Corium International, Inc.
Form 10-Q
February 12, 2018
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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 December 31, 2017

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 February 8, 2018, there were approximately 36,123,945 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 December 31, 2017	As of September 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,230	$ 57,466
Accounts receivable	4,856	4,641
Unbilled accounts receivable	407	169
Inventories	2,526	2,300
Prepaid expenses and other current assets	1,263	982
Total current assets	54,282	65,558
Property and equipment, net	12,922	12,176
Intangible assets, net	7,149	7,117
TOTAL ASSETS	$ 74,353	$ 84,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,712	$ 3,978
Accrued expenses and other current liabilities	4,132	6,411
Long-term debt, current portion	26,298	13,172
Recall liability, current portion	221	114
Deferred contract revenues, current portion	390	626
Total current liabilities	38,753	24,301
Long-term debt, net of current portion	25,994	39,027
Recall liability, net of current portion	1,698	1,811
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	69,945	68,639
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 150,000,000 shares authorized; 36,117,913 and 36,004,602 shares issued and outstanding as of December 31, 2017 and September 30, 2017	36	36
Additional paid-in capital	232,945	231,457
Accumulated deficit	(228,573)	(215,281)
Total stockholders' equity	4,408	16,212

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 74,353	$ 84,851

See accompanying notes to condensed financial statements.

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CORIUM INTERNATIONAL, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended December 31,	
	2017	2016
Revenues:		
Product revenues	$ 5,921	$ 5,738
Contract research and development revenues	3,154	963
Other revenues	240	267
Total revenues	9,315	6,968
Costs and operating expenses:		
Cost of product revenues	3,284	4,081
Cost of contract research and development revenues	3,605	2,120
Research and development expenses	10,238	5,998
General and administrative expenses	3,300	3,005
Amortization of intangible assets	177	177
Total costs and operating expenses	20,604	15,381
Loss from operations	(11,289)	(8,413)
Interest income	122	28
Interest expense	(2,123)	(2,042)
Loss before income taxes	(13,290)	(10,427)
Income tax expense	2	2
Net loss and comprehensive loss	$ (13,292)	$ (10,429)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.37)	$ (0.46)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,073,008	22,453,172

See accompanying notes to condensed financial statements

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CORIUM INTERNATIONAL, INC.

Condensed Statement of Stockholders' Equity

(In thousands, except share data)

(Unaudited)

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance - September 30, 2017	36,004,602	$ 36	$ 231,457	$ (215,281)	$ 16,212
Issuance of common stock under Employee Stock Purchase Plan	64,547	—	213	—	213
Issuance of common stock upon exercise of stock options	48,764	—	140	—	140
Stock-based compensation expense	—	—	1,135	—	1,135
Net loss and comprehensive loss	—	—	—	(13,292)	(13,292)
Balance - December 31, 2017	36,117,913	$ 36	$ 232,945	$ (228,573)	$ 4,408

See accompanying notes to condensed financial statements.

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CORIUM INTERNATIONAL, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended December 31,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss and comprehensive loss	$ (13,292)	$ (10,429)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of property and equipment	225	318
Amortization of intangible assets	177	177
Noncash amortized debt issuance costs on long-term debt and capital leases	100	68
Noncash amortized discount on long-term debt and capital leases	4	4
Stock-based compensation expense	1,135	870
Issuance of payment-in-kind notes in lieu of cash interest payments	—	458
Changes in operating assets and liabilities:		
Accounts receivable	(215)	2,172
Unbilled accounts receivable	(238)	(211)
Inventories	(226)	492
Prepaid expenses and other current assets	(281)	(94)
Accounts payable	3,415	1,053
Accrued expenses and other current liabilities	(2,279)	(742)
Deferred contract revenues	(236)	(67)
Recall liability	(6)	(144)
Net cash used by operating activities	(11,717)	(6,075)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(652)	(827)
Payments for patents and licensing rights	(209)	(212)
Net cash used by investing activities	(861)	(1,039)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on long-term debt	(11)	(19)
Principal payments on capital lease obligations	—	(73)
Proceeds from exercise of stock options	140	222
Proceeds from issuance of common stock under Employee Stock Purchase Plan	213	226
Net cash provided by financing activities	342	356
NET DECREASE IN CASH AND CASH EQUIVALENTS	(12,236)	(6,758)
CASH AND CASH EQUIVALENTS — Beginning of period	57,466	39,833
CASH AND CASH EQUIVALENTS — End of period	$ 45,230	$ 33,075
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 2,020	$ 1,512
Cash paid for income taxes	$ —	$ 1

SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable	$ 349	$ 219
Unpaid transaction costs associated with issuance of long-term debt	$ —	$ 544

See accompanying notes to condensed financial statements.

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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 December 31, 2017, statements of operations and comprehensive loss for the three months ended December 31, 2017 and 2016, statement of stockholders' equity for the three months ended December 31, 2017, and statements of cash flows for the three months ended December 31, 2017 and 2016 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 December 31, 2017, its results of operations for the three months ended December 31, 2017 and 2016, and its cash flows for the three months ended December 31, 2017 and 2016. The financial data and the other financial information contained in these notes to the financial statements related to the three-month periods are also unaudited. The results of operations for the three months ended December 31, 2017 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.

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Liquidity

With the exception of fiscal 2013, the Company has incurred losses from operations since fiscal 2006 and has an accumulated deficit of $228.6 million as of December 31, 2017. The Company has financed its operations primarily through the proceeds from the sale of equity securities, and various debt and capital lease financings.

The Company believes that its existing cash and cash equivalents will not be sufficient to fund operations in compliance with its debt covenants as currently planned through the next 12 months, which raises substantial doubt about the Company's ability to continue as a going concern. The Company has based this belief on assumptions and estimates that may prove to be wrong, and the Company could spend its available financial resources less or more rapidly than currently expected. The Company will continue to require additional sources of cash to develop product candidates and to fund development and commercialization operations. Management intends to seek additional capital through collaborative or other funding arrangements with partners, equity and/or debt financings, or through other sources of financing. The Company is also pursuing alternatives to its current debt covenants, including refinancing the existing debt. In the event that additional financing is required from outside sources, the Company may not be able to raise such financing on terms acceptable to the Company or at all. If the Company is unable to raise additional capital when required or on acceptable terms, the Company 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 the Company's business plans, and its business, operating results and financial condition would be adversely affected.

