —We incur expenses related to our contract research and development revenues from our partner-funded and co-funded product development agreements. These expenses consist primarily of personnel costs, materials, supplies, and overhead costs. We generally expense all contract research and development costs, including costs to be subsequently reimbursed under development contracts, in the periods in which they are incurred. Our costs of contract research and development revenues will fluctuate depending on the timing and stage of our various partner programs. In certain cases, contract research and development costs exceed contract research and development revenues, either due to timing differences between expenses and revenues or due to the nature of the underlying contracts. We enter into certain research and development arrangements that we do not expect to be profitable because we expect the long-term benefits of those arrangements to outweigh the short-term costs. Furthermore, we have entered, and expect to continue to enter, into other research and development arrangements in which we will share the costs of development (or co-development) with our partners, resulting in our costs significantly exceeding our revenues on such projects.

The differences between contract research and development revenues and contract research and development costs are a function of the specific project activities undertaken in any given period, as well as the proportion of the expenses that are attributable to co-funded development programs. In addition, revenue recognition policies may restrict or delay the recognition of certain revenues, while costs continue to be recognized in full, or, in some cases, may accelerate the recognition of revenues. As a result of these revenue timing and expense composition differences, any or all of our contract research and development projects may not be profitable in certain periods, but may be profitable in other periods. This relationship between changes in revenue and changes in related costs is also impacted by changes in the activity under co-development programs where development costs are shared with our partner. For example, during periods of higher development activities, co-development programs will result in higher costs, which may not be reflected to the same extent, if at all, in revenues.

Research and Development Expenses —Research and development expenses include costs incurred to develop our proprietary products using our transdermal drug delivery technologies. These costs consist primarily of personnel costs, materials and supplies, overhead and facility costs, preclinical and nonclinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to increase in future periods as we continue to invest in research and development activities related to clinical development of our proprietary pipeline, as well as other future development programs. See “Results of Operations” below for more detailed discussion of research and development expenses.

General and Administrative Expenses — General and administrative expenses consist primarily of personnel costs, including stock-based compensation, for employees in our administration, finance, business development, human resources and information technology functions. Other expenses include professional fees for accounting and legal services, and costs of consultants and other outside services. We expect that our general and administrative expenses will increase with growth in our revenues, increasing compliance activities related to the Sarbanes-Oxley Act, and the continued development of our product pipeline.

Interest Income— Interest income consists primarily of interest earned on our cash and cash equivalents balances.

Interest Expense— Interest expense consists primarily of the interest charges associated with our Convertible Notes, long-term debt and our capital lease obligations. The interest expense related to the Convertible Notes consists of interest payable semi-annually in cash beginning on September 15, 2018 and the amortization of the related debt discount and issuance costs. The majority of our interest associated with the CRG term loan, which was terminated in March 2018, was paid quarterly in cash, except when an allowable portion of the interest due was converted at our election into payment-in-kind, or PIK, notes. Commencing in September 2017, we began paying all of the quarterly interest due on the CRG term loan in cash. For further discussion, see "Liquidity and Capital Resources—Description of Certain Indebtedness."

Other Income—Other income consists of the change in the fair value of a warrant issued in connection with the Convertible Notes.

Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

(In thousands, except percentages)	Three Months Ended June 30, 2018	2017	Change $	Change %
Revenue:				
Product revenues	$ 5,901	$ 5,906	$ (5)	— %
Contract research and development revenues	1,529	1,936	(407)	(21)
Other revenues	240	267	(27)	(10)
Total revenues	7,670	8,109	(439)	(5)
Costs and operating expenses:				
Cost of product revenues	3,507	3,935	(428)	(11)
Cost of contract research and development revenues	2,339	2,977	(638)	(21)
Research and development expenses	8,305	9,122	(817)	(9)
General and administrative expenses	3,325	3,284	41	1
Amortization of intangible assets	183	159	24	15
Loss on disposal of equipment	4	6	(2)	(33)
Total costs and operating expenses	17,663	19,483	(1,820)	(9)
Loss from operations	(9,993)	(11,374)	1,381	12
Interest income	332	77	255	331
Interest expense	(3,370)	(2,087)	(1,283)	(61)
Other income	640	—	640	NM
Loss before income taxes	(12,391)	(13,384)	993	7
Income tax expense	—	—	—	—
Net loss and comprehensive loss	$ (12,391)	$ (13,384)	$ 993	7 %

Revenues

Product revenues were essentially unchanged for the three months ended June 30, 2018 compared to the same period in fiscal 2017. While revenues from Clonidine TDS decreased by $0.7 million, as no units were shipped in the three months ended June 30, 2018, revenues from Crest Whitestrips increased by $0.5 million due to increased global demand for these products and revenues from Fentanyl TDS increased by $0.2 million, as more units were shipped. We expect shipments of clonidine to resume in the three months ended September 30, 2018.

Contract research and development revenues decreased $0.4 million, or 21%, for the three months ended June 30, 2018 compared to the same period in fiscal 2017. This decrease was primarily driven by a decrease of $0.2 million in revenues related to development activities for Twirla, a $0.2 million decrease in revenues for a late-stage partnered development program and a $0.3 million decrease in revenues related to various partnered development activities. These decreases were partially offset by an increase of $0.3 million in revenues from P&G development activities associated with implementing the increase in production capacity for Crest Whitestrips.

Cost of Product Revenues

Cost of product revenues decreased $0.4 million, or 11%, for the three months ended June 30, 2018 compared to the same period in fiscal 2017, primarily as a result of no Clonidine TDS units shipped during the period. While total product revenues remained constant, the total cost of product revenues decreased by 11% primarily due to changes in our product mix between the periods.

Cost of Contract Research and Development Revenues

Cost of contract research and development revenues decreased $0.6 million, or 21%, for the three months ended June 30, 2018 compared to the same period in fiscal 2017, primarily as a result of a $0.7 million decrease in costs related to a co-development program that has reached the clinical trial stage, and a $0.3 million decrease in costs related to our other partnered contract feasibility programs. These decreases were partially offset by a $0.5 million increase in costs from P&G development activities associated with the increase in production capacity for Crest Whitestrips.

Research and Development Expenses

Research and development expenses decreased $0.8 million, or 9%, for the three months ended June 30, 2018 compared to the same period in fiscal 2017, driven primarily by a $0.9 million decrease in expense for our lead Alzheimer's program, Corplex Donepezil, primarily as a result of decreased expenses for our bioequivalence studies, and a $0.2 million decrease in expense for our other proprietary programs as we prioritized Corplex Donepezil ahead of our other clinical-stage programs. These decreases were partially offset by a $0.3 million increase in expense for preclinical development work on several proprietary feasibility programs.

General and Administrative Expenses

General and administrative expenses were approximately equal for the three months ended June 30, 2018 compared to the same period in fiscal 2017.

Interest Expense

Interest expense increased $1.3 million, or 61%, for the three months ended June 30, 2018 compared to the same period in fiscal 2017, primarily as a result of a $1.7 million increase in amortization of the debt discount and issuance costs related to the Convertible Notes. This increase was partially offset by a decrease of $0.4 million in interest expense due to the repayment of the CRG term loan in March 2018, at which time interest no longer continued to accrue on that loan. The annual interest rate of the $52 million CRG loan was 15%, and the coupon rate of the $120 million Convertible Notes is 5%.

Comparison of the Nine Months Ended June 30, 2018 and 2017

(In thousands, except percentages)	Nine Months Ended June 30, 2018	2017	Change $	Change %
Revenue:				
Product revenues	$ 18,512	$ 16,301	$ 2,211	14 %
Contract research and development revenues	7,813	5,320	2,493	47
Other revenues	720	801	(81)	(10)
Total revenues	27,045	22,422	4,623	21
Costs and operating expenses:				
Cost of product revenues	10,806	10,892	(86)	(1)
Cost of contract research and development revenues	9,238	7,891	1,347	17
Research and development expenses	30,511	22,650	7,861	35
General and administrative expenses	10,728	9,288	1,440	16
Amortization of intangible assets	541	514	27	5
Loss on disposal of equipment	4	6	(2)	(33)
Total costs and operating expenses	61,828	51,241	10,587	21
Loss from operations	(34,783)	(28,819)	(5,964)	(21)
Interest income	617	149	468	314
Interest expense	(7,903)	(6,178)	(1,725)	(28)
Loss on extinguishment of long-term debt	(2,258)	—	(2,258)	NM
Other income	640	—	640	NM
Loss before income taxes	(43,687)	(34,848)	(8,839)	(25)
Income tax expense	2	2	—	—
Net loss and comprehensive loss	$(43,689)	$(34,850)	$ (8,839)	(25)%

Revenues

Product revenues increased $2.2 million, or 14%, for the nine months ended June 30, 2018 compared to the same period in fiscal 2017. The increase was primarily driven by a $1.5 million increase in revenues from Crest Whitestrips due to increased global demand for these products, a $0.6 million increase in revenues from Fentanyl TDS and a $0.1 million increase in revenues from Clonidine TDS as more units for these two products were shipped.

Contract research and development revenues increased $2.5 million, or 47%, for the nine months ended June 30, 2018 compared to the same period in fiscal 2017. This increase was driven by a $1.6 million increase in revenues related to development activities for Twirla, a $0.9 million increase in revenues from P&G development activities associated with the increase in production capacity for Crest Whitestrips, and a $0.6 million increase in revenues for a late-stage partnered development program. These increases were partially offset by a $0.3 million decrease in revenues related to various partnered development activities and a $0.3 million decrease in revenues from our co-development programs related to the timing of project activities.

Cost of Product Revenues

Cost of product revenues decreased $0.1 million, or 1%, for the nine months ended June 30, 2018 compared to the same period in fiscal 2017. While total product revenues increased by 14%, total cost of product revenues decreased by 1% due to changes in our product mix between the periods.

Cost of Contract Research and Development Revenues

Cost of contract research and development revenues increased $1.3 million, or 17%, for the nine months ended June 30, 2018 compared to the same period in fiscal 2017, primarily as a result of a $1.9 million increase in costs related to the Twirla program, a $0.9 million increase in costs associated with the increased production capacity for P&G, and a $0.7 million increase in costs for a late-stage partnered development program. These increases were partially offset by a $1.9 million decrease in costs related to a co-development program and $0.2 million decrease in costs related to our various partnered contract feasibility programs.

While cost of contract research and development revenues increased 17% for the nine months ended June 30, 2018 compared to the same period in fiscal 2017, contract research and development revenues increased by 47%. The difference was primarily the result of the timing of project activities and corresponding milestone payments for one of our co-development programs.

Research and Development Expenses

Research and development expenses increased $7.9 million, or 35%, for the nine months ended June 30, 2018 compared to the same period in fiscal 2017, primarily driven by a $7.0 million increase in expense for our lead Alzheimer's program, Corplex Donepezil, as we initiated the second BE study and several supportive clinical studies in the first quarter of fiscal 2018, and a $2.3 million increase in expense for preclinical development work on several proprietary feasibility programs. This increased investment was partially offset by a $1.4 million decrease in expense for our other proprietary programs as we prioritized Corplex Donepezil ahead of our other clinical-stage programs.

General and Administrative Expenses

General and administrative expenses increased $1.4 million, or 16%, for the nine months ended June 30, 2018 compared to the same period in fiscal 2017, primarily as a result of a $0.6 million increase in legal, consulting and outside services expenses, including one-time expenses related to the pursuit of alternative refinancing opportunities for the CRG term loan, and a $0.5 million increase in stock-based compensation expense.

Interest Expense

Interest expense increased $1.7 million, or 28%, for the nine months ended June 30, 2018 compared to the same period in fiscal 2017, primarily as a result of a $2.3 million increase in amortization of the debt discount and issuance costs related to the Convertible Notes. This increase was partially offset by a decrease of $0.6 million in interest expense due to the repayment of the CRG term loan in March 2018, at which time interest no longer continued to accrue on that loan. The annual interest rate of the $52 million CRG loan was 15%, and the coupon rate of the $120 million Convertible Notes is 5%.

Liquidity and Capital Resources

With the exception of fiscal 2013, we have incurred losses from operations since fiscal 2006 and have an accumulated deficit of $259.0 million as of June 30, 2018. We have financed our operations primarily through the proceeds from the sale of equity securities, and various debt and capital lease financings.

During the nine months ended June 30, 2018, we issued $120.0 million aggregate principal amount of Convertible Notes due in 2025 (see Note 4 to our financial statements included in this Quarterly Report on Form 10-Q). We used the proceeds from the issuance of the Convertible Notes to prepay in full all outstanding borrowings, fees and other amounts due under the earlier term loan agreement with CRG. With the addition of the $61.5 million net proceeds arising from the issuance of the Convertible Notes and simultaneous retirement of the CRG indebtedness, we believe that our existing cash and cash equivalents will be sufficient to fund operations as currently planned beyond the next 12 months. Consequently, we believe there is no longer substantial doubt regarding our ability to continue as a going concern because we are no longer required to maintain compliance with covenants related to liquidity or revenues. Our unaudited condensed financial statements as of June 30, 2018 included in this Quarterly Report on Form 10-Q have been prepared under the assumption that we will continue as a going concern for the next 12 months.