The Company is currently in compliance with the covenants under the Company's term loan agreement with CRG, a structured debt and equity investment management firm. However, the Company anticipates that, based on its current operating plan for products and services currently under contract, and without securing additional sources of external funding, its current cash and cash equivalent balances will not be sufficient to maintain compliance with the minimum liquidity financial covenant through the next 12 months. Additionally, the Company anticipates that these revenues will not be sufficient to maintain compliance with the minimum annual revenue covenant of $50.0 million for the 12 months ending June 30, 2018. Failure to meet either covenant would be considered an event of default on the Company's debt obligation, and could result in the acceleration of the Company's existing indebtedness, causing the outstanding principal of approximately $52.5 million, plus an early prepayment premium and an additional fee, to be immediately due and payable to CRG. As of December 31, 2017, the prepayment premium was 7.5% and the additional fee was 1.0%. Effective January 1, 2018, the prepayment premium was 3.25%. The Company may not have sufficient cash and cash equivalents to repay all of the outstanding debt in full if repayment of such debt were accelerated. Due to these uncertainties, there is substantial doubt about the Company's ability to continue as a going concern.

The unaudited condensed financial statements as of December 31, 2017 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company's ability to continue as a going concern is dependent upon its uncertain ability to secure new sources of revenue, obtain additional equity and/or debt financing or refinancing, generate operating efficiencies, reduce expenditures and amend or obtain a waiver on the financial covenants of the existing term loan agreement with CRG. The unaudited condensed financial statements as of December 31, 2017 do not include any adjustments that might result from the outcome of this uncertainty.

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.

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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 the three months ended December 31, 2017, three partners accounted for 98% of the Company's revenues and three partners accounted for 97% of accounts receivable as of December 31, 2017. For the three months ended December 31, 2016, three partners accounted for 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 months ended December 31, 2017 and 2016, 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. This ASU is 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 Codification.

The Company anticipates adopting the new revenue recognition standard on the effective date of 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

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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 evaluating changes to its accounting processes, internal controls and disclosures to support the new standard.

In July 2015, the Financial Accounting Standards Board issued ASU No. 2015-11, “Inventory (Topic 330): Simplifying the Measurement of Inventory.” This ASU applies to inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this update is required to be recorded at the lower of cost or net realizable value, which is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. This ASU is effective prospectively for annual reporting periods beginning after December 15, 2016, and interim periods thereafter; early adoption is permitted. The Company adopted the provision of this ASU effective October 1, 2017 and the adoption of this ASU did not have a material impact on the Company’s financial position, results of operations or cash flows.

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 all leases to be recognized in the statement of financial position. 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 March 2016, the FASB issued ASU 2016-09, “Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting” (“ASU 2016-09”). ASU 2016-09 modifies U.S. GAAP by requiring, among other things, the following: (1) all excess tax benefits and tax deficiencies are to be recognized as income tax expense or benefit on the income statement (excess tax benefits are recognized regardless of whether the benefit reduces taxes payable in the current period); (2) excess tax benefits are to be classified along with other income tax cash flows as an operating activity in the statement of cash flows; (3) an entity can still follow the current U.S. GAAP practice of making an entity-wide accounting policy election to estimate the number of awards that are expected to vest or may instead account for forfeitures when they occur; and (4) classification of cash paid by an employer to the taxing authorities when directly withholding shares for tax withholding purposes as a financing activity in the statement of cash flows. The Company adopted the provisions of this ASU effective October 1, 2017. The Company has elected to continue to estimate expected forfeitures and the adoption of the remaining provisions in the ASU did not have a material impact on the Company’s 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”. 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. 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.

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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 months ended December 31, 2017. 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 December 31, 2017			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	$ 45,424	$ —	$ —	$ 45,424

	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 Level III liabilities as of December 31, 2017 and September 30, 2017.

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The carrying values of the Company's long-term debt reflects the principal amount, adjusted for any unamortized debt issuance costs and discount. The following financial liabilities have carrying values which differ from their fair value as estimated by the Company based on market quotes for instruments with similar terms and remaining maturities (in thousands):

	As of December 31, 2017		
	Carrying Value	Fair Value	Difference
Long-term debt	$ 52,292	$ 55,350	$ 3,058

	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 December 31, 2017	As of September 30, 2017
Raw materials	$ 1,760	$ 1,683
Work in process	479	264
Finished goods	287	353
Total inventories	$ 2,526	$ 2,300

4. Long-Term Debt

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

	As of December 31, 2017	As of September 30, 2017
Term loan agreement expiring June 30, 2019, less unamortized issuance costs of $597 and $697 and unamortized discount of $23 and $27 as of December 31, 2017	$ 51,883	$ 51,779

and September 30, 2017. See terms of the agreement below.

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	409	420
Total	52,292	52,199
Less current portion	26,298	13,172
Long-term portion	$ 25,994	$ 39,027

On July 13, 2012, the Company completed a $35.0 million term loan agreement with CRG, a structured debt and equity investment management firm. In August 2012 and December 2012, the Company drew down $29.0 million and $6.0 million under this agreement. On November 14, 2014, the agreement was amended to, among other things, increase the principal amount available under the term loan by $10.0 million, extend the interest-only period to June 30, 2018, and extend the maturity from June 30, 2017 to June 30, 2019. The amended agreement provides for a maximum borrowing of $45.0 million, excluding PIK notes, as defined below. The amended agreement requires 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 June 30, 2018, with interest continuing to accrue on the unpaid principal at a simple annual rate of 15%. In addition, the amended agreement contains a provision whereby the Company can, 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 additional notes (payment-in-kind (“PIK”) notes). Amounts outstanding under the term loan agreement are collateralized by all of the Company’s assets. The amended agreement also provides for a prepayment

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premium, the amount of which varies with the date on which prepayment is made, if the Company chooses to repay principal prior to June 30, 2018, or upon other specified events, including a change of control. On December 4, 2014, the Company borrowed the remaining $10.0 million of principal provided for in the amended agreement.

As of December 31, 2017 and September 30, 2017, the Company had converted $7.5 million of interest into PIK notes, each of which added to the then-outstanding principal, and is included in the principal balances shown as of those dates. As of December 31, 2017, the principal amount outstanding under the term loan agreement, including all PIK notes, was $52.5 million. From January 1, 2018 through December 31, 2018, the prepayment premium will be equal to 3.25% of the aggregate value of the principal and PIK notes outstanding at the time of prepayment. For prepayments on or after January 1, 2019, there is no prepayment premium.

The term loan agreement was amended in December 2016 to modify the financial covenants for minimum annual revenues (beginning with the 12 months ended June 30, 2017) in exchange for a fee equal to 1.0% of the aggregate principal amount of all loans and PIKs advanced by CRG to the Company under the term loan agreement. This fee will be due upon the loan maturity date of June 30, 2019 or upon the earlier acceleration of the loan pursuant to its terms. Based on the current loan balance and projected PIK borrowings, this fee is expected to be approximately $0.5 million. The Company has been in continuous compliance with the financial covenants since the inception of the loan.

5. Collaboration and Partner Arrangements

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

	Three Months Ended December 31,	
	2017	2016
Mayne	$ 2,032	$ 1,407
Par	—	363
P&G	4,815	4,021
Agile	2,323	1,078
Other	145	99
Total revenues	$ 9,315	$ 6,968

Included in total revenues above is profit sharing, which totaled $0.3 million for the three months ended December 31, 2017, compared to $0.4 million for the corresponding period 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 2013. The warrants were recorded as equity instruments at the date of their issuances based on the terms of the warrants.

As of December 31, 2017 and September 30, 2017, warrants to purchase 51,386 shares of common stock were outstanding, with a weighted average exercise price of $9.26 per share. All of the common stock warrants are exercisable at any time up to ten years from issuance. These warrants expire at various dates between December 2020 and November 2021. The fair value of these warrants was recorded in stockholders’ equity upon issuance.

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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 December 31, 2017 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 December 31, 2017 and September 30, 2017 with a par value of $0.001 per share. As of December 31, 2017, there were 36,117,913 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 OfferingSM 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 offer and sale of these shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus (File No. 333-204025) filed by the Company with the SEC on May 8, 2015 and declared effective by the SEC on May 21, 2015, as supplemented by a prospectus supplement dated and filed with the SEC on December 30, 2015. 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.

8. Stock-Based Compensation

Equity Incentive Plans

As of December 31, 2017 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 10, 2017 and January 11, 2016, the Company’s board of directors authorized an increase of 902,298 and 888,776 shares to be added to the total number of shares of common stock issuable under the 2014 Plan. As of December 31, 2017 and September 30, 2017, the Company had reserved 5,012,065 and 5,060,829 shares of common stock for issuance pursuant to the 2014 Plan. As of December 31, 2017 and September 30, 2017, the Company had 258,964 and 1,129,232 shares of common stock available for issuance pursuant to the 2014 Plan.

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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 three months ended December 31, 2017 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	803,650	$ 11.59		
Options exercised	(48,764)	$ 2.87		
Options forfeited / cancelled	(2,937)	$ 5.02		
Options expired	(445)	$ 2.22		
Balance - December 31, 2017	4,538,726	$ 6.06	7.23	$ 18,060
Options exercisable - December 31, 2017	2,739,351	$ 4.54	6.04	$ 14,137
Options vested and expected to vest - December 31, 2017	4,362,537	$ 5.96	7.15	$ 17,690

All outstanding stock options under the Corium Plans as of December 31, 2017 have an exercise price between $2.12 and $14.12 per share.

The weighted-average fair value of the stock options granted for the three months ended December 31, 2017 were estimated using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended December 31, 2017
Expected term (in years)	5.27 - 6.57
Risk-free interest rate	2.08% - 2.24%
Expected volatility	68 % - 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.

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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 three months ended December 31, 2017 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 and released	—	$ —
Forfeited	—	$ —
Nonvested - December 31, 2017	214,375	$ 8.12

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 10, 2017 and January 11, 2016, the Company’s board of directors reserved an additional 267,565 and 257,631 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 December 31, 2017 and September 30, 2017, there were 571,852 and 636,399 shares of common stock available for issuance pursuant to the 2014 ESPP.

For the three months ended December 31, 2017, the Company recorded stock-based compensation expense related to the 2014 ESPP of $46,000, compared to $94,000 for the corresponding period in fiscal 2017. For the three months ended December 31, 2017 and 2016, the Company issued 64,547 and 69,886 shares of common stock to employees pursuant to the 2014 ESPP.

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The fair value of the purchase rights granted under the 2014 ESPP for the offering periods beginning May 20, 2016, November 20, 2016, May 20, 2017 and November 20, 2017 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 December 31, 2017
Fair value of common stock	$ 3.79 – $ 10.95
Grant price	$ 3.22 – $ 9.31
Expected term (in years)	0.50 – 2.00
Expected volatility	56 % – 87 %
Risk-free interest rate	0.89 % – 1.77 %
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, or $3.79, $4.82, $6.54, and $10.95 for the offering periods commencing May 20, 2016, November 20, 2016, May 20, 2017 and November 20, 2017.

Grant Price — 85% of the fair market value of the Company's common stock on the first day of the offering period, or $3.22, $4.10, $5.56, and $9.31 for the offering periods commencing May 20, 2016, November 20, 2016, May 20, 2017 and November 20, 2017.

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 months ended December 31, 2017 and 2016 is classified in the condensed statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended December 31,	
	2017	2016
Cost of product revenues	$ 109	$ 102
Cost of contract research and development revenues	81	51
Research and development	220	151
General and administrative	725	566
Total stock-based compensation	$ 1,135	$ 870

As of December 31, 2017, there was a total of $9.8 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 2.9 years.

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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 months ended December 31, 2017, the Company made an immaterial amount of settlement payments to Actavis compared to $0.1 million for the corresponding period in fiscal 2017. The outstanding balance of the recall liability was $1.9 million as of December 31, 2017 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 months ended December 31, 2017 and 2016 (in thousands, except share and per share data):

	Three Months Ended December 31,	
	2017	2016
Basic and diluted net loss per share		
Net loss attributable to common stockholders, basic and diluted	$ (13,292)	$ (10,429)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,073,008	22,453,172
Net loss per share attributable to common stockholders, basic and diluted	$ (0.37)	$ (0.46)

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 December 31,	
	2017	2016
Stock options to purchase common stock	4,538,726	4,037,737
Unvested restricted stock unit awards	214,375	110,000
Shares authorized under the 2014 ESPP	571,852	433,803
Common stock warrants	51,386	51,386

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11. Income Taxes

The Company did not record a provision for Federal income taxes for the three months ended December 31, 2017 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 three months ended December 31, 2017 and 2016 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 "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code and will affect the Company's fiscal year ending September 31, 2018, including, but not limited to reducing the U.S. federal corporate tax rate from 35 percent to 21 percent and limitations on net operating losses ("NOLs") generated after December 31, 2017. Section 15 of the Internal Revenue Code stipulates that the Company's fiscal year ending September 31, 2018 will have a blended corporate tax rate of 24.53 percent, which is based on the applicable tax rates before and after the Tax Act and the number of days in the year.