Description of Certain Indebtedness — We have borrowed funds from a variety of sources, including Convertible Notes, a term loan with CRG, and notes payable with lessors for tenant improvements to our leased facilities.

Since 2012, we had borrowed $45.0 million from CRG pursuant to a term loan agreement and subsequent amendments thereto. The amended agreement provided for a maximum borrowing of $45.0 million, excluding payment-in-kind, or PIK, notes. The amended agreement required interest to be paid quarterly at a simple annual rate of 15%, and all outstanding principal be repaid in four equal quarterly payments beginning on September 30, 2018, with interest continuing to accrue on the unpaid principal at a simple annual rate of 15%. In addition, the amended agreement contained a provision whereby we could, at each quarterly payment due date on or prior to June 30, 2018, choose to convert that portion of each quarterly interest obligation equal to 3.5% of the then-outstanding principal into PIK notes. Since inception of the amended agreement, we converted $7.5 million of interest into PIK notes, each of which were added to the then-outstanding principal. Amounts outstanding under the term loan agreement were collateralized by all of our assets.

The amended agreement also provided for a prepayment premium, the amount of which varied with the date on which prepayment was made if we chose to prepay principal on or prior to December 31, 2018, or upon other specified events, including a change of control. For the period January 1, 2018 through December 31, 2018, the prepayment premium was equal to 3.25% of the aggregate value of the principal and PIK notes outstanding at the time of prepayment. An additional exit fee of 1.0% of the aggregate value of the principal and PIK notes outstanding was due at the time of repayment of the loan, whether paid early or upon the maturity date.

On March 5, 2018, we terminated the term loan agreement with CRG, as amended, and prepaid in full all outstanding borrowings, fees and other amounts due thereunder, in an aggregate amount of approximately $54.8 million plus accrued interest. This amount included total prepayment fees equal to 4.25% of the principal amount then outstanding. The loss on extinguishment of the CRG debt was $2.3 million and is included in our Statement of Operations and Comprehensive Loss for the three and nine months ended June 30, 2018 presented with our financial statements in this Current Report on Form 10-Q. We were in continuous compliance with the financial covenants from inception through termination of the CRG loan.

In March 2018, we issued $120.0 million aggregate principal amount of convertible senior notes due 2025, which aggregate principal amount included the exercise in full by the initial purchaser of the Convertible Notes of an option to purchase $20.0 million of such Convertible Notes. The Convertible Notes are senior, unsecured obligations and accrue interest at an interest rate of 5.00% per year, payable in cash semi-annually in arrears on March 15 and September 15 of each year, beginning on September 15, 2018. The Convertible Notes have a maturity date of March 15, 2025, unless earlier converted or repurchased in accordance with their terms. We received $116.2 million in net proceeds from the sale of the Convertible Notes, after deducting payments for offering fees and expenses of $3.8 million.

The Convertible Notes were issued pursuant to an indenture, dated as of March 5, 2018, by and between us and U.S. Bank National Association, as trustee, or the Indenture. Pursuant to their terms, the Convertible Notes will be convertible into cash, shares of our common stock, or a combination of cash and shares of our common stock, at our election, as discussed in more detail below. The Convertible Notes have an initial conversion rate of 58.0552 shares of common stock per $1,000 principal amount, which is equivalent to an initial conversion price of approximately $17.22 per share of common stock. The conversion rate and the corresponding conversion price will be subject to adjustment upon the occurrence of certain events, including but not limited to, stock splits and dividends, rights offerings, cash dividends, or a make-whole fundamental change (as described in the Indenture).

We may not redeem the Convertible Notes prior to March 15, 2022. We may redeem for cash all or any portion of the Convertible Notes, at our option, on or after March 15, 2022 if certain conditions are met, including, but not limited to, if the last reported sales price per share of our common stock has exceeded 130% of the conversion price for each of at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter.

Noteholders may convert their Convertible Notes at their option only in the following circumstances:

- at any time during a calendar quarter after June 30, 2018, if the last reported sales price per share of our common stock exceeds 130% of the conversion price for each of at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
- during the five consecutive business days immediately after any five consecutive trading day period (such five consecutive trading day period, referred to as the measurement period) in which the trading price per $1,000 principal amount of Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of our common stock on such trading day and the conversion rate on such trading day;
- upon the occurrence of certain corporate events or distributions on our common stock;
- we call the Convertible Notes for redemption; and
- at any time from, and including, September 15, 2024 until the close of business on the scheduled trading day immediately before the maturity date.

We also have other credit facilities under which we have borrowed funds, including notes payable to lessors for tenant improvements of leased facilities. For further details, see Note 7 to our financial statements contained in our Annual Report on Form 10-K for the fiscal year ended September 30, 2017, which was filed with the SEC on December 29, 2017.

In connection with certain of our partner arrangements, our partners purchase equipment that we use in the production and development of their products. This reduces our need for financing and lowers the manufacturing cost of these products for those partners, but generally limits our ability to use this equipment for our own or other partners' products.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended June 30,	
	2018	2017
Cash used by operating activities	$ (32,380)	$ (27,153)
Cash used by investing activities	(4,827)	(2,787)
Cash provided by financing activities	62,264	56,670

Cash Flows from Operating Activities — Cash used by operating activities for the nine months ended June 30, 2018 was $32.4 million, primarily driven by our net loss of $43.7 million, as we continued to generate negative cash flows from operations as a result of research and development spending in excess of cash flows provided by our commercial activities. Depreciation, amortization, stock-based compensation and other non-cash expenses, totaling $9.0 million, were all consistent with normal operations with the exception of the $2.2 million loss on extinguishment of long-term debt and the $0.6 million of other income. The $2.3 million in cash provided by changes in operating assets and liabilities as of June 30, 2018 compared to their balances as of September 30, 2017 was the result of offsetting sources and uses of cash, consisting primarily of:

- $1.1 million in cash provided by a decrease in accounts receivable, primarily related to lower revenue for the three months ended June 30, 2018;

- $1.0 million in cash provided by an increase in accrued expenses and other current liabilities primarily related to the higher amount of clinical trial expenses accrued but not paid;
- $0.6 million in cash provided by a decrease in inventory levels due primarily to the decreased production of generic products for the three months ended June 30, 2018; and
- $0.2 million in cash provided by an increase in accounts payable, resulting primarily from increased research and development expenses, including clinical trial costs invoiced but not paid; partially offset by:
- a $0.5 million use of cash from a decrease in deferred contract revenues as a result of the recognition of revenue related to upfront payments received from partners for development activities.

Cash used by operating activities for the nine months ended June 30, 2017 was $27.2 million, primarily driven by our net loss of $34.9 million, as we continued to generate negative cash flows from operations as a result of research and development spending in excess of cash flows provided by our commercial activities. Depreciation, amortization, stock-based compensation and other non-cash expenses, totaling $5.7 million, were all consistent with normal operations. The $2.0 million cash provided by net operating assets and liabilities was the result of offsetting sources and uses of cash, including:

- $2.5 million in cash provided by an increase in accounts payable, resulting primarily from increased research and development expenses, including clinical trial costs, raw material purchases, and legal and professional fees invoiced but not paid as of June 30, 2017; and
- $0.2 million in cash provided by a decrease in prepaid expenses and other current assets at June 30, 2017, compared to September 30, 2016, primarily related to monthly amortization of prepaid insurance balances, partially offset by:
- a $0.3 million use of cash from a decrease in the recall liability, primarily reflecting the ongoing payments made on a quarterly basis to reduce this liability;
- a $0.2 million use of cash from an increase in accounts receivable, primarily related to increased receivables outstanding at June 30, 2017 compared to September 30, 2016, as a result of increased contract research and development activities during the nine months ended June 30, 2017; and
- a $0.2 million use of cash from a decrease in deferred contract revenues.

Cash Flows from Investing Activities — Cash used by investing activities for the nine months ended June 30, 2018 was $4.8 million, consisting of capital expenditures of $4.0 million for equipment and leasehold improvements to support operations, including the acquisition of a new production line for P&G, and expenditures of $0.8 million relating to the acquisition of patent and licensing rights.

Cash used by investing activities for the nine months ended June 30, 2017 was $2.8 million, consisting of capital expenditures of $2.0 million for equipment and leasehold improvements to support operations, and expenditures of $0.8 million relating to the acquisition of patent and licensing rights.

Cash Flows from Financing Activities — Cash provided by financing activities for the nine months ended June 30, 2018 was $62.3 million, consisting primarily of $120.0 million in cash provided by proceeds from the issuance of the Convertible Notes, $0.4 million in cash provided by proceeds from the issuance of common stock under our 2014 ESPP, and $0.4 million provided from the exercise of stock options. The cash provided by financing activities was partially offset by a $54.8 million use of cash for prepayment in full of all outstanding borrowings, fees and other amounts due under the CRG term loan, and a $3.8 million use of cash for payment of issuance costs associated with the Convertible Notes.

Cash provided by financing activities for the nine months ended June 30, 2017 was $56.7 million, consisting primarily of $56.1 million in net proceeds from the issuance of common stock in connection with our two underwritten public offerings, $0.4 million in cash provided by proceeds from the issuance of common stock under our 2014 ESPP, and $0.2 million provided from the exercise of stock options.

Contractual Obligations

The following table summarizes our contractual obligations as of June 30, 2018 (in thousands):

	Payments Due by Period				
Contractual Obligations:	**Less Than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More Than 5 Years**	**Total**
Convertible notes obligations	$ —	$ —	$ —	$120,000	$120,000
Interest on convertible notes obligations	6,167	12,000	12,000	12,000	42,167
Long-term debt obligations	49	108	124	105	386
Interest on long-term debt obligations	25	40	24	6	95
Operating lease obligations	1,411	2,185	1,329	1,205	6,130
Total contractual obligations	$ 7,652	$ 14,333	$ 13,477	$133,316	$168,778

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Segment Information

We have one business activity and operate in one reportable segment.

Critical Accounting Policies and Estimates

Our condensed financial statements are prepared in accordance with U.S. GAAP. The preparation of these condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses, and related disclosures. These estimates form the basis for judgments we make about the carrying values of our assets and liabilities, which are not readily apparent from other sources. We base our estimates and judgments on historical experience and on various other assumptions that we believe are reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

We believe that the assumptions and estimates associated with revenue recognition, income taxes, stock-based compensation, and other debt- and equity-linked instruments have the greatest potential impact on our condensed financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

There have been no material changes to our critical accounting policies or estimates as compared to the critical accounting policies and estimates described in our Annual Report on Form 10-K for the fiscal year ended September 30, 2017.

Recent Accounting Pronouncements

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.”

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2014-09, "*Revenue from Contracts with Customers, (Topic 606)*", or ASU 2014-09. This ASU affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets, unless those contracts are within the scope of other standards. The guidance in this ASU supersedes the revenue recognition requirements in "*Revenue Recognition, (Topic 605)*" and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance also includes a set of disclosure requirements that will provide users of financial statements with comprehensive information about the nature, amount, timing, and uncertainty of revenue and cash flows arising from a reporting organization's contracts with customers. In August 2015, the Financial Accounting Standards Board issued ASU No. 2015-14, "*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*," which defers the effective date of ASU 2014-09 by one year. These ASUs are effective for public companies with annual reporting periods, and interim periods within those years, beginning after December 15, 2017, and permits the use of either the retrospective or modified retrospective method, with early adoption permitted as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. In April 2016, the FASB issued ASU 2016-10, "*Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*," which further clarifies guidance related to identifying performance obligations and licensing implementation guidance contained in ASU 2014-09. In May 2016, the FASB issued ASU 2016-12, "*Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*," which addresses narrow-scope improvements to the guidance on collectibility, noncash consideration, and completed contracts at transition and provides a practical expedient for contract modifications at transition and an accounting policy election related to the presentation of sales taxes and other similar taxes collected from customers. In December 2016, the FASB issued ASU No. 2016-20, "*Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*," which clarifies areas for correction or improvement in the Accounting Standards Codification.

We will adopt the new revenue recognition standard effective October 1, 2018, utilizing the modified retrospective method. We are in the process of evaluating the impact the adoption of this standard will have on our financial statements and have performed an initial review of our major contracts with partners. Based on the initial reviews, we believe the adoption of the new standard will not have a significant quantitative impact on product revenues, as the timing of revenue recognition for product sales, profit sharing and royalties is not expected to significantly change. For our collaboration and partner arrangements, the consideration we are eligible to receive under these arrangements typically consists of nonrefundable upfront payments, reimbursement of research and development costs and milestone payments. We believe the adoption of the new standard will not have a significant quantitative impact on the revenue recognition of the reimbursement of research and development costs as the timing of the revenue recognition is not expected to significantly change. We continue to review the impact that this new standard will have on the timing of recognition for nonrefundable upfront payments and milestone payments as well as on our financial statement disclosures and have not made a determination on the impact to our financial statements. We are also evaluating changes to our accounting processes, internal controls and disclosures required to support the new standard

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*", or ASU 2016-02, which supersedes existing guidance on accounting for leases in "*Leases (Topic 840)*" and generally requires separating leases into liability and asset components to be presented in the statement of financial position. Certain qualitative disclosures are also required to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. The provisions of ASU 2016-02 are effective for annual reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of this ASU are to be applied using a modified retrospective approach. We are evaluating the effect, if any, this ASU may have on our future financial position, results of operations or cash flows.