The SEC staff issued Staff Accounting Bulletin 118 ("SAB 118"), which provides guidance on accounting for the tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the 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 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 cannot determine a provisional estimate to be included in the financial statements, 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 Tax Act.

The Company's analysis of the impact of the Tax Act is incomplete, and the Company was not able to make reasonable estimates of the effects as of December 31, 2017. Therefore, the Company has not recorded any provisional adjustments. The Company expects the Tax Act will result in a decline in deferred tax assets as a result of the lower U.S. corporate tax rate, however, due to the existence of a full valuation allowance the impact on income tax expense will likely be immaterial.

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.

13. Subsequent Events

On January 16, 2018, pursuant to the provisions of the 2014 Plan and the ESPP Plan, the board of directors authorized and approved the registration of 1,444,716 additional shares of the Company's common stock subject to issuance by the Company under the 2014 Plan and 409,224 additional shares of the Company's common stock subject to issuance by the Company under the 2014 ESPP.

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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," "see 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. 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. In addition to our proprietary Alzheimer's program, our late-stage pipeline includes a contraceptive patch co-developed with Agile Therapeutics, or Agile, and additional transdermal products that are being developed with other partners.

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, 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.

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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, and (4) products currently awaiting Food and Drug Administration, or FDA, approval.

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	Pivotal Bioequivalence
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 by Teva.

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 P&G commercially launched in 2009. P&G currently sells Crest Whitestrips products globally.

In addition to commercialized products, we have a number of product candidates in late 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 January 2017, Agile announced top-line data from a completed Phase 3 clinical trial. Agile had initiated this trial after receipt of a Complete Response Letter, or CRL, from the FDA in February 2013 in response to Agile's previous New Drug Application, or NDA, filing in April 2012. As recommended by the FDA in the February 2013 CRL, Agile conducted a third Phase 3 clinical trial which was completed in 2016. In June 2017, Agile resubmitted its NDA with the results of the additional Phase 3 clinical trial and, in July 2017, the FDA notified Agile of its acceptance of the resubmitted NDA for review. Agile's Prescription Drug User Fee Act, or PDUFA, goal date for this resubmission was December 26, 2017. On December 22, 2017, Agile disclosed that the FDA had issued a CRL in response to the resubmission of their NDA, which stated that the FDA could not approve Agile's NDA in its current form. Agile further 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 observations noted during an FDA inspection of our facility must be resolved. The CRL

also recommended that Agile address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates. Agile disclosed that they had submitted an amendment to their NDA on December 1, 2017 in response to an information request from the FDA on the issues related to the quality adhesion test methods cited in the CRL, and further disclosed that while the CRL acknowledged receipt of the Agile NDA amendment, the FDA stated that the amendment had not been reviewed prior to the FDA's issuance of the CRL. In addition, on November 20, 2017 and December 1, 2017, we provided responses to the FDA addressing each of the observations made during the FDA's facility inspection.

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Agile has also disclosed that it intends to request a meeting with the FDA as soon as possible to discuss the points raised in the CRL and to establish a path to approval for Twirla. We are working closely with Agile to address the non-clinical issues raised in the CRL as quickly as possible.

In addition to our partnered products, we are developing several Corium-funded 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 the fourth fiscal quarter of 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. Specifically, the FDA advised us that if we can adequately demonstrate bioequivalence, or BE, 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 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 the fourth calendar quarter of fiscal 2016, we initiated our pilot bioequivalence study for Corplex Donepezil, and we completed the study in April 2017. The pilot 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 pilot 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 has 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 pilot 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 pilot study could serve as the pivotal study and we have provided additional data requested by the FDA for this purpose. However, since we are uncertain as to the length or outcome of that review, we initiated dosing of our pivotal BE study for Corplex Donepezil in October 2017. The design of the pivotal BE study is similar to the pilot study and is a single center, randomized, multiple dose, two-way crossover study in healthy volunteers, conducted at the same site as the pilot BE study. Dosing in the first treatment period was completed in December 2017 and dosing in the second treatment period commenced in January 2018, with topline results expected in the second quarter of calendar 2018. We are targeting submission of a Section 505(b)(2) NDA for this product candidate in the fourth quarter of calendar 2018.

We are currently focusing our resources and clinical development efforts on Corplex Donepezil, the highest priority of our proprietary programs, and plan to defer the next stage of clinical trials for our other proprietary programs, including Corplex Memantine, pending further progress on our donepezil program. 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.

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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.

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

Components of Statements of Operations

Revenues

During the three months ended December 31, 2017 and 2016, we recognized revenues in three categories: product revenues, contract research and development revenues, and other revenues.

Product Revenues —Product revenues consist 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 three months ended December 31, 2017 and 2016.

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 their sales of the product. For the three months ended December 31, 2017, product revenues related to Clonidine TDS decreased, compared to the same period in fiscal 2017 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 will be higher than fiscal 2017 revenues, product revenues beyond 2018 could be again adversely impacted by the increased competition experienced in fiscal 2017.

Our product revenues from Fentanyl TDS consisted of revenues from the sale of products we manufactured and shipped to Mayne and Par, a wholly-owned subsidiary of Endo Pharmaceuticals, or Endo. Product revenues related to Fentanyl TDS increased for the three months ended December 31, 2017, compared to the same period in fiscal 2017, as a result of increased units shipped. In March 2017, Mayne acquired the product from Par, and although orders and forecasts have increased since Mayne acquired the product, we expect that our product revenues from Fentanyl TDS in fiscal 2018 will be lower than fiscal 2017 as a result of continued competition.

Product revenues from Crest Whitestrips consisted of revenues from the sale of products manufactured and shipped to P&G. Revenues increased for the three months ended December 31, 2017, 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 effectively reached the limits of our current production capacity for Crest Whitestrips, but expect to complete the expansion of our capacity to meet the growing demand by the second half of fiscal 2018.

Contract Research and Development Revenues —We also generate 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 three months ended December 31, 2017, compared to the same period in fiscal 2017, due primarily to increased development activities related to Twirla. Given Agile’s recent guidance on the potential timeline needed to address the FDA’s concerns regarding the approval of

the NDA for Twirla, we currently expect that our revenues from contract research and development in fiscal 2018 will be similar to those of fiscal 2017.

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Other Revenues —Other revenues consist 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, and from license revenue earned primarily from our agreement with P&G, whereby we receive milestone payments upon commercial launch approval of each new product developed by us using our intellectual property. 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.

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 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.

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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 long-term debt and our capital lease obligations. The majority of our interest expense associated with the CRG term loan is paid periodically in cash, except when an allowable portion of the interest due is 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.”