In May 2017, the FASB issued ASU No. 2017-09, "*Compensation-Stock Compensation (Topic 718) – Scope of Modification Accounting (Topic 718)*." This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification, and provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply the modification accounting described in Topic 718. This guidance states that an entity should account for the effects of a modification unless all three of the following conditions are met:

(1) The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.

(2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.

(3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

This ASU is effective for annual periods beginning after December 15, 2017 and we will adopt the standard effective October 1, 2018. The adoption of this standard is not expected to have a material impact on our future financial position, results of operations or cash flows.

Income Taxes

There have been no material changes under income taxes as disclosed in our Annual Report on Form 10-K for the fiscal year ended September 30, 2017, with the exception of the following:

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the 2017 Tax Act. The 2017 Tax Act makes broad and complex changes to the U.S. tax code and will affect the Company's fiscal year ending September 30, 2018, including, but not limited to reducing the U.S. federal corporate tax rate from 35 percent to 21 percent and creating limitations on net operating losses, or NOLs, generated after December 31, 2017. Because our fiscal years do not coincide with the federal tax year, Section 15 of the Internal Revenue Code requires that our fiscal year ending September 30, 2018 will have a blended corporate tax rate of 24.53 percent, which is based on the applicable tax rates in effect before and after December 31, 2017 weighted by the number of days in our fiscal year before and after December 31, 2017.

The SEC staff issued Staff Accounting Bulletin 118, or SAB 118, which provides guidance on accounting for the tax effects of the 2017 Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the enactment date of the 2017 Tax Act enactment date for companies to complete the accounting under ASC 740, "*Income Taxes*". In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the 2017 Tax Act for which the accounting under ASC 740 is complete. To the extent that a company's accounting for certain income tax effects of the 2017 Tax Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in the financial statements. If a company is unable to determine such a provisional estimate, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the 2017 Tax Act.

Although our analysis of the 2017 Tax Act is incomplete, we do not currently have the necessary information available, prepared, or analyzed in sufficient detail to make reasonable estimates of the impact of the 2017 Tax Act on our financial statements, we expect there will be no impact on our financial statements due to the full valuation allowance applied to our deferred tax assets.

The 2017 Tax Act also limits the use of Net Operating Loss carryforwards, or NOLs, generated after December 31, 2017 to 80% of taxable income. We do not expect profitability in the near term, nor have we conducted an analysis of our NOLs generated to date, so the future impact of such NOL limitations is not yet known.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to certain market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities as follows:

Interest Rate Risk

We had cash and cash equivalents of $82.5 million as of June 30, 2018. Our cash and cash equivalents are held in a variety of interest-earning instruments, including money market funds. Such interest-earning instruments carry a degree of interest rate risk. To date, fluctuations in interest income have not been significant. We have borrowed $120.0 million under the Convertible Notes. The interest rate of our borrowings under the Convertible Notes is fixed. As of June 30, 2018, the carrying value of the Convertible Notes, net of the portion of proceeds allocated to equity and net of debt discount and issuance costs was $70.0 million. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

The primary objective of our investment activities is to preserve principal while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. Due to the short-term nature of our investments, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Regulations under the Exchange Act require public companies, including us, to maintain "disclosure controls and procedures," which are defined in Rule 13a-15(e) and Rule 15d-15(e) to mean a company's controls and other procedures that are designed to ensure that information required to be disclosed 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer or persons performing similar functions, as appropriate to allow timely decisions regarding required or necessary disclosures. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. Based on the evaluation of the effectiveness of the disclosure controls and procedures by our management as of the end of the fiscal quarter covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have 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

Regulations under the Exchange Act require public companies, including our company, to evaluate any change in our "internal control over financial reporting" as such term is defined in Rule 13a-15(f) and Rule 15d-15(f) of the Exchange Act. In connection with their evaluation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer did not identify any change in our internal control over financial reporting during the fiscal quarter covered by this Quarterly Report on Form 10-Q that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are involved in various legal proceedings arising from the normal course of business activities. We are not presently a party to any litigation the outcome of which, we believe, if determined adversely against us, would individually or in the aggregate have a material adverse effect on our business, operating results, cash flows or financial condition.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and related notes. The occurrence of any of the events or developments described in the following risk factors could have a material adverse effect on our business, financial condition, results of operations and prospects. In such an event, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We have limited operating revenues and a history of operational losses and may not achieve or sustain profitability.

We have incurred significant operating and net losses since our inception. For fiscal 2017, we recorded net revenues of $31.9 million and net loss of $47.8 million. For fiscal 2016, we recorded net revenues of $33.0 million and net loss of $36.7 million. For the nine months ended June 30, 2018, we recorded net revenues of $27.0 million and net loss of $43.7 million. As of June 30, 2018, we had stockholders' equity of $24.9 million. We expect to continue to incur net operating losses for at least the next several years as we seek to advance our products through clinical development and regulatory approval, prepare for and, if approved, proceed to further commercialization, and expand our operations. Our ability to generate sufficient revenues from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flow is uncertain, and we may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow. In particular, we expect our operating expenses and research and development expenses to continue to increase in the near-term as we expand our operations and continue to invest in our proprietary technologies and products, and may not be able to generate sufficient revenues to offset this anticipated increase in expenses.

We are dependent on the commercial success of our Clonidine TDS, Fentanyl TDS and Crest Whitestrips, and although we are generating revenues from sales of our products, there may be additional declines in revenues generated by our Clonidine TDS and Fentanyl TDS products.

We anticipate that, in the near term, our ability to become profitable will depend upon the commercial success of the products marketed by our partners. To date, we have generated limited revenues from sales of these products and, in addition, we have incurred liability in the past in association with product recalls of Fentanyl TDS. Our Fentanyl TDS product revenues in fiscal 2017 and fiscal 2016 were $2.2 million and $6.4 million, respectively. In March 2017, Mayne acquired the rights to the transdermal fentanyl agreements from Par and is marketing the product in the United States. Our product revenues from Fentanyl TDS declined in fiscal 2017 compared to fiscal 2016 as a result of a significant decrease in demand and the continued impact of increased competition from other generic companies. We expect that our revenues from Fentanyl TDS in fiscal 2018 and beyond will be lower than fiscal 2017 as a result of continued pressure on market pricing and the timing of orders from Mayne.

Fentanyl TDS relies on a reservoir patch design instead of a matrix patch design. Although both reservoir and matrix patches have been subject to safety concerns and recalls in the past, our current competitors, most of whom use a matrix patch, may raise questions about the design and safety of a reservoir patch and the FDA may decide that the current reservoir patch design is a less safe design and may require the use of matrix patch technology instead. This would result in a more substantial decrease in our revenues and could harm our operating results.

Our product revenues from Clonidine TDS in fiscal 2017 and fiscal 2016 were $3.7 million and $6.8 million, respectively. The product revenues in fiscal 2017 decreased compared to fiscal 2016 due to increased competition resulting in fewer units shipped, and lower profit sharing earned as Mayne's market share and pricing both declined. Although we expect that our product revenues from Clonidine TDS in fiscal 2018 may be higher than fiscal 2017 revenues, product revenues beyond 2018 could be impacted by these trends as well as those factors described in further detail in "—*Continued consolidation in the pharmaceutical industry, and particularly in the generic pharmaceutical industry, could impact our existing partnerships, products and product candidates and cause disruption in our business*."

In addition to the risks discussed elsewhere in this section, our ability to continue to generate revenues from our commercialized products will depend on a number of factors, including, but not limited to:

- achievement of broad market acceptance and coverage by third-party payors for our products;
- the effectiveness of our partners' efforts in marketing and selling our products;
- the effects of competition and cost-containment initiatives on product pricing by our partners;
- our ability to successfully manufacture commercial quantities of our products at acceptable cost levels and in compliance with regulatory requirements;
- the timing of new product launches;
- our ability to maintain a cost-efficient organization and, to the extent we seek to do so, to partner successfully with additional third parties;
- our ability to expand and maintain intellectual property protection for our products successfully;
- the efficacy and safety of our products; and
- our ability to comply with regulatory requirements, which are subject to change.

Because of the numerous risks and uncertainties associated with our commercialization efforts, including our reliance on our partners for the marketing and distribution of our products, and other factors, we are unable to predict the extent to which we will continue to generate revenues from our products, or the timing for when or the extent to which we will become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We depend on a few partners for a significant amount of our revenues, and if we lose any of our significant partners, our business could be harmed.

The majority of our revenues come from only a few partners. For fiscal 2017, three partners, Mayne, P&G and Agile, individually comprised approximately 22%, 53%, and 18%, respectively, of our total revenues, and for the nine months ended June 30, 2018, the same three partners individually comprised approximately 23%, 55% and 21%, respectively. We expect that revenues from a limited number of partners will continue to account for a large portion of our revenues in the future. The loss by us of any of these partners, or a material reduction in their purchases or their market pricing or a failure to obtain regulatory approval for any of our partners' pipeline products, could harm our business, results of operations, financial condition and prospects. In addition, if any of these partners were to fail to pay us in a timely manner, it could harm our cash flow.

We or our partners may choose not to continue developing or commercializing a product or product candidate at any time during development or after approval, which would reduce or eliminate our potential return on investment for that product or product candidate.

We currently have seven products on the market, two of which are drugs approved under Abbreviated New Drug Applications, or ANDAs, and five consumer products. In addition, two drug product candidates that we have developed in partnership with other companies are the subject of pending applications for approval by the FDA and we have several self-funded drug product candidates in preclinical and clinical stages of research and development.

At any time, we or our partners may decide to discontinue the development of a drug product candidate or not to continue commercializing a marketed product for a variety of reasons, including the appearance of new technologies that make our product obsolete, the position of our partner in the market, competition from a competing product, stability or other manufacturing issues related to the product or product candidate, failure of our partners or us to design and conduct successful clinical trials or obtain regulatory approval for our product candidates, unacceptable safety profile of a product candidate, or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. If one of our partners terminates a development program or ceases to market an approved or commercial product, we will not receive any future milestone payments, royalties or transfer payments relating to that program or product under our partnership agreement with that party.

Near-term product revenue growth relies on the success of the Twirla contraceptive patch.

Near-term growth in our product revenues will require the approval and successful launch of Agile's product candidate, the Twirla® contraceptive patch, also referred to as AG200-15. Our collaboration partner Agile, who is responsible for funding and conducting all clinical trials for Twirla, has conducted Phase 3 clinical studies and filed a New Drug Application, or NDA, with the FDA for Twirla in April 2012. The FDA issued a Complete Response Letter, or CRL, in February 2013, identifying certain issues, including a request for additional clinical data from an additional Phase 3 clinical trial, as well as chemistry, manufacturing and control, or CMC, information, which needed to be addressed before approval could be granted. In January 2017, Agile announced top-line data from its third Phase 3 clinical trial initiated after receipt of the 2013 Complete Response Letter. In June 2017, Agile resubmitted its NDA and, in July 2017, the FDA notified Agile of its acceptance of the resubmitted NDA for review. Agile's PDUFA goal date for the resubmission was December 26, 2017.

On December 22, 2017, Agile disclosed that the FDA had issued a Complete Response Letter in response to the resubmission of its NDA, which stated that the FDA could not approve Agile's NDA in its current form. Agile reported that the CRL identified deficiencies relating to quality adhesion test methods, the need for Agile to address whether the *in vivo* adhesion properties of Twirla may have contributed to the SECURE Phase 3 clinical trial results, and also stated that observations noted during an inspection of our facility must be resolved. Agile further reported that the CRL also recommended that Agile address the implications of clinical trial subject patch compliance, and withdrawal and dropout rates. Agile has disclosed that it has met with the FDA in April 2018 in a Type A meeting to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla, and the FDA informed Agile that it continued to have significant concerns regarding the adhesion properties of Twirla in Agile's clinical trials, and that Agile needed to address the Twirla *in vivo* adhesion properties by reformulating the transdermal system and conducting a formal adhesion study with the new formulation. In June 2018, Agile submitted a formal dispute resolution request to the FDA. The dispute pertains to the determination from the FDA's reviewing Division of Bone, Reproductive and Urologic Products, or DBRUP, that concerns surrounding the *in vivo* adhesion properties of Twirla prevent its approval and cannot be addressed through Agile's proposed patient compliance programs. In July 2018, Agile reported that the Office Director of the FDA's Office of Drug Evaluation III, or ODEIII, has affirmed the position of DBRUP and denied their appeal of the CRL. In addition, Agile disclosed that it intends to appeal the ODEIII decision to the Office of New Drugs. We cannot assure you that Agile will be able to ultimately obtain regulatory approval for the Twirla product candidate, or that we will receive FDA approval to manufacture the product. If we or Agile fail to achieve any of these critical activities, or experience significant delays in doing so, our near-term growth prospects would be limited, and it would create uncertainty around the value and usefulness of the Twirla manufacturing facility and equipment.

Since 2003, we have devoted substantial resources to the development of the Twirla contraceptive patch in collaboration with Agile. The success of the Twirla product would be an important factor in the growth of our manufacturing business over the next few years. We received revenues from scale-up and manufacture of this product in calendar 2017, and, prior to Agile's announcement on December 22, 2017 that it had received a CRL on its NDA for this product candidate, we had expected additional revenues from the remaining scale-up activities as well as commercial manufacture beginning in fiscal 2018. We expect that the CRL and the subsequent dispute resolution process that Agile has initiated will delay Twirla commercial manufacturing revenues, if any, to after fiscal 2018 and, based on the FDA responses reported by Agile to the issues raised in the CRL, we also expect a reduction in our remaining 2018 contract research and development revenues, the majority of which were expected to come from pre-commercial activities related to Twirla. Further, if Twirla is not approved and launched, or if we are not approved as a manufacturer of Twirla, we will not realize our anticipated revenue growth. In addition, we have not agreed upon certain commercial terms related to the commercial supply of Twirla to Agile, including transfer pricing, which require further negotiation. If we are unable to agree upon terms, this could further delay the launch timing of the product and negatively impact our revenues.

Further, one of the three buildings in our manufacturing campus in Grand Rapids, Michigan has been built out and exclusively dedicated for the anticipated commercial production of Twirla. Agile owns all of the manufacturing equipment dedicated to the production of Twirla, and we own all of the building improvements necessary to manufacture in a GMP environment. Although some of the manufacturing equipment used in that building may be repurposed for other uses with Agile's permission, it would be expensive and time consuming to do so. If Twirla is not approved and successfully launched, if we do not receive regulatory approval to manufacture the product or if market adoption is less than forecasted, our business and financial growth prospects would be significantly harmed.

We are dependent on numerous third parties in our supply chain for the commercial supply of our products, and if we fail to maintain our supply relationships with these third parties, develop new relationships with other third parties or suffer disruptions in supply, we may be unable to continue to commercialize our products or to develop our product candidates.

We rely on a number of third parties for the supply of active ingredients and other raw materials for our products and the clinical supply of our product candidates. Our ability to commercially supply our products and to develop our product candidates depends, in part, on our ability to successfully obtain the active pharmaceutical ingredients used in the products, in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to commercialize our products, or develop any other product candidates.

We also rely on certain third parties as the current sole source of the materials they supply. Although many of these materials are produced in more than one location or are available from another supplier, if any of these materials becomes unavailable to us for any reason, we likely would incur added costs and delays in identifying or qualifying replacement materials and there can be no assurance that replacements would be available to us on acceptable terms, or at all. In certain cases, we may be required to obtain regulatory approval to use alternative suppliers, and this process of approval could delay production of our products or development of product candidates indefinitely.

If our third-party suppliers fail to deliver the required commercial quantities of sub-components and starting materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and on a timely basis, the continued commercialization of our products and the development of our product candidates would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

We face intense competition, in both our delivery systems and products, including from generic drug products, and if our competitors market or develop alternative treatments that are approved more quickly or marketed more effectively than our product candidates or are demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies, drug delivery companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, salesforces, manufacturing capabilities, research and development capabilities, experience in obtaining regulatory approvals for drug product candidates and other resources than us.

Many pharmaceutical companies are developing transdermal drug delivery systems, including 3M, Johnson & Johnson, Lohmann Therapie-Systeme, Mylan, Hisamitsu (through its subsidiary, Noven), and Teva. Some of these transdermal systems under development, if successfully commercialized, would directly compete with our proprietary products, including Corplex Donepezil. In the field of microneedle transdermal systems, other participants include 3M, Zosano, Theraject, Micron Biomedical, Lohmann Therapie-Systeme, Fujifilm and several academic institutions. Several of these competitors may also partner with larger pharmaceutical companies, which could provide them with significantly increased resources to develop and market their products.

We also face competition from third parties in obtaining allotments of fentanyl and other controlled substances under applicable annual quotas of the Drug Enforcement Administration, or the DEA, recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients in clinical trials, and in identifying and acquiring or in-licensing new products and product candidates.

Our competitors may develop products that are more effective, better tolerated, more adhesive, less irritating to the skin, subject to fewer or less severe side effects, more useful, more widely- prescribed or accepted, or less costly than ours. In addition, since transdermal products are worn by patients over an extended time period compared to other dosage forms, they need to be acceptable to patients and caregivers in terms of ease of use, comfort and wearability. For each product we commercialize, sales and marketing efficiency, payor reimbursement and formulary access are likely to be significant competitive factors. We do not have internal sales or marketing departments, and there can be no assurance that we can develop or contract out these capabilities in a manner that will be cost-efficient and competitive with the sales and marketing efforts of our competitors, especially because some or all of those competitors could expend greater economic resources than we do and/or employ third-party sales and marketing channels. Such competition could lead to reduced market share for our products and contribute to downward pressure in our pricing, which could harm our business, results of operations, financial condition and prospects.

Continued consolidation in the pharmaceutical industry, and particularly in the generic pharmaceutical industry, could impact our existing partnerships, products and product candidates and cause disruption in our business.

Our Fentanyl TDS and Clonidine TDS products, as well as several of our product candidates, compete within the pharmaceutical industry, and particularly within the generic pharmaceutical industry. There are a limited number of companies with sufficient scale and commercial reach to effectively market these products. Recent trends in this industry are toward additional market consolidation, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. For example, in August 2016, Teva completed the acquisition of the generic business of Allergan and the FTC required that Teva divest certain products, including the Clonidine TDS product that we manufactured for Teva. Since the acquisition, Mayne has had a lower market share and reduced pricing compared to Teva, and if either of those trends continue or accelerate, it would adversely affect our operating results. For other products and product candidates, increased consolidation could lead to other divestitures, more intense competition and pricing pressure, and the potential discontinuation of funding for development-stage programs. Any of these events could result in a decrease in our revenues, harm our operating results or otherwise disrupt our business.

We face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The commercial use of our products and clinical use of our product candidates expose us to the risk of product liability claims. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, as is the case with Fentanyl TDS and Clonidine TDS, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in injury to a patient or even death. We have had 19 past legal proceedings related to Fentanyl TDS, all of which have been settled and dismissed with prejudice. We cannot offer any assurance that we will not face other product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

Fentanyl TDS is an opioid pain reliever that contains fentanyl, which is a regulated "controlled substance" under the Controlled Substances Act of 1970, or the CSA, and could result in harm to patients relating to its potent effects as an opioid drug and its potential for abuse. In addition, a liability claim may be brought against us even if our products or product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our products or, if approved, our product candidates;
- decreased demand for our products or, if approved, our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; and/or
- loss of revenues.

We have obtained product liability insurance coverage for our Fentanyl TDS and our other commercial products and clinical trials, with a $10 million per occurrence and a $20 million annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage based on sales of our products, approval of other product candidates, or otherwise, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of our products and our product candidates. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, results of operations, financial condition and prospects.

We have been subject to product recalls in the past, and may be subject to additional product recalls in the future that could harm our reputation and could negatively affect our business.

We may be subject to product recalls, withdrawals or seizures if any of the products we formulate, manufacture or sell fail to meet their specifications or are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale, or distribution of any of our products. In 2008 and 2010, Actavis voluntarily recalled certain lots of Fentanyl TDS due to imperfections in our manufacturing processes, including an issue that resulted in some patches that may have released the active ingredient at a faster rate than the rate provided in the product specifications. Any similar recall, withdrawal or seizure in the future, particularly if they involve our own proprietary product candidates, could materially and adversely affect consumer confidence in our brands, increase product liability exposure and lead to decreased demand for our products. In addition, a recall, withdrawal or seizure of any of our products would require significant management attention, would likely result in substantial and unexpected expenditures, and would harm our business, financial condition, and results of operations.

If we or our partners are unable to achieve and maintain adequate levels of coverage and reimbursement for our products, or any future products we may seek to commercialize, their commercial success may be severely hindered.

For our products that are available only by prescription, successful sales by our partners depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Our proprietary self-funded drug development programs incorporate active drug ingredients that have been previously approved and marketed and that generally are available as less expensive generic products in non-transdermal dosage forms. If our products do not demonstrate superior efficacy or safety profiles or other benefits compared to existing products or dosage forms, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments or co-insurance payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies, which are the lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, results of operations, financial condition and prospects.

Most of our partners depend on wholesale pharmaceutical distributors for retail distribution of our products and, if our partners lose any of their significant wholesale pharmaceutical distributors, our business could be harmed.

The majority of our partners' pharmaceutical sales are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. The loss of any of these wholesale pharmaceutical distributors' accounts or a material reduction in their purchases could have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot assure you that we or our partners can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our results of operations may be adversely affected by demand fluctuations outside our ability to control or influence.

In general, our marketing partners are required to provide us with 12-month rolling forecasts of their demand on a quarterly basis, and are also required to place firm purchase orders with us based on the near-term portion of those forecasts. If wholesaler or market demand for these products is lower than forecasted, our marketing partners or their wholesaler customers may accumulate excess inventory. Additionally, our marketing partners may price our products at levels that result in lost contract sales to their wholesaler customers. If such conditions persist, our marketing partners may sharply reduce subsequent purchase orders for a sustained period of time until such excess inventory is consumed, if ever. Significant and unplanned reductions in our manufacturing orders have occurred in the past and our results of operations were harmed. If such reductions occur again in the future, our revenues will be negatively impacted, we will lose our economies of scale, and our revenues may be insufficient to fully absorb our overhead costs, which could result in larger net losses. Conversely, if our marketing partners experience significantly increased demand, we may not be able to manufacture such unplanned increases in a timely manner, especially following prolonged periods of reduced demand. As we have no control over these factors, including our marketing partners' decisions on pricing, our purchase orders could fluctuate significantly from quarter to quarter, and the results of our operations could fluctuate accordingly.

Our MicroCor technology has not been incorporated into a therapeutic commercial product and is still at a relatively early stage of development.

Our MicroCor technology, utilizing proprietary microneedle arrays, has not been incorporated into a therapeutic commercial product and is still at a relatively early stage of development. Although we have conducted clinical trials for our product candidate MicroCor hPTH(1-34), additional studies are required for this product candidate and there is no guarantee that future clinical trials will prove that the technology is effective or does not have harmful side effects. Any failures or setbacks in utilizing our MicroCor technology, including adverse effects resulting from the use of this technology in humans, could have a detrimental impact on this product candidate and our ability to enter into new corporate collaborations regarding this technology, which would harm our business and financial position. To date, no pharmaceutical product incorporating microneedle technology has been approved by the FDA for commercial sale.

In addition, our MicroCor product candidates have been manufactured in small quantities for preclinical studies and Phase 1 and Phase 2a clinical trials. In the future, preparation for later stage clinical trials and potential commercialization would require us to take steps to increase the scale of production of MicroCor product candidates. In order to conduct larger or late-stage scale clinical trials for a MicroCor product candidate and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, we will need to manufacture it in larger quantities. We may not be able to increase successfully the manufacturing capacity for any such product candidates in a timely or cost-effective manner or at all. Significant scale-up of manufacturing may require additional processes, technologies and validation studies, which are costly and could require additional sources of funding, may not be successful and may not be approved by the FDA. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the finished product or active pharmaceutical ingredients. If we are unable to successfully scale-up the manufacture of any MicroCor product candidate in sufficient quality and quantity, the development of that product candidate and regulatory approval or commercial launch for any resulting drug products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, if we are unable to find a partner for our Corplex Donepezil product, we may have to access other sources of funding to commercialize the product, which may adversely impact our financial results.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and experience, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential formulary coverage and reimbursement for the subject product candidate, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than a collaboration with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of one or more product candidates, reduce or delay one or more of our development programs, delay potential commercialization, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenues.

The results and anticipated timelines of our clinical trials are uncertain and may not support continued development of a product candidate, which would adversely affect our prospects for future revenue growth.

We are required to demonstrate the safety and efficacy of products that we develop for each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. In addition, we cannot be assured that we will be able to maintain our planned timelines. Even successfully completed large-scale clinical trials may not result in marketable products. If any of our product candidates fail to achieve the primary endpoint in clinical trials, if safety issues arise or if the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. In addition, we may face challenges in clinical trial protocol design.