Results of Operations

Comparison of the Three Months Ended December 31, 2017 and 2016

	Three Months Ended December 31,		Change	
(In thousands, except percentages)	2017	2016	$	%
Revenues:				
Product revenues	$ 5,921	$ 5,738	$ 183	3 %
Contract research and development revenues	3,154	963	2,191	228
Other revenues	240	267	(27)	(10)
Total revenues	9,315	6,968	2,347	34
Costs and operating expenses:				
Cost of product revenues	3,284	4,081	(797)	(20)
Cost of contract research and development revenues	3,605	2,120	1,485	70
Research and development expenses	10,238	5,998	4,240	71
General and administrative expenses	3,300	3,005	295	10
Amortization of intangible assets	177	177	—	—
Total costs and operating expenses	20,604	15,381	5,223	34
Loss from operations	(11,289)	(8,413)	(2,876)	(34)
Interest income	122	28	94	336
Interest expense	(2,123)	(2,042)	(81)	(4)
Loss before income taxes	(13,290)	(10,427)	(2,863)	(27)
Income tax expense	2	2	—	—
Net loss and comprehensive loss	$ (13,292)	$ (10,429)	$ (2,863)	(27) %

Revenues

Product revenues increased $0.2 million, or 3%, for the three months ended December 31, 2017 compared to the same period in fiscal 2017. The increase was primarily driven by a $0.6 million increase in revenues from Crest Whitestrips due to increased global demand for these products and a $0.2 million increase in revenues from Fentanyl TDS due to an increase in the number of units shipped. The increases were partially offset by a $0.6 million decrease in revenues from Clonidine TDS due primarily to fewer units shipped and lower profit-sharing earned as our partner’s market share and pricing both declined.

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Contract research and development revenues increased $2.2 million, or 228%, for the three months ended December 31, 2017 compared to the same period in fiscal 2017. This increase was driven by a $1.2 million increase in revenues related to expanded development activities for Twirla in support of the regulatory filing and anticipated commercialization of the product, a $0.5 million increase in revenues related to a late-stage partnered development program, a $0.2 million increase in revenues related to P&G development activities and a $0.1 million increase in revenues related to our co-development programs.

Cost of Product Revenues

Cost of product revenues decreased $0.8 million, or 20%, for the three months ended December 31, 2017 compared to the same period in fiscal 2017, primarily as a result of fewer units of Clonidine TDS shipped for the three months ended December 31, 2017. While product revenues increased by 3%, cost of product revenues decreased by 20% primarily related to changes in our product mix between the periods.

Cost of Contract Research and Development Revenues

Cost of contract research and development revenues increased $1.5 million, or 70%, for the three months ended December 31, 2017 compared to the same period in fiscal 2017, primarily as a result of a $1.3 million increase in costs related to the Twirla program, as development activities shifted to support of the regulatory filing and anticipated commercialization of the product, a $0.5 million increase in costs related to a late-stage partnered development program, and a $0.2 million increase in costs related to a partnered contract feasibility program. These increases were partially offset by a $0.6 million decrease in costs related to a co-development program, based on completion of certain development stages during fiscal 2017.

While cost of contract research and development revenues increased 70% for the three months ended December 31, 2017 compared to the same period in fiscal 2017, contract research and development revenues increased by 228%. Although overall loses on our partner contract research and development programs decreased significantly, this was primarily the result of the timing of project activities and corresponding milestone payments for one of our co-development programs during this period compared to the same period in fiscal 2017.

Research and Development Expenses

Research and development expenses increased $4.2 million, or 71%, for the three months ended December 31, 2017 compared to the same period in fiscal 2017, driven primarily by a $3.8 million increase in expense for our lead Alzheimer’s program, Corplex Donepezil, as we initiated the pivotal BE study and supportive clinical studies in the first quarter of fiscal 2018, and a $0.9 million increase in expense for preclinical development work on proprietary feasibility programs. This increased investment was partially offset by a $0.6 million decrease in expense for our other proprietary programs as we prioritized Corplex Donepezil ahead of our other self-funded programs.

General and Administrative Expenses

General and administrative expenses increased $0.3 million, or 10%, for the three months ended December 31, 2017 compared to the same period in fiscal 2017, primarily as a result of an increase of $0.2 million in stock-based compensation expense.

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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 $228.6 million as of December 31, 2017. We have financed our operations primarily through the proceeds from the sale of equity securities, and various debt and capital lease financings.

We believe that our existing cash and cash equivalents will not be sufficient to fund operations in compliance with our debt covenants, as currently planned through the next 12 months, which raises substantial doubt about 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 will continue to require additional sources of cash to develop product candidates and to fund development and commercialization operations. 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 are pursuing alternatives to our current debt covenants, including refinancing the existing debt. In the event that additional financing is required from outside sources, we may not be able to raise such financing on terms acceptable to us 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.

We are currently in compliance with the covenants under our term loan agreement with CRG, a structured debt and equity investment management firm. However, we anticipate that, based on our current operating plan for products and services currently under contract, and without securing additional sources of external funding, our current cash and cash equivalent balances will not be sufficient to maintain compliance with the minimum liquidity financial covenant through the next 12 months. Additionally, we anticipate that our revenues will not be sufficient to maintain compliance with the minimum annual revenue covenant of $50.0 million for the 12 months ending June 30, 2018. Failure to meet either covenant would be considered an event of default on our debt obligation, and could result in the acceleration of our existing indebtedness, causing the outstanding principal of approximately $52.5 million, plus an early prepayment premium and an additional fee, to be immediately due and payable to CRG. As of December 31, 2017, the prepayment premium was 7.5% and the additional fee was 1.0%. Effective January 1, 2018, the prepayment premium was 3.25% and the additional fee remains at 1.0%. We may not have sufficient cash and cash equivalents to repay all of the outstanding debt in full if repayment of such debt were accelerated. Due to these uncertainties, there is substantial doubt about our ability to continue as a going concern.

The unaudited condensed financial statements as of December 31, 2017 have been prepared under the assumption that we will continue as a going concern for the next 12 months. Our ability to continue as a going concern is dependent upon our uncertain ability to secure new sources of revenue, obtain additional equity and/or debt financing or refinancing, generate operating efficiencies, reduce expenditures and amend or obtain a waiver of the financial covenants of the existing term loan agreement with CRG. The unaudited condensed financial statements as of December 31, 2017 do not include any adjustments that might result from the outcome of this uncertainty.

Description of Certain Indebtedness — We have several credit facilities under which we have borrowed funds, including a term loan with CRG, and notes payable with lessors for tenant improvements to our leased facilities. As of December 31, 2017, we were in compliance with all covenants under each of these credit facilities.