If the clinical trials for any of the product candidates in our pipeline are delayed or terminated, our prospects for future revenue growth would be adversely impacted. For example, we face numerous risks and uncertainties with our product candidates, including our ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, the need to modify or delay our clinical trials or to perform additional trials and the risk of failing to obtain FDA and other regulatory authority approvals. As a result, our product candidates may never be successfully commercialized.

Further, we may make a strategic decision to discontinue development of product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs and others in our pipeline cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products, which could in turn decrease our revenues and harm our business.

Due to our reliance and our partners' reliance on third-party contract research organizations to conduct our clinical trials, we are unable to directly control or monitor the timing, conduct, expense and quality of our clinical trials, which could adversely affect our clinical data and results and related regulatory approvals.

We and our partners extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We and our partners rely on independent third-party contract research organizations, or CROs, to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bioanalytical analysis. Many important aspects of the services performed for us and our partners by the CROs are out of our direct control. If there is any dispute or disruption in our or our partners' relationship with our CROs, clinical trials may be delayed. Moreover, in our regulatory submissions, we and our partners rely on the quality and validity of the clinical work performed by third-party CROs. If any of these CROs' processes, methodologies or results were determined to be invalid or inadequate, our or our partners' own clinical data and results and related regulatory approvals could be adversely affected. Furthermore, we rely on timely and accurate activity reporting from our CROs to form the principal basis of our clinical trial expense accruals. If our CROs inaccurately or incompletely report activities that drive costs, or if such reports are not delivered in a timely manner, our clinical trial expense accruals may be inaccurate, and could materially understate or over-state our clinical trial expenses in any given period.

We may need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.

Our management, personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. We will need to further expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities.

Our need to manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures, including the implementation of new enterprise resource management software;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities for our products and product candidates effectively and in a cost-effective manner;
- manage our relationship with our partners related to the commercialization of our products and product candidates;
- manage our clinical trials effectively;
- manage our internal manufacturing operations effectively and in a cost-effective manner while increasing production capabilities for our current product candidates to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. Because we rely on consultants for certain functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our use of consultants, we may be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, may not achieve our research, development and commercialization goals.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully commercialize our products, develop our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on our management and scientific personnel, including our President and Chief Executive Officer, Peter Staple, our Chief Financial Officer, Robert Breuil, our Chief Technology Officer and Vice President, Research and Development, Parminder Singh and our other executive officers. The loss of the services of any of these individuals could impede, delay or prevent the continuing commercialization of our products and the development of our product candidates and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we may provide stock options and restricted stock unit awards that vest over time. The value to employees of stock options and restricted stock unit awards that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to compete with offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. For example, we do not currently have a chief medical officer, and we cannot assure you that, if we require such a position to be filled, we will be able to hire a qualified candidate for this position. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. These companies also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;

- higher-than-expected acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, results of operations, financial condition and prospects. Other than our ongoing efforts to partner our proprietary products, we have no current plan, commitment or obligation to enter into any transaction described above.

Our business involves the use of hazardous materials and we and our third-party suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our manufacturing activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our products and product candidates and other hazardous compounds. We are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our facilities pending use and disposal and we dispose of certain materials directly through incineration. We cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our employees and others, and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures we utilize for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We have dismissed employees in the past for improper handling and theft of our product components, and although we reported their actions to all relevant authorities, any similar incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in Menlo Park, California, near major earthquake and fire zones. Our manufacturing facilities are in Grand Rapids, Michigan, where other natural disasters or similar events, like blizzards, tornadoes, fires or explosions or large-scale accidents or power outages, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or our Grand Rapids facility, that damaged critical infrastructure, such as enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations at either location, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

Our business and operations would suffer in the event of failures in our internal computer systems.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, attacks by computer hackers, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability or damage to our reputation, and the further commercialization and development of our products and product candidates could be delayed.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. For example, we estimate annual market revenues based on patient prescriptions using an analysis of third-party information and third-party market research data. If this third-party data underestimates or overestimates actual revenues for a given period, adjustments to revenues may be necessary in future periods. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

Changes in accounting standards and their interpretations could adversely affect our operating results.

U.S. GAAP are subject to interpretation by the Financial Accounting Standards Board, or FASB, the American Institute of Certified Public Accountants, the SEC, and various other bodies that promulgate and interpret appropriate accounting principles. These principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change. For example, in May 2014, the FASB issued Accounting Standards Update No. 2014-09, "*Revenue from Contracts with Customers, (Topic 606)*," which supersedes the revenue recognition requirements in "*Revenue Recognition, (Topic 605)*." We anticipate adopting this new standard on the effective date of October 1, 2018, utilizing the modified retrospective method. We are in the process of evaluating the impact the adoption of this standard will have on our financial statements and evaluating potential changes to our accounting processes, internal controls and disclosures required to support the new standard. Any additional new accounting standards could have a significant effect on our reported financial results, which could in turn cause our stock price could decline. For further discussion, see "—Recent Accounting Pronouncements."

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

The Tax Cuts and Jobs Act of 2017 has significantly changed the U.S. federal income taxation of corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, permitting immediate expensing of certain capital expenditures, adopting elements of a territorial tax system, imposing a one-time transition tax on all undistributed earnings and profits of certain U.S.-owned foreign corporations, revising the rules governing net operating losses and the rules governing foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury and Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

Although our analysis of the 2017 Tax Act is incomplete, we do not currently have the necessary information available, prepared, or analyzed in sufficient detail to make reasonable estimates of the impact of the 2017 Tax Act on our financial statements, we expect there will be no impact on our financial statements due to the full valuation allowance applied to our deferred tax assets.

While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our securities. For further discussion, see "—Income Taxes."

Risks Related to Our Financial Position and Capital Requirements

We have had significant and increasing operating expenses and in the future may require additional funding to continue as a going concern.

With the issuance of the Convertible Notes in March 2018, we believe that our existing cash and cash equivalents will be sufficient to fund operations as currently planned beyond the next 12 months, which alleviates the substantial doubt that existed in prior periods regarding our ability to continue as a going concern. We have based this belief on assumptions and estimates that may prove to be wrong, and we could spend our available financial resources less or more rapidly than currently expected. We may continue to require additional sources of cash to develop product candidates and to fund development and commercialization operations. In the event that additional financing is required, we intend to seek additional capital through collaborative or other funding arrangements with partners, equity and/or debt financings, or through other sources of financing. We may not be able to raise such financing on acceptable terms or at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of the product development programs or commercialization efforts or other aspects of our business plans, and our business, operating results and financial condition would be adversely affected.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the timing and amount of revenues from sales of our approved products and any subsequently approved product candidates, including the product candidates of our partners, that are commercialized;
- the timing, rate of progress and cost of any ongoing or future clinical trials and other product development activities for our product candidates that we may develop, in-license or acquire;
- the size and cost of our commercial infrastructure;
- the timing of FDA approval of our product candidates and the product candidates of our partners, if at all;
- costs associated with marketing, manufacturing and distributing any subsequently approved product candidates;
- costs and timing of completion of any additional outsourced commercial manufacturing supply arrangements that we may establish;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our products and our product candidates;
- costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation;
- costs associated with any product recall that could occur;
- costs of operating as a public company;
- the effect of competing technological and market developments;
- our ability to acquire or in-license products and product candidates, technologies or businesses;
- personnel, facilities and equipment requirements; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may undertake.

We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be diluted. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts, or other aspects of our business plan. We also may be required to relinquish, license or otherwise dispose of rights to products or product candidates that we would otherwise seek to commercialize or develop ourselves on terms that are less favorable than might otherwise be available. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

Our level of indebtedness could adversely affect our ability to raise additional capital to fund our operations, limit our ability to react to changes in the economy or our industry and prevent us from meeting our obligations.

Our level of debt and related debt service obligations could have important adverse consequences to us, including:

- heightening our vulnerability to downturns in our business or our industry or the general economy and restricting us from making improvements or acquisitions, or exploring business opportunities;
- requiring a significant portion of our available cash to be dedicated to the payment of principal and interest on our indebtedness, therefore reducing our ability to use our available cash to fund our operations, capital expenditures and future business opportunities;
- limiting our ability to adjust to changing market conditions and placing us at a competitive disadvantage compared to our competitors who have greater capital resources; and
- subjecting us to financial and other restrictions in any future debt instruments, the failure with which to comply could result in an event of default under the applicable debt instrument that allows the lender to demand immediate repayment of the related debt.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay product development, sales and marketing, capital and other expenditures, sell assets, seek additional capital or restructure or refinance our indebtedness. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations.

Our ability to utilize our net operating loss carryforwards, or NOLs, and research and development income tax credit carryforwards may be limited.

As of September 30, 2017, we had net operating loss carry forwards, or NOLs, for federal and state income tax purposes of $181.5 million and $31.4 million, respectively. If not utilized, these NOLs will expire beginning in 2026 and 2018 for federal and state income tax purposes, respectively. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ‘‘ownership change,’’ generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income may be limited. We believe that, with our initial public offering, or the IPO, and other transactions that have occurred over the past four years, we may have triggered an ‘‘ownership change’’ limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Furthermore, under the Tax Cuts and Jobs Act of 2017, although the treatment of tax losses generated in taxable years ending before January 1, 2018 has generally not changed, tax losses generated in taxable years beginning after December 31, 2017 may be utilized to offset no more than 80% of taxable income annually. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments, and we expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. Accordingly, our revenues will depend on development funding and the achievement of development and clinical milestones under our existing collaboration arrangements, as well as any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, fewer units sold or decreased unit pricing of certain marketed products directly reduces our profit sharing revenues. In connection with Teva's acquisition of the generic business of Allergan, it divested the Clonidine TDS product to Mayne in August 2016. Since the acquisition, Mayne has had a lower market share and reduced pricing compared to Teva, and if either of those trends continue or accelerate, it would adversely affect our operating results. In addition, product revenues related to Fentanyl TDS declined in fiscal 2017 compared to fiscal 2016 as a result of a significant decrease in demand and the continued impact of increased competition from other generic companies. There have been, and will likely continue to be, material variations in quantities of Fentanyl TDS ordered by Mayne from quarter to quarter, and we expect that our product revenues from Fentanyl TDS in fiscal 2018 and beyond will be lower than fiscal 2017 as a result of continued pressure on market pricing and the timing of orders from Mayne. Furthermore, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair market value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price, stock price volatility, and industry comparables, the magnitude of the expense that we must recognize may vary significantly. Finally, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our products and product candidates, which may vary depending on, among other things, FDA guidelines and requirements, and the quantity of production;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates and the product candidates of our partners, should they receive approval, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of clinical studies for our product candidates, the product candidates of our partners or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

Our results of operations and liquidity could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations and liquidity could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our results of operations and liquidity could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we market our products primarily in the United States, our partners have extensive global operations, indirectly exposing us to risk.

Risks Related to Regulation of our Products and Product Candidates

Our currently marketed products, and any of our product candidates that we or our partners commercialize, will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our or our partners' ability to commercialize such products.

Even after we achieve U.S. regulatory approval for a product, or after we or our partners commercialize an FDA-regulated product that does not require premarket approval (such as the P&G consumer teeth whitening products), we will be subject to continued regulatory review and compliance obligations. For example, with respect to our drug products, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A drug product's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice, or cGMP, requirements, which are regulations addressing the proper design, monitoring, and control of manufacturing processes and facilities, and with the FDA's Good Clinical Practice, or GCP, and the FDA's Good Laboratory Practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

In the case of Fentanyl TDS and any of our product candidates containing controlled substances, we will also be subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, including the Quality System Regulation requirements for the medical device components of our products or similar requirements, if applicable. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requesting that we initiate a product recall, or requiring notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

Since 2010, the FDA has inspected our facility several times and has issued Forms 483 identifying inspectional observations. Our most recent inspection was a general inspection and a pre-approval inspection for the Twirla NDA product in the fall of 2017, pursuant to which the FDA issued a Form 483 with three observations. We have promptly responded to these observations as a part of our ongoing obligations under the FDA's quality system regulation. The FDA has advised us that the status of our manufacturing facilities remain at Voluntary Action Indicated, or VAI, which means that no regulatory action by the FDA is required. We have not received approval for commercial manufacture of the Twirla product, for which an NDA submitted by Agile has not yet been approved, and cannot assure you that we will receive approval in the future.

If we, our products or product candidates or the manufacturing facilities for our products or product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose fines or other civil or criminal penalties;
- suspend any ongoing clinical trials;
- deny or reduce quota allotments for the raw material for commercial production of our controlled substance products;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; and/or
- seize or detain products or require us to initiate a product recall.

In addition, our or our partners' product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

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

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

Fentanyl TDS and certain of our other drug product candidates contain active ingredients which are classified as controlled substances, which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the CSA, and the regulations of the DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States.

A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Fentanyl TDS is regulated by the DEA as a Schedule II controlled substance.

Various states also independently regulate controlled substances. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. Adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For our products or product candidates containing controlled substances, we and our partners, suppliers, contractors and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. These regulations are extensive and include regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, record keeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of drug candidates including controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our products containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our pharmaceutical systems containing controlled substances. In particular, among other things, there is a risk that these regulations may interfere with the supply of the drugs used in our clinical trials, and in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances.

There has been an increased public awareness of the problems associated with the potential for abuse of opioid-based medications. Federal, state and local governmental agencies have increased their level of scrutiny of commercial practices of companies marketing and distributing opioid products, resulting in investigations, litigation and regulatory intervention affecting other companies. A number of counties and municipalities have filed lawsuits against pharmaceutical wholesale distributors, pharmaceutical manufacturers and retail chains related to the distribution and/or sale of prescription opioid pain medications. Policy makers and regulators are seeking to reduce the impact of opioid abuse on families and communities and are focusing on policies aimed at reversing the potential for abuse. In furtherance of those efforts, FDA has developed an Action Plan and has committed to enhance safety labeling, require new data, strengthen post-market requirements, update the REMS program, expand access to and encourage the development of abuse-deterrent formulations and alternative treatments, and re-examine the risk-benefit profile of opioids to consider the wider public health effects of opioids, including the risk of misuse. For example, at the FDA's request, Endo Pharmaceuticals, Inc. voluntarily withdrew its opioid OPANA® ER from the market due to the FDA's concerns regarding the risks associated with use of the product. Several states also have passed laws and have employed other clinical and public health strategies to curb prescription drug abuse, including prescription limitations, increased physician education requirements, enhanced monitoring programs, tighter restrictions on access, greater oversight of pain clinics, and tax assessments on the distribution and/or sale of opioids. This increasing scrutiny and related governmental and private actions, even if not related to a product that we make, could have an unfavorable impact on the overall market for opioid-based products such as our Fentanyl TDS product, or otherwise negatively affect our business.

In addition to the level of commercial success of our approved products, our future growth is also dependent on our ability to successfully develop a pipeline of product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval or that any approved products will be successfully commercialized.

Our long-term growth will be limited unless we successfully develop a pipeline of additional product candidates. We do not have internal new drug discovery capabilities, and our primary focus is on developing improved transdermal drug delivery systems by reformulating FDA-approved drugs using our proprietary technologies. This process involves several challenges, including the ability to successfully formulate products that can cross the skin at sufficient rates and do not cause significant skin irritation.

Near-term revenue growth in our manufacturing business is dependent on the ability of our collaboration partner, Agile, to gain FDA approval of the Twirla transdermal contraceptive patch and for the product to be brought to market. Agile has conducted three Phase 3 clinical studies and had initially filed an NDA with the FDA for Twirla in April 2012. The FDA issued a Complete Response Letter in February 2013 identifying certain issues, including a request for additional clinical data and chemistry, manufacturing and control, or CMC, information, which needed to be addressed before approval could be granted. In June 2017, Agile resubmitted its NDA and, in July 2017, the FDA notified Agile of its acceptance of the resubmitted NDA for review. Agile's PDUFA goal date for the resubmission was December 26, 2017.

On December 22, 2017, Agile announced that the FDA had issued a Complete Response Letter in response to the resubmission of their NDA, which stated that the FDA could not approve Agile's NDA in its current form. Agile disclosed that the CRL identified deficiencies relating to quality adhesion test methods, the need for Agile to address whether the *in vivo* adhesion properties of Twirla may have contributed to the SECURE Phase 3 clinical trial results, and also stated that the observations noted during the inspection of our facility must be resolved. Agile further reported that the CRL also recommended that Agile address the implications of clinical trial subject patch compliance and withdrawal and dropout rates. Agile disclosed that it has met with the FDA in April 2018 in a Type A meeting to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla, and the FDA informed Agile that it continued to have significant concerns regarding the adhesion properties of Twirla in Agile's clinical trials, and that Agile needed to address the Twirla *in vivo* adhesion properties by reformulating the transdermal system and conducting a formal adhesion study with the new formulation. In June 2018, Agile submitted a formal dispute resolution request to the FDA. The dispute pertains to the determination from the FDA's reviewing Division of Bone, Reproductive and Urologic Products, or DBRUP, that concerns surrounding the *in vivo* adhesion properties of Twirla prevent its approval and cannot be addressed through Agile's proposed patient compliance programs. In July 2018, Agile reported that the Office Director of the FDA's Office of Drug Evaluation III, or ODEIII, has affirmed the position of DBRUP and denied their appeal of the CRL. In addition, Agile disclosed that it intends to appeal the ODEIII decision to the Office of New Drugs. Even if Twirla is eventually approved by the FDA, Mylan has successfully marketed a generic version of the Ortho Evra contraceptive patch since April 2014, so the Twirla product may face established competition in the contraceptive patch market. In addition, the FDA conducted a pre-approval inspection of our manufacturing facility for the Twirla NDA in the fall of 2017 and we have not yet received approval for commercial manufacture of the Twirla product. We cannot assure you that Agile will be able to obtain regulatory approval for the Twirla product, or successfully launch and commercialize the product, or that we will receive approval to manufacture the product, any of which would limit our near-term growth prospects, and would create uncertainty around the value and usefulness of our Twirla manufacturing facility and equipment. We have one partnered product candidate that is the subject of a pending ANDA submitted by our partner to the FDA, and other product candidates in clinical development. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries. Obtaining approval of an NDA or ANDA (or foreign equivalents) is a lengthy, expensive and uncertain process. The FDA and other regulatory authorities in foreign countries also have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons.

For example, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of clinical trials;
- the FDA may not deem a product candidate safe and effective for its proposed indication, or may deem a product's safety risks to outweigh its clinical or other benefits;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to support approval, or the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- the FDA may disagree with our or our partners' interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or ANDA;
- the FDA may require additional pre-clinical studies or clinical trials;
- the FDA may not approve of our manufacturing processes, test methods and facilities; or
- the FDA may change its approval policies or adopt new regulations.

Any of our product candidates may fail to achieve their specified endpoints in clinical trials. For example, while we have received positive results in the Corplex Donepezil pilot bioequivalence study, the FDA may ultimately request additional clinical data in the context of an NDA review. If that were to occur, future studies may not be consistent with these earlier positive results. Although we have stored the blood samples from the second BE study for later analysis, there can be no assurances that the samples will remain stable throughout the length of the NDA review period. In addition, we are required to perform certain ancillary studies to be included in our NDA submission and we cannot guarantee that the results of these studies will be positive. Further, we cannot be assured that we will be able to maintain our planned timelines. Also, product candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with the design of clinical trials and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we or our partners request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we or our partners believe are necessary or desirable for the successful commercialization of our product candidates.

If we are unable to expand our pipeline and obtain regulatory approval for our product candidates on the timelines we anticipate, we will not be able to execute our business strategy effectively and our ability to substantially grow our revenues will be limited, which would harm our long-term business, results of operations, financial condition and prospects.

We manufacture our products internally and may be unable to manufacture them at acceptable cost levels, and we could encounter manufacturing failures that could impede or delay commercial production of our current products or our product candidates, if approved, or the preclinical and clinical development or regulatory approval of our product candidates.

Our ability to successfully launch and grow our products will require the ability to manufacture commercial quantities of our products at increasing scale and at acceptable cost levels while remaining in compliance with continuously evolving regulatory requirements. Any failure in our internal manufacturing operations, or inability to scale up, could cause us to be unable to meet the demand for our products and lose potential revenues, delay the preclinical and clinical development or regulatory approval of our product candidates, and harm our reputation. Our internal manufacturing operations may encounter difficulties involving, among other things, raw material supplies of sufficient quality and quantity, production yields, regulatory compliance, quality control and quality assurance, obtaining DEA quotas that allow us to produce in the quantities needed to execute on our business plan, and shortages of qualified personnel. Our ability to commercially supply our products, and regulatory approval of our product candidates, could be impeded, delayed, limited or denied if the FDA does not maintain the approval of our manufacturing processes and facilities. In addition, we have no experience producing our MicroCor system in commercial quantities. We have experienced product recalls in the past and we may encounter difficulties when we attempt to manufacture commercial quantities of our product candidates in the quantities needed for our preclinical studies or clinical trials. Such difficulties could result in commercial supply shortfalls of our products, delay in the commercial launch of any of our product candidates, if approved, delays in our preclinical studies, clinical trials and regulatory submissions, or the recall or withdrawal of our products from the market.

We must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. In addition, we must obtain and maintain necessary DEA and state registrations, and must establish and maintain processes to assure compliance with DEA and state requirements governing, among other things, the storage, handling, security, recordkeeping and reporting for controlled substances. We must also apply for and receive a quota for fentanyl for our Fentanyl TDS product. Any failure to comply with these requirements may result in penalties, including fines and civil penalties, suspension of production, suspension or delay in product approvals, product seizure or recall, operating restrictions, criminal prosecutions, withdrawal of product approvals or severe reputational harm, any of which could adversely affect our business. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of commercialization, preclinical studies and clinical trials, regulatory submissions or approvals of our products or product candidates, entail higher costs or result in us being unable to effectively commercialize our approved products.

Clinical drug development for our product candidates is expensive, time consuming, uncertain and susceptible to change, delay or termination.

Clinical drug development for our product candidates is very expensive, time-consuming and difficult to design and implement. Our product candidates are in varying stages of development ranging from pre-clinical feasibility studies to registration. We estimate that clinical trials for these product candidates, if and when initiated, will continue for several years and may take significantly longer than expected to complete. In addition, we, our partners, the FDA, an independent Institutional Review Board, or an IRB, or other regulatory authorities, including state and local agencies, may suspend, delay or terminate our clinical trials at any time, for various reasons, including:

- failure to obtain IRB approval of each site;
- inability to recruit suitable patients or subjects to participate in a trial;
- lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;

- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays in or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation;
- delays in obtaining regulatory authorization to commence a study, or ''clinical holds'' or delays requiring suspension or termination of a study by a regulatory agency, such as the FDA, before or after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs and clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our collaboration partners or their employees, or our CROs or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for controlled substances;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; or
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We or our partners may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we or our partners view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. Even after the completion of Phase 3 or other pivotal clinical studies such as bioequivalence studies, we may have to address additional issues raised by the FDA in response to the NDA or ANDA filed by us or our partners, such as the issues with the Agile contraceptive patch. In the event that we or our partners abandon or are delayed in the clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively, we may not be able to become profitable, our reputation in the industry and in the investment community could be significantly damaged and our stock price could decrease significantly.

We have in the past relied and expect to continue to rely on third parties to conduct and oversee our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We have in the past relied and expect to continue to rely on third-party CROs to conduct and oversee our clinical trials. To date, we have contracted with several U.S. and foreign CROs to conduct the Phase 1, Phase 2a and bioequivalence clinical trials for our proprietary products.

We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's GCP regulations and state regulations governing the handling, storage, security and recordkeeping for controlled substances. These CROs and third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authority may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites, or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

We have conducted and may in the future conduct clinical trials for our products or product candidates outside the United States and the FDA may not accept data from such trials.

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States. For example, our CRO conducted the Phase 1 and Phase 2a clinical trials for our MicroCor hPTH(1-34), and the Phase 1 trials for our Corplex Donepezil and Corplex Memantine products in Australia. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be conducted in accordance with GCP requirements and the FDA must be able to validate the data from the study through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data is considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, such studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, including the development and commercial launch of any product candidates impacted by such a decision by the FDA.

If the FDA concludes that certain of our product candidates do not satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or Section 505(b)(2), or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We and our collaboration partners are developing several proprietary product candidates, for which we and our partners intend to seek FDA approval through the Section 505(b)(2) regulatory pathway.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we or our partners would need to generate in order to obtain FDA approval. If the FDA does not allow us or our partners to pursue the Section 505(b)(2) regulatory pathway as anticipated, we or our partners may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we or our partners are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we or our partners submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our 505(b)(2) NDAs or our partners' 505(b)(2) NDAs for up to 30 months depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we or our partners are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products. The FDA or foreign regulatory agencies will determine the regulatory pathway for our Alzheimer's product candidates, Corplex Donepezil and Corplex Memantine, which could impact cost, timing and design of our clinical trials and marketing for these product candidates.

There is no general FDA guidance on whether bioequivalence studies can be relied on for approval of a transdermal formulation under the Section 505(b)(2) regulatory pathway where the reference listed drug is an oral dosage form. It is possible that for drugs with a long half-life such as donepezil and memantine, as opposed to drugs with a short half-life, the plasma profile of the drug in the bloodstream for transdermal delivery will closely match the plasma profile seen with oral administration. For this reason, a bioequivalence regulatory strategy for approval of these products via the 505(b)(2) pathway may be possible. Following review of our pre-IND submissions for both Corplex Donepezil and Corplex Memantine, the FDA provided guidance on our development plans and registration pathway. The agency advised us that if we can adequately demonstrate bioequivalence between Corplex Donepezil and oral Aricept in our planned PK bioequivalence studies, additional clinical efficacy studies would not be required. Additionally, in August 2016, after review of our pre-IND submission of Corplex Memantine, the FDA concurred with our development plans for this product, including our proposal for pivotal studies based on the demonstration of PK bioequivalence between Corplex Memantine and oral Namenda XR® extended release capsules. If the FDA's position on the regulatory pathway changes, or if our studies do not adequately support bioequivalence, more expensive and time-consuming studies may be needed, resulting in a longer clinical development timeline for these product candidates.