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Our term loan agreement with CRG was amended in November 2014 to increase the principal amount of the term loan from $35.0 million to $45.0 million, excluding all then-current and future PIK notes. The amended agreement extended the interest-only period to June 30, 2018, and continues to require that cash interest be paid quarterly at a simple annual rate of 15%, while continuing to permit us to convert that portion of each quarterly interest obligation equal to 3.5% of the then-outstanding principal, including all then-outstanding PIK notes, into additional PIK notes. This PIK note option applies to all interest due on or prior to June 30, 2018. Commencing on September 30, 2018, all then-outstanding principal, including the PIK notes, must be repaid quarterly in four equal installments, with interest continuing to accrue on the unpaid principal at a simple annual rate of 15%. The agreement has financial covenants, including a minimum annual revenues requirement and a minimum liquidity requirement. On November 11, 2015, the term loan agreement was further amended to modify the minimum annual revenue covenant (beginning with the 12 months ended June 30, 2016) and the minimum liquidity covenant. On December 19, 2016, we and CRG entered into an Amendment Agreement No. 2, or CRG Amendment #2, to amend our term loan agreement with CRG. Pursuant to the CRG Amendment #2, we and CRG agreed to amend the minimum annual revenue covenant for the twelve month period ended June 30, 2017 such that we would be required to have revenues of at least $25.0 million for that period in exchange for a fee equal to 1.0% of the aggregate principal amount of all loans and PIKs advanced by CRG to us under the term loan agreement. This fee will be due upon the loan maturity date of June 30, 2019 or upon the earlier acceleration of the loan pursuant to its terms. Based on the current loan balance and projected PIK borrowings, this fee is expected to be approximately $0.5 million. We have been in continuous compliance with all of our CRG financial covenants since the inception of the loan.

As of December 31, 2017, the principal amount outstanding under the term loan agreement, including all PIK notes, was $52.5 million. The amounts outstanding under the term loan agreement are collateralized by all of our assets and the agreement provides for an early prepayment premium, which starting January 1, 2018 is equal to 3.25% of the principal amount outstanding at the time of early prepayment, if we choose to repay principal prior to June 30, 2018, or upon other specified events, including a change of control.

We also have other credit facilities under which we have borrowed funds, including notes payable to lessors for tenant improvements made to 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 these partners, but generally limits our ability to use this equipment for our own or other partners' products.

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Cash Flows

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

	Three Months Ended December 31,	
	2017	2016
Cash used by operating activities	$ (11,717)	$ (6,075)
Cash used by investing activities	(861)	(1,039)
Cash provided by financing activities	342	356

Cash Flows from Operating Activities — Cash used by operating activities for the three months ended December 31, 2017 was $11.7 million, primarily driven by our net loss of $13.3 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 $1.6 million, were all consistent with normal operations. The immaterial change in cash due to changes in operating assets and liabilities as of December 31, 2017 compared to their balances as of September 30, 2017 was the result of offsetting sources and uses of cash, including:

- a $2.3 million use of cash from a decrease in accrued expenses and other current assets resulting primarily from decreases in accrued incentive compensation as a result of payments made during the three months ended December 31, 2017;
- a $0.3 million use of cash from an increase in prepaid expenses and other current assets, primarily related to prepaid costs associated with the potential refinancing of our long-term debt;
- a $0.2 million use of cash resulting from an increase in accounts receivable primarily related to increased partner receivables outstanding, as a result of increased contract research and development revenues during the first fiscal quarter of 2018;
- a $0.2 million use of cash resulting from an increase in unbilled accounts receivable, primarily as a result of increased cost true-up related to Clonidine TDS for the three months ended December 31, 2017, compared to the three months ended September 30, 2017;
- a $0.2 million use of cash related to an increase in inventories to support production needs; and
- a $0.2 million use of cash related to a decrease in deferred contract revenues, primarily related to completion of development activities related to upfront payments previously received; partially offset by:
- $3.4 million in cash provided by an increase in accounts payable, resulting primarily from increased spending related to research and development expenses, including clinical trial costs incurred but not paid.

Cash used by operating activities for the three months ended December 31, 2016 was $6.1 million, which was primarily driven by our net loss of $10.4 million. Depreciation, amortization, stock-based compensation and other non-cash expenses, totaling $1.9 million, were all consistent with normal operations. The $2.4 million cash provided by changes in operating assets and liabilities was the result of offsetting sources and uses of cash, including:

- $2.2 million in cash provided by a decrease in accounts receivable, primarily related to decreased partner receivables outstanding at December 31, 2016 compared to September 30, 2016 as a result of increased collections during the three months ended December 31, 2016;
- $1.1 million in cash provided by an increase in accounts payable resulting primarily from the higher level of research and development expenses, including clinical trial costs incurred but not paid as of December 31, 2016; and
- $0.5 million in cash provided by a decrease in inventories due primarily to the lower level of production and corresponding shipments during the three months ended December 31, 2016, partially offset by;
- a $0.7 million use of cash from a decrease in accrued expenses and other current liabilities resulting primarily from decreases in accrued expenses related to payroll, partner cost true-up credits and clinical trial expenses;

· a $0.2 million use of cash from an increase in unbilled accounts receivable, primarily as a result of a higher level of profit sharing receivable due on Clonidine TDS as of December 31, 2016;

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- a $0.1 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; and
- a $0.1 million use of cash from an increase in prepaid expenses and other current assets, primarily as a result of increased prepaid deposits associated with clinical trial expenses.

Cash Flows from Investing Activities — Cash used by investing activities for the three months ended December 31, 2017 was $0.9 million, consisting of capital expenditures of $0.7 million for equipment and leasehold improvements to support operations and expenditures of $0.2 million relating to the acquisition of patent and licensing rights.

Cash used by investing activities for the three months ended December 31, 2016 was $1.0 million, consisting of capital expenditures of $0.8 million for property and equipment to support operations and expenditures of $0.2 million relating to acquisition of patent and licensing rights.

Cash Flows from Financing Activities — Cash provided by financing activities for the three months ended December 31, 2017 was $0.3 million, consisting primarily of $0.2 million in cash provided by proceeds from the issuance of common stock under our 2014 ESPP and $0.1 million provided from the exercise of stock options.

Cash provided by financing activities for the three months ended December 31, 2016 was $0.4 million, consisting primarily of $0.2 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

As of December 31, 2017, there were no material changes in our commitments under contractual obligations as described in our Annual Report on Form 10-K for the fiscal year ended September 30, 2017.

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 and stock-based compensation 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.