We are in active consultations with a small number of non-U.S. regulatory bodies to determine whether regulatory approval based upon bioequivalence would be possible. We have received feedback from two leading European regulatory agencies, based on review of our pilot study results, that the bioequivalence regulatory pathway is available for Corplex Donepezil in those countries. In addition, we have had preliminary consultations with Pharmaceuticals and Medical Devices Agency, Japan, who have indicated that regulatory approval based on bioequivalence in Japan is not available at this time. If non-U.S. regulatory bodies determine that the bioequivalence pathway is not available, we will need to perform more expensive, time-consuming preclinical tests and/or clinical trials, likely including clinical efficacy and safety studies to seek regulatory approval in the relevant non-U.S. jurisdictions or we will not be able to commercialize our Alzheimer's product candidates in these jurisdictions. Even in countries where the bioequivalence pathway is available, the regulatory agencies are likely to require us to repeat the BE studies using local study subjects and the reference product approved in the relevant country, which would result in additional expense and time before Corplex Donepezil could be approved in those jurisdictions. Further, we cannot assure you that these additional BE studies will be successful.

While the ability to obtain approval on the basis of a single pharmacokinetic bioequivalence study would save expense and time, this regulatory pathway will not allow us to market our products based on any potential advantages with respect to the rate of adverse events, such as gastrointestinal side effects, compared to the existing oral formulations of these products. We would need to perform additional, expensive, time-consuming studies in Alzheimer's patients to generate data to demonstrate any of these potential benefits. We cannot guarantee that these additional studies, if performed, would demonstrate the superiority of our products. Further, if no benefit is shown from these studies, this could have an adverse impact on the competitive position of our products in the marketplace, which could harm our business, results of operations, financial condition and prospects. In addition, we cannot be assured that there will be any particular exclusivity allowance for our products under the single bioequivalence regulatory pathway.

The products that we make and develop may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Undesirable side effects caused by product candidates could cause us, or our partners, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our partners, to cease further development of or deny approval of product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

The labeling for our Fentanyl TDS product, which is common to all fentanyl transdermal products, includes warnings of serious adverse events relating to abuse potential, respiratory depression and death, and risks relating to accidental exposure, drug interactions and exposure to heat.

Agile has conducted three Phase 3 clinical studies of its product candidate, Twirla. The safety population in the first two of these studies included patients who received at least one dose of either Twirla or a combination oral contraceptive. In the combined safety population of Agile's Phase 3 trials, there were a total of 22 serious adverse events, or SAEs, of which 16 were from the Twirla group and three (0.2% of the overall Twirla safety population) of which were considered to be possibly related to the study drug. In the third Phase 3 clinical trial (the ''SECURE'' trial), which was completed in December 2016 and enrolled over 2,000 women, 2.0% of those participants experienced serious adverse events, and 0.6% of the subjects had SAEs that were considered potentially study drug related. Agile has stated that it believes that, if approved, Twirla will have a label consistent with other marketed hormonal contraceptive products containing ethinyl estradiol and levonorgestrel, including labeling that warns of risks of certain serious conditions, including venous and arterial blood clot events, such as heart attacks, thromboembolism and stroke, as well as liver tumors, gallbladder disease, and hypertension. Regulatory authorities may require the inclusion of additional statements in the Twirla label, which may include a ''black box'' warning or contraindication.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our products, other products with the same or related active ingredients, or our or our partners' product candidates, after obtaining U.S. regulatory approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we or our partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our products.

Healthcare reform measures could hinder or prevent the commercial success of our products and product candidates.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenues and profitability and the future revenues and profitability of our partners. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, President Obama signed one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, (ii) established annual fees on manufacturers of certain branded prescription drugs and (iii) enacted a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. The Bipartisan Budget Act of 2018, signed into law by President Trump on February 9, 2018, increased the point-of-sale discount manufacturers must agree to offer under the Medicare part D coverage gap discount program from 50% to 70%, starting in 2019.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and imaging centers. On February 9, 2018, President Trump signed into law the Bipartisan Budget Act of 2018, which, among other things, extended the 2% reduction in Medicare payments that originally went into effect on April 1, 2013 through fiscal year 2027. The Bipartisan Budget Act of 2018 also raised the spending cap on non-defense spending for fiscal years 2018 and 2019. While healthcare funding is one component of non-defense spending, we cannot predict whether the increase in the cap on non-defense spending will have any impact on Medicare, Medicaid or other healthcare funding or, if it does, the magnitude of any such impact, nor can we predict whether levels of Medicare, Medicaid or other healthcare funding will increase or decrease in the future.

Likewise, the annual Medicare Physician Fee Schedule update, which, until recently, was based on a target-setting formula system called the Sustainable Growth Rate, or SGR, was adjusted to reflect the comparison of actual expenditures to target expenditures. Because one of the factors for calculating the SGR was linked to the growth in the U.S. gross domestic product, or GDP, the SGR formula often resulted in a negative payment update when growth in Medicare beneficiaries' use of services exceeded GDP growth. Congress repeatedly intervened to delay the implementation of negative SGR payment updates. For example, on April 1, 2014, with the enactment of the Protecting Access to Medicare Act of 2014, Congress prevented the 24% cut that was to occur by continuing the previously implemented 0.5% payment increase through December 31, 2014 and maintaining a 0% payment update from January 1, 2015 through March 31, 2015. However, on April 14, 2015, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015, which was signed into law by President Obama on April 16, 2015. This law repeals the SGR methodology from the physician payment formula, institutes a 0% update to the Medicare Physician Fee Schedule for the January 1 to July 1, 2015 period, a 0.5% payment update for July 2015 through the end of 2019, and a 0% payment update for 2020 through 2025. For 2026 and subsequent years, the payment update will be either 0.75% or 0.25%, depending on which Alternate Payment Model the physician participates. The Bipartisan Budget Act of 2018 reduces the payment update for 2019 from 0.5% to 0.25%. In addition, there is increasing legislative attention to opioid abuse in the United States, including passage of the 2016 Comprehensive Addiction and Recovery Act and the 21st Century Cures Act, or the Cures Act, which, among other things, strengthens state prescription drug monitoring programs and expands educational efforts for certain populations. The Cures Act, which was signed into law on

December 13, 2016 also, among other things, requires the manufacturer of an investigational drug for a serious disease or condition to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug.

The Bipartisan Budget Act of 2018 also includes a number of other Medicare, Medicaid and other healthcare policy and payment provisions in addition to those discussed above. These provisions include, among others:

- increasing civil and criminal penalties for healthcare fraud and abuse laws, including, for example, increasing criminal fines for violations of the Federal Anti-Kickback Statute from
- $25,000 to $100,000 and corresponding prison sentences from no more than five years to no more than ten years; and
- repealing the Independent Payment Advisory Board that was established by the Affordable Care Act and intended to reduce the rate of growth in Medicare spending.

The provisions of the Bipartisan Budget Act of 2018 relating to Medicare, Medicaid and other healthcare funding are extensive and complex and, while we are continuing to evaluate their impact on our business, there can be no assurance that they will not adversely impact our business, results of operations or financial condition.

We expect that the current administration and U.S. Congress will continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Since taking office, President Trump has supported the repeal of all or portions of the Affordable Care Act. In January 2017, President Trump issued an executive order in which he stated that it is his Administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Affordable Care Act to the maximum extent permitted by law. In October 2017, President Trump issued another executive order that directed his Administration to expand access to (i) association health plans that allow businesses to group together to self-insure or purchase group health insurance, (ii) short-term, limited-duration insurance plans for consumers, and (iii) tax-advantaged health reimbursement arrangements that employers can establish for employees. Further, in December 2017, the U.S. Congress passed the Tax Cuts and Jobs Act, which included a provision that eliminates the penalty under the Affordable Care Act's individual mandate and could impact the future state of the health insurance exchanges established by the Affordable Care Act. There is still uncertainty with respect to the additional impact President Trump's Administration and the U.S. Congress may have, if any. Any changes will likely take time to unfold and could impact coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act.

However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us, our industry or the market for healthcare products like ours.

We also expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures, and may adversely affect our operating results.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we or our partners conduct our business. The laws and regulations that may affect our ability to operate include, without limitation:

- the Federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal physician sunshine requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by certain manufacturers to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, all of which govern the conduct of certain electronic healthcare transactions and protect the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Risks Related to Our Intellectual Property

We may not be able to obtain and enforce patent rights or other intellectual property rights that cover our drug delivery systems, products, product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our drug delivery systems and technologies will depend in part on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets, and to prevent third parties from infringing upon our proprietary rights. Our ability to protect any of our approved products, product candidates or drug delivery systems from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Some of the drugs we use in our products have been approved for many years and therefore our ability to obtain any patent protection relating to the drug ingredients in our products may be limited.

Our patent portfolio related to our transdermal drug delivery systems and technologies includes patents and patent applications in the United States and foreign jurisdictions where we believe there is a significant market opportunity for our products. The covered technology and the scope of coverage vary from country to country. Any patents that we may obtain may be narrow in scope and thus easily circumvented by competitors. Further, in countries where we do not have granted patents, third parties may be able to make, use, or sell products identical to, or substantially similar to our products or product candidates.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any existing patents or any patents we might obtain or license may not provide us with sufficient protection for our products and product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us.

Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be held valid or enforceable by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us.

We believe that the development of our Corplex Donepezil product candidate includes certain inventions that are unique and not duplicative of any prior art and we have filed multiple patent applications covering these inventions. We have had two U.S. patents issue, however there can be no assurance that we will be successful in obtaining issued patents from the remaining patent applications related to our Corplex Donepezil technology.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties;
- any patents we obtain for our in-licensed issued patents may not be valid or enforceable; or
- we may not develop additional proprietary technologies that are patentable.

If we or our licensors fail to prosecute, maintain and enforce patent protection for our drug delivery technologies, products or product candidates, our ability to develop and commercialize our technologies, products or product candidates could be adversely affected and we might not be able to prevent competitors from making, using and selling competing technologies or products. This failure to properly protect the intellectual property rights relating to our technologies, products or product candidates could have a material adverse effect on our business, financial condition and results of operations. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Furthermore, in connection with our license agreement with P&G, we granted to P&G an exclusive license for certain fields of use to our Corplex technology and related know-how. P&G may sublicense their rights under that license, at any time, and we do not have any assurance that they will continue to use us as their development partner in the future.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and proprietary information and invention agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our licensees, partners and suppliers. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

If we or our partners are sued for infringing intellectual property rights of third parties, it would be costly and time consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our partners to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our products and product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our drug delivery systems, technologies, products or product candidates infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, drug delivery systems or their methods of use. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our products, product candidates, technologies or methods.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our products, product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our products, product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

A substantial portion of our partners' products and product candidates are generic versions of pre-existing brand name drugs and we may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our partners' products and/or product candidates and/or proprietary technologies infringe their intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug and this type of litigation can be costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. In addition to facing litigation risks directly, we have agreed to indemnify several of our partners against claims of infringement caused by our proprietary technologies, and we have entered or may in the future enter into cost-sharing agreements with some of our partners that could require us to pay some of the costs of patent litigation brought against those partners whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third party claims that we or our partners infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and/or grant cross-licenses to intellectual property rights for our products or technologies; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we or our partners can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, results of operations, financial condition and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers.

As is common in the biotechnology and pharmaceutical industry, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

Risks Relating to Ownership of our Common Stock

Our principal stockholder has substantial control over our business, which may be disadvantageous to other stockholders.

Affiliates of EW Healthcare Partners, or EWHP, beneficially own or control approximately 26% of the voting power of our outstanding common stock. In addition, Ron Eastman, a Managing Director of EWHP, is a member of our board of directors. As a result of its ability to control a significant percentage of the voting power of our outstanding common stock, EWHP may have substantial control over matters requiring approval by our stockholders, including the election and removal of directors, amendments to our certificate of incorporation and bylaws, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions. EWHP may have interests that are different from those of other stockholders. Moreover, this concentration of share ownership makes it difficult for other stockholders to replace directors and management without the consent of EWHP. In addition, this significant concentration of share ownership may adversely affect the price at which prospective buyers are willing to pay for our common stock because investors may perceive disadvantages in owning stock in a company with a single stockholder with this level of control.

Our common stock may be affected by limited trading volume and we expect that the price of our common stock will fluctuate substantially.