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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. This ASU is 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 Codification.

We anticipate adopting the new revenue recognition 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 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 evaluating changes to our accounting processes, internal controls and disclosures to support the new standard

In July 2015, the Financial Accounting Standards Board issued ASU No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory." This ASU applies to inventory that is measured using first-in, first-out or average

cost. Inventory within the scope of this update is required to be recorded at the lower of cost or net realizable value, which is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. This ASU is effective prospectively for annual reporting periods beginning after December 15, 2016, and interim periods thereafter; early adoption is permitted. We adopted the provision of this ASU effective October 1, 2017 and the adoption of this ASU did not have a material impact on our financial position, results of operations or cash flows.

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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 all leases to be recognized in the statement of financial position. 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 March 2016, the FASB issued ASU 2016-09, “Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”, or ASU 2016-09. ASU 2016-09 modifies U.S. GAAP by requiring among other things, the following: (1) all excess tax benefits and tax deficiencies are to be recognized as income tax expense or benefit on the income statement (excess tax benefits are recognized regardless of whether the benefit reduces taxes payable in the current period); (2) excess tax benefits are to be classified along with other income tax cash flows as an operating activity in the statement of cash flows; (3) in the area of forfeitures, an entity can still follow the current U.S. GAAP practice of making an entity-wide accounting policy election to estimate the number of awards that are expected to vest or may instead account for forfeitures when they occur; and (4) classification of cash paid by an employer to the taxing authorities when directly withholding shares for tax withholding purposes as a financing activity in the statement of cash flows. We adopted the provisions of this ASU effective October 1, 2017. We have elected to continue to estimate expected forfeitures and the adoption of the remaining provisions in the ASU did not have a material impact on our 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”. 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. 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 Tax Act. The Tax Act makes broad and complex changes to the U.S. tax code and will

affect the Company’s fiscal year ending September 31, 2018, including, but not limited to reducing the U.S. federal corporate tax rate from 35 percent to 21 percent and limitations on net operating losses, or NOLs, generated after December 31, 2017. Section 15 of the Internal Revenue Code stipulates that our fiscal year ending September 31, 2018 will have a blended corporate tax rate of 24.53 percent, which is based on the applicable tax rates before and after the Tax Act and the number of days in the year.

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The SEC staff issued Staff Accounting Bulletin 118, or SAB 118, which provides guidance on accounting for the tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the 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 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 cannot determine a provisional estimate to be included in the financial statements, 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 Tax Act.

Our analysis of the impact of the Tax Act is incomplete, and we have not been able to make reasonable estimates of the effects as of December 31, 2017. Therefore, we have not recorded any provisional adjustments. We expect the Tax Act will result in a decline in deferred tax assets as a result of the lower U.S. corporate tax rate, however, due to the existence of a full valuation allowance, the impact on income tax expense will likely be immaterial.

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 $45.2 million as of December 31, 2017. 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 also had total outstanding long-term debt principal of $52.9 million as of December 31, 2017, of which $26.3 million was due within 12 months. The interest rate of our borrowings under the term loan agreement with CRG is fixed. 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.

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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.

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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 three months ended December 31, 2017, we recorded net revenues of $9.3 million and net loss of $13.3 million. As of December 31, 2017, we had stockholders' equity of $4.4 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, a wholly-owned subsidiary of Endo, 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. Although orders and forecasts have increased since Mayne acquired the product from Par, we expect that our revenues from Fentanyl TDS in fiscal 2018 will be lower than fiscal 2017 as a result of continued competition. 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 harm our operating results.

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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. In August 2016, Teva completed its acquisition of the generic business of Allergan, which resulted in the divestiture of the Clonidine TDS product to Mayne. We expect that our product revenues from Clonidine TDS in fiscal 2018 will be higher than fiscal 2017 revenues, but product revenues beyond 2018 could also 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 three months ended December 31, 2017, the same three partners individually comprised approximately 22%, 52% and 25%, 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.

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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, failure of our partners or us to design and conduct successful clinical trials or obtain regulatory approval for our product candidates, 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.

Our near term product revenue growth heavily relies on the success of the Twirla contraceptive patch.

The near term growth of our product revenues heavily relies on 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 their 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 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 the withdrawal and dropout rates. Agile has announced that it intends to request a meeting with the FDA as soon as possible to discuss the points raised in the CRL and a path to approval for Twirla. 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 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 is a key component of our business growth 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 will delay Twirla commercial manufacturing revenues, if any, to after fiscal 2018 and, depending on the outcome of Agile's meeting with the FDA to discuss the CRL, there may also be a reduction in our 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

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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 prospects will 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 commercialization and clinical testing. 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 Actavis/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, Lohmann Therapie-Systeme, Fujifilm and several academic institutions. Several of these

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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

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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.

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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

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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. As of yet, 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 of 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 continue development and commercialization of 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

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manufacturing and delivering such product candidate to patients, 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 the one 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. For example, while we have received positive results in the Corplex Donepezil pilot bioequivalence study, future studies may not be consistent with these earlier positive results. In addition, while we initiated dosing in the second and final treatment period of our Corplex Donepezil pivotal study in January 2018, 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

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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 will 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

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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;

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- 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,

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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

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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 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.

Risks Related to Our Financial Position and Capital Requirements

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

We believe that our existing cash and cash equivalents will not be sufficient to fund operations in compliance with our debt covenants as currently planned through the next 12 months, which raises substantial doubt about 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 will continue to require additional sources of cash to develop product candidates and to fund development and commercialization operations. 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 are also pursuing alternatives to our current debt covenants, including refinancing the existing debt. In the event that additional financing is required from outside sources, 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.

We are currently in compliance with the covenants under our term loan agreement with CRG. However, we anticipate that, based on our current operating plan for products and services currently under contract, and without securing additional sources of external funding, our current cash and cash equivalent balances will not be sufficient to maintain compliance with the minimum liquidity financial covenant through the next 12 months. Additionally, we anticipate that our revenues will not be sufficient to maintain compliance with the minimum annual revenue covenant of $50.0 million for the 12 months ending June 30, 2018. Failure to meet either covenant would be considered an event of default on our debt obligation, and could result in the acceleration of our existing indebtedness, causing the outstanding principal of approximately $52.5 million, plus an early prepayment premium and an additional fee, to be immediately due and payable to CRG. As of January 1, 2018, the prepayment premium was 3.25% and the additional fee was 1.0%. We may not have sufficient cash and cash equivalents to repay all of the outstanding debt in full if repayment of such debt were accelerated. Due to these uncertainties, there is substantial doubt about our ability to continue as a going concern.