There has been a limited public market for our common stock and there can be no assurance that an active trading market for our common stock will develop. This could adversely affect your ability to sell our common stock in short time periods or possibly at all. The trading prices of the securities of pharmaceutical companies have been highly volatile. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- the success of, and fluctuations in, the commercial sales of Clonidine TDS, Fentanyl TDS and Crest Whitestrips products or any other products approved for commercialization;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- the execution of our partnering, manufacturing and other aspects of our business plan;
- variations in the level of expenses related to our commercialization activities;
- the performance of third parties on whom we rely for clinical trials, marketing, sales and distribution, including their ability to comply with regulatory requirements;

- the results of our or our partners' preclinical studies and clinical trials;
- variations in the level of expenses related to our product candidates or preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- price and volume fluctuations in the overall stock market;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC and announcements relating to our or our partners' interactions with the FDA or any foreign regulatory agency, litigation or other disputes, strategic transactions, intellectual property or fentanyl or other controlled substances impacting us or our business;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- ratings downgrades by any securities analysts who follow our common stock;
- the development and sustainability of an active trading market for our common stock;
- future sales of our common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- the impact of dilution to our stockholders, including as a result of the conversion of the Convertible Notes; and
- the possibility that the Notes do not convert into equity and must be repaid in cash.

In addition, the stock markets, and in particular The Nasdaq Global Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. However, for as long as we are an ‘‘emerging growth company’’ under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years following our IPO. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We have begun a process of transitioning from our previous financial tracking system to an updated enterprise resource planning system, but have not determined the timing for such a transition. Our current system has been in place since our founding and the transition will be costly and require new training and extensive changes to our system of internal financial reporting. There is no guarantee that we will be able to transition smoothly and maintain effective internal controls over the reporting process during this transition.

If securities or industry analysts stop publishing research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Future sales of our common stock or securities convertible into our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock or securities convertible into our common stock in the public market, or the perception that these sales might occur may reduce the prevailing market price of our common stock and make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, any sales of securities by us or existing stockholders could have a material adverse effect on the market price of our common stock.

On December 30, 2015, we entered into a sales agreement with Cantor Fitzgerald & Co., as agent, pursuant to which we were able to offer and sell shares of our common stock with aggregate proceeds of up to $20.0 million. As of June 30, 2018, all of the shares of common stock available for sale pursuant to the sales agreement remained available to be sold. The offer and sale of these shares will require the filing of a new registration statement, or an amendment to an existing one, because the registration statement on Form S-3 that was filed with the SEC on May 8, 2015 (File No. 333-204025), including the related prospectus that covered the offer and sale of shares pursuant to the agreement with Cantor Fitzgerald, has expired. Sales of these shares could have a material adverse effect on the market price of our common stock.

In addition, on December 30, 2015, we filed a registration statement on Form S-3 (File No. 333-208800), which was declared effective by the SEC on January 20, 2016, to register for resale 9,353,304 shares of our common stock held by EWHP, or approximately 26% of our total outstanding shares of common stock as of the date of this offering memorandum. As a result, such shares are freely tradable under the Securities Act of 1933, as amended, or the Securities Act, and sales of these shares could have a material adverse effect on the market price of our common stock.

On June 7, 2018, we filed a registration statement on Form S-3 (File No. 333-225497), which was declared effective by the SEC on July 18, 2018, that registers the offer and sale of up to $150,000,000 aggregate dollar amount of our securities in one or more offerings, in amounts, at prices and on the terms that we will determine at the time of the offering and which will be set forth in a prospectus supplement and any related free writing prospectus. Any sales of these securities could have a material effect on the market price of our common stock.

Anti-takeover provisions in our charter documents and Delaware law might deter acquisition bids for us that you might consider favorable.

Our restated certificate of incorporation and restated bylaws contain provisions that may make the acquisition of our company more difficult without the approval of our board of directors. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- authorize the issuance of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval, and which may include rights superior to the rights of the holders of common stock;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the board of directors is expressly authorized to make, alter, or repeal our bylaws; and
- establish advance notice requirements for nominations for elections to our board or for proposing matters that can be acted upon by stockholders at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. These anti-takeover provisions and other provisions under Delaware law could discourage, delay or prevent a transaction involving a change in control of our company, even if doing so would benefit our stockholders. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing so as to cause us to take certain corporate actions you desire.

We qualify as an "emerging growth company" as defined in the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We qualify as an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including certain reduced financial statement reporting obligations, reduced disclosure obligations about our executive compensation arrangements, exemptions from the requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements, and exemption from the auditor's attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our April 2014 IPO, (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years, or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. We may also be restricted from paying dividends under the terms of future indebtedness. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, realization of any gain on your investment in our common stock will depend entirely on the appreciation of the price of our common stock, which may never occur. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

Risk Factors Related to the Notes

We have indebtedness in the form of convertible senior notes, which could limit the cash flow available for our operations, adversely affect our financial condition and results of operations, and impair our ability to satisfy our obligations under the notes or respond to changes in our business.

The Convertible Notes mature on March 15, 2025, unless earlier converted or repurchased in accordance with their terms. Prior to March 15, 2022, we may not redeem the Convertible Notes. On or after March 15, 2022, we may redeem for cash all or any portion of the Convertible Notes, at our option, if certain conditions are met, including, but not limited to, that the last reported sales price per share of our common stock has exceeded 130% of the conversion price for each of at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter.

Holders of the Convertible Notes may convert all or a portion of their Convertible Notes at their option at any time prior to the close of business on the scheduled trading day immediately prior to March 15, 2025, in multiples of $1,000 principal amount, only under the following circumstances:

- at any time during a calendar quarter after June 30, 2018, if the last reported sales price per share of our common stock exceeds 130% of the conversion price for each of at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;

- during the five consecutive business days immediately after any five consecutive trading day period (such five consecutive trading day period, referred to as the measurement period) in which the trading price per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of our common stock on such trading day and the conversion rate on such trading day;

- upon the occurrence of certain corporate events or distributions on our common stock;

- we call such Convertible Notes for redemption; and

- at any time from, and including, September 15, 2024 until the close of business on the scheduled trading day immediately before the maturity date.

The Convertible Notes are convertible into shares of our common stock at an initial conversion rate of 58.0552 shares of common stock per $1,000 principal amount of the Convertible Notes, which is equivalent to an initial conversion price of approximately $17.22 per share of common stock. As of June 30, 2018, the Convertible Notes were convertible into 6,968,641 shares of our common stock. The conversion rate and the corresponding conversion price will be subject to adjustment upon the occurrence of certain events, including, but not limited to, stock splits and dividends, rights offerings, cash dividends, or a make-whole fundamental change, but will not be adjusted for any accrued and unpaid interest. The conversion of some or all of the Convertible Notes into shares of our common stock will dilute the ownership interests of existing stockholders. In addition, we are required to repay amounts due under the Convertible Notes in the event that there is an event of default for the Convertible Notes. There can be no assurance that we will be able to repay this indebtedness when due, or, if necessary, that we will be able to refinance this indebtedness on acceptable terms or at all.

As a result of the issuance of the Convertible Notes, we have approximately $120 million of long-term indebtedness. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;

- limiting our ability to obtain additional financing;

- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;

- limiting our flexibility to plan for, or react to, changes in our business;

- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the Convertible Notes; and

- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the Convertible Notes, and our cash needs may increase in the future. In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under any of our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and any of our other indebtedness becoming immediately payable in full.

The Convertible Notes are effectively subordinated to any of our future secured indebtedness.

The Convertible Notes are our senior, unsecured obligations and will rank equal in right of payment with any of our future senior, unsecured indebtedness, senior in right of payment to any future indebtedness that is expressly subordinated to the Convertible Notes and effectively subordinated to any of our future secured indebtedness, to the extent of the value of the collateral securing that indebtedness. As of June 30, 2018, we had approximately $120 million of long-term indebtedness. The Indenture governing the Convertible Notes does not prohibit us from incurring additional indebtedness, including senior or secured indebtedness, in the future.

If a bankruptcy, liquidation, dissolution, reorganization or similar proceeding occurs with respect to us, then the holders of any of our secured indebtedness may proceed directly against the assets securing that indebtedness. Accordingly, those assets will not be available to satisfy any outstanding amounts under our unsecured indebtedness, including the Convertible Notes, unless the secured indebtedness is first paid in full. The remaining assets, if any, would then be allocated pro rata among the holders of our senior, unsecured indebtedness, including the Convertible Notes. There may be insufficient assets to pay all amounts then due.

We may be unable to raise the funds necessary to repurchase the Convertible Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion, and any of our other indebtedness may limit our ability to repurchase the Convertible Notes or pay cash upon their conversion.

Noteholders may require us to repurchase their Convertible Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Convertible Notes or pay the cash amounts due upon conversion. In addition, applicable law, regulatory authorities and the agreements governing any of our other indebtedness may restrict our ability to repurchase the Convertible Notes or pay the cash amounts due upon conversion. Our failure to repurchase Convertible Notes or to pay the cash amounts due upon conversion when required will constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing any of our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under such other indebtedness and the Convertible Notes.

Provisions in the Indenture could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in the Convertible Notes and the Indenture could make a third party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then noteholders will have the right to require us to repurchase their Convertible Notes for cash. In addition, if a takeover constitutes a make-whole fundamental change (as described in more detail in the Indenture), then we may be required to temporarily increase the conversion rate, which would require us to issue additional shares to the holders of the Convertible Notes upon conversion and result in additional dilution to our stockholders. In either case, and in other cases, our obligations under the Convertible Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that noteholders or holders of our common stock may view as favorable.

The accounting method for the Convertible Notes could adversely affect our reported financial condition and results.

The accounting method for reflecting the Convertible Notes on our balance sheet, accruing interest expense for the Convertible Notes and reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our financial condition and results.

Under applicable accounting principles, the initial liability carrying amount of the Convertible Notes will be valued as described in Note 4 to our financial statements included in this Quarterly Report on Form 10-Q. We will reflect the difference between the principal amount of the Convertible Notes over the value of the liability component as debt discount for accounting purposes, which will be amortized into interest expense over the term of the Convertible Notes. As a result of this amortization and amortization of the debt issuance costs, the interest expense we will recognize for the Convertible Notes for accounting purposes will be greater than the cash interest payments we will pay on the Convertible Notes, which will result in lower reported income or higher reported loss. The lower reported income or higher reported loss resulting from this accounting treatment could depress the trading price of our common stock and the Convertible Notes.

In addition, because we intend to settle conversions by paying the conversion value in cash up to the principal amount being converted and any excess in shares, we expect to be eligible to use the treasury stock method to reflect the shares underlying the Convertible Notes in our diluted earnings per share. Under this method, if the conversion value of the Convertible Notes exceeds the principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all the Convertible Notes were converted and that we issued shares of our common stock to settle the excess. However, if reflecting the Convertible Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the Convertible Notes does not exceed their principal amount for a reporting period, then the shares underlying the Convertible Notes will not be reflected in our diluted earnings per share. In addition, if accounting standards change in the future and we are not permitted to use the treasury stock method, then our diluted earnings per share may decline.

Furthermore, if any of the conditions to the convertibility of the Convertible Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the Convertible Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their Convertible Notes and could materially reduce our reported working capital.

We may still incur substantially more debt or take other actions which would intensify the risks discussed above.

We may incur substantial additional debt in the future, subject to the restrictions contained in our future debt instruments. We are not restricted under the terms of the Indenture governing the Convertible Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt, repurchasing our stock, pledging our assets, making investments, paying dividends, guaranteeing debt or taking a number of other actions that are not limited by the terms of the Indenture governing the Convertible Notes that could have the effect of diminishing our ability to make payments on the Convertible Notes when due.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

On May 14, 2018, we issued a warrant to purchase 350,000 shares of our common stock to Cantor Fitzgerald in connection with its role as the initial purchaser in the Company's offering of the Convertible Notes, which has a term of 7 years, an exercise price of $17.22 per share.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
31.1	Certification of Periodic Report by Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Periodic Report by Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002					X
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					X
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					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

* This certification is deemed not filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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, in the City of Menlo Park, State of California, on August 10, 2018.

CORIUM INTERNATIONAL, INC.

By: /s/ Peter D. Staple
Peter D. Staple
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Robert S. Breuil
Robert S. Breuil
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter D. Staple, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Corium International, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 10, 2018

/s/ Peter D. Staple
Peter D. Staple
Chief Executive Officer
(Principal Executive Officer*)*

EXHIBIT 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert S. Breuil, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Corium International, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 10, 2018

/s/ Robert S. Breuil
Robert S. Breuil
Chief Financial Officer
(Principal Financial Officer)

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

I, Peter D. Staple, Chief Executive Officer of Corium International, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: August 10, 2018

/s/ Peter D. Staple
Peter D. Staple
Chief Executive Officer
(Principal Executive Officer*)*

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

I, Robert S. Breuil, Chief Financial Officer of Corium International, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: August 10, 2018

/s/ Robert S. Breuil
Robert S. Breuil
Chief Financial Officer
(Principal Financial Officer)