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;

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- 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 independent registered public accounting firm has concurred with our determination that there is substantial doubt about our ability to continue as a going concern and we may be unable to remain a going concern absent additional sources of capital.

We have incurred significant operating and net losses since our inception and expect to continue to incur net operating losses for at least the next several years. Without additional sources of capital, these conditions raise substantial doubt about our ability to continue as a going concern, which means that without additional external funding, we may be unable to continue operations for the foreseeable future or realize assets and discharge liabilities in the ordinary course of operations. As a result, our independent registered public accounting firm included an explanatory paragraph with respect to this uncertainty in its report that is included with our financial statements in our most recent Annual Report on Form 10-K for the fiscal year ended September 30, 2017. Such an opinion may materially and adversely affect the price per share of our common stock and may otherwise limit our ability to raise additional funds through the issuance of debt or equity securities or otherwise. Further, the perception that we may be unable to continue as a going concern may impede our ability to raise additional funds or operate our business due to concerns with respect to our ability to discharge our contractual obligations.

We have prepared our financial statements on a going concern basis, which contemplates that we will be able to realize our assets and discharge our liabilities and commitments in the ordinary course of business. Our financial

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statements included in our most recent Annual Report on Form 10-K do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. Without additional funds, however, we may be unable to continue as a viable entity, in which case our stockholders may lose all or some of their investment in us.

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.

As of December 31, 2017, the amount of our total long-term debt was approximately $52.3 million, which is primarily pursuant to our term loan agreement with CRG, formerly Capital Royalty. In November 2014, we amended our term loan agreement with CRG to increase the outstanding loan principal amount to $45.0 million (excluding payment-in-kind, or PIK notes), extend the maturity date to June 30, 2019, and extend the quarterly interest only payments through June 30, 2018, with principal and interest payments due in four quarterly installments beginning September 30, 2018. On December 4, 2014, we borrowed the remaining $10.0 million of principal provided for in the amended agreement and no principal funds remain available to us for borrowing under the CRG term loan agreement. On November 11, 2015, the term loan agreement was further amended to modify the financial covenants with respect to the minimum annual revenues requirement (beginning with the 12 months ended June 30, 2016) and minimum liquidity requirement, and, on December 19, 2016, the term loan agreement was amended again to modify the financial covenants with respect to the minimum annual revenues requirement (for the 12 months ended June 30, 2017), all as described in further detail in "—The terms of our term loan agreement place restrictions on our operating and financial flexibility."

Our outstanding 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 restrictive covenants in our 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.

The terms of our term loan agreement place restrictions on our operating and financial flexibility.

During any such times when we have outstanding borrowings under the term loan agreement with CRG, we will be required to maintain certain deposits and minimum balances as well as be prohibited from engaging in significant business transactions without the prior consent of CRG, including a change of control or the acquisition by us of another company, or engaging in new business activities which are substantially different from our current business activities. These restrictions could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders. In addition, under the term loan agreement with CRG, we are subject to covenants relating to our business, including, but not limited to covenants relating to the achievement of minimum annual revenues and minimum liquidity. For the twelve months

ended June 30, 2018, the minimum annual revenues required by our covenant are $50 million, and the minimum liquidity covenant

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throughout the term of the loan requires us to maintain a cash balance in excess of $10 million, provided, however, that our cash balance may decrease below $10 million for no more than five non-consecutive business days during any quarter. The failure to meet either of these covenants is considered an event of default under the term loan agreement. We are also required to pay a prepayment penalty if we choose to repay the principal prior to maturity or upon other specified events, including an event of default or a change of control. In the event of a default under this agreement, all of our repayment obligations may be accelerated in full. In the event that we do not have sufficient capital to repay the amounts then owed, we may be required to renegotiate such arrangements on terms less favorable to us, pursue strategic alternatives, including sale of our company or our significant assets, or to cease operations. Furthermore, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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 three 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.

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. Although orders and forecasts have increased since Mayne acquired the product from Par, we expect that our product revenues from Fentanyl TDS in fiscal 2018 will be lower than fiscal 2017 as a result of continued competition. 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;

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- 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 our 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

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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, 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 to manufacture the Twirla product 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.

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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 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-

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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, and greater oversight of pain clinics. 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.

Our near term revenue growth 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 the withdrawal and dropout rates. Agile has announced that it intends to request a meeting with the FDA as soon as possible to discuss the points raised in the CRL and a path to approval for Twirla. 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 to manufacture 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;

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- 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, future studies may not be consistent with these earlier positive results. In addition, we are required us 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, while we initiated dosing in our Corplex Donepezil pivotal study in October 2017, we cannot be assured that we will be able to maintain our planned timelines. Furthermore, 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

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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;

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- 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 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

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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

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FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. Moreover, 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 formal feedback from a leading European

regulatory agency, based on review of our pilot study results, that the bioequivalence regulatory pathway is available for Corplex Donepezil in that country and have received formal feedback from another major European country that the bioequivalence regulatory pathway is likely to be available. We have submitted the data from our pilot BE study with the regulatory authorities in that European country for review. In addition, we have had preliminary conversations with Pharmaceuticals and Medical Devices Agency, Japan, who have indicated that regulatory approval based on bioequivalence in Japan is unlikely. 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

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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 pivotal 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 pivotal 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 2,032 women, 1.97% of those participants experienced serious adverse events, and 0.7% 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;

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- 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.

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.

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

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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. 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.

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. The U.S. Congress has also made several attempts to repeal or modify the Affordable Care Act. The House and Senate have passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. In May 2017, the House of Representatives voted to pass the American Healthcare Act of 2017, which proposed to repeal certain portions of the Affordable Care Act and add material new provisions. However, the Senate failed to pass the American Healthcare Act after several attempts in July and September 2017. There is still uncertainty with respect to the 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

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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.

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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 no issued patents and there can be no assurance that we will be successful in obtaining issued patents from the pending 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;

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- 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 or 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

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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

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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;

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- 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 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; and
- changes in accounting principles.

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

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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 may offer and sell, from time to time through Cantor Fitzgerald, shares of our common stock with aggregate proceeds of up to $20.0 million. As of December 31, 2017, all of the shares of common stock available for sale pursuant to the sales agreement remained available to be sold, subject to certain conditions as specified in the sales agreement, and 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 report. 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.

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;

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- 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 are also restricted from paying dividends under the term loan agreement with CRG. 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.

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

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

Not applicable.

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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

		Incorporated by Reference				
Exhibit Number	Description of Document	Form	File No.	Exhibit	Filing Date	Filed Herewith
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.

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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 February 12, 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)