

AGILE THERAPEUTICS INC
Form 10-Q
November 07, 2016
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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 September 30, 2016

OR

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

For the transition period from _____ to _____

Commission File Number 001-36464

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

23-2936302

(I.R.S. Employer Identification No.)

101 Poor Farm Road

Princeton, New Jersey 08540

(Address including zip code of principal executive offices)

(609) 683-1880

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if smaller reporting company)

Smaller reporting company

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

There were 28,757,719 shares of the registrant's common stock, \$0.0001 par value, outstanding as of November 4, 2016.

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Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For The Quarter Ended September 30, 2016

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes statements that are, or may be deemed, forward-looking statements. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms believes, estimates, anticipates, expects, plans, intends, may, could, might, will, should, approximately or, in each case, their negative or other variations thereof and terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-Q and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned development of Twirla and our other product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our development and validation of manufacturing capabilities, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-Q, they may not be predictive of results or developments in future periods.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the success and timing of our clinical trials;
- our inability to timely obtain from our third party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial;
- our ability along with Corium to complete successfully the qualification and validation of equipment related to the expansion of Corium's manufacturing facility;
- our ability to obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- our available cash;
- regulatory developments in the United States and foreign countries;
- our plans to develop and commercialize our product candidates;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;

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- the rate and degree of market acceptance of any of our product candidates;
 - the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
 - our ability to obtain additional funding;
 - our ability to obtain and maintain intellectual property protection for our product candidates;
 - the successful development of our sales and marketing capabilities;
 - the performance of third-party manufacturers; and
 - our ability to successfully implement our strategy.
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Any forward-looking statements that we make in this Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-Q. You should also read carefully the factors described in the Risk Factors section of this Form 10-Q to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third party research, surveys and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Table of Contents**Agile Therapeutics, Inc.****Part I Financial Information****ITEM 1. Financial Statements****Agile Therapeutics, Inc.****Balance Sheets****(Unaudited)****(in thousands, except par value and share data)**

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,670	\$ 34,395
Prepaid expenses	3,094	3,690
Total current assets	54,764	38,085
Property and equipment, net	12,330	12,318
Other assets	18	18
Total assets	\$ 67,112	\$ 50,421
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,889	\$ 2,387
Accrued expenses	1,755	2,653
Loan payable, current portion	3,486	2,336
Warrant liability	238	406
Total current liabilities	8,368	7,782
Loan payable, long-term	12,077	12,896
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.0001 par value, authorized 150,000,000 shares; 28,757,719 shares issued and outstanding as of September 30, 2016 and 22,315,612 shares issued and outstanding as of December 31, 2015;	3	2
Additional paid-in capital	234,931	194,468
Accumulated deficit	(188,267)	(164,727)
Total stockholders' equity	46,667	29,743
Total liabilities and stockholders' equity	\$ 67,112	\$ 50,421

See accompanying notes to unaudited financial statements.

Table of Contents**Agile Therapeutics, Inc.****Statements of Operations****(Unaudited)****(in thousands, except par value and share data)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 4,911	\$ 7,162	\$ 15,415	\$ 18,709
General and administrative	2,180	1,803	6,497	5,215
Total operating expenses	7,091	8,965	21,912	23,924
Loss from operations	(7,091)	(8,965)	(21,912)	(23,924)
Other income (expense)				
Interest expense	(784)	(551)	(1,879)	(1,525)
Interest income	33	1	83	4
Change in fair value of warrants	38	104	168	45
Loss on extinguishment of debt				(1,036)
Loss before benefit from income taxes	(7,804)	(9,411)	(23,540)	(26,436)
Benefit from income taxes				
Net loss	\$ (7,804)	\$ (9,411)	\$ (23,540)	\$ (26,436)
Net loss per share - basic and diluted	\$ (0.27)	\$ (0.42)	\$ (0.84)	\$ (1.21)
Weighted-average shares outstanding basic and diluted	28,754,458	22,272,777	28,110,587	21,923,070

See accompanying notes to unaudited financial statements.

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Agile Therapeutics, Inc.

Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	\$ (23,540)	\$ (26,436)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	14	14
Noncash stock based compensation	2,607	2,129
Noncash interest	759	417
Loss on extinguishment of debt		1,036
Change in fair value of warrants	(168)	(45)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	595	(530)
Other assets		
Accounts payable and accrued expenses	(648)	3,005
Net cash used in operating activities	(20,381)	(20,410)
Cash flows from investing activities		
Acquisition of property and equipment	(25)	(288)
Net cash used in investing activities	(25)	(288)
Cash flows from financing activities		
Proceeds from issuance of long-term debt		16,265
Repayment of term loan		(15,784)
Principal payments of long-term debt	(985)	
Return of principal payments of long-term debt	985	
Cash paid for debt financing costs	(175)	(423)
Proceeds from the issuance of common stock, net	37,527	19,330
Proceeds from exercise of stock options	329	532
Net cash provided by financing activities	37,681	19,920
Net increase (decrease) in cash and cash equivalents	17,275	(778)
Cash and cash equivalents, beginning of period	34,395	40,182
Cash and cash equivalents, end of period	\$ 51,670	\$ 39,404
Supplemental disclosure of noncash financing activities		
Fair value of common stock warrants issued	\$	\$ 1,184
Supplemental cash flow information		
Interest paid	\$ 1,125	\$ 1,098
Income taxes paid	\$	\$

See accompanying notes to unaudited financial statements.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2016

(in thousands, except share and per share data)

1. Organization and Description of Business

Nature of Operations

Agile Therapeutics, Inc. ("Agile" or the "Company") was incorporated in Delaware on December 22, 1997. Agile is a women's health specialty pharmaceutical company focused on the research, development and commercialization of new prescription contraceptive products. The Company's activities since inception have consisted principally of raising capital and performing research and development. The Company is headquartered in Princeton, New Jersey.

The Company is devoting substantially all of its efforts toward research and development of its transdermal patch for use in contraception, and raising capital. The Company has not generated product revenue to date and is subject to a number of risks similar to those of other early stage companies, including dependence on key individuals, the difficulties inherent in the development of commercially usable products, the potential need to obtain additional capital necessary to fund the development of its products, and competition from larger companies. The Company has incurred losses each year since inception. As of September 30, 2016, the Company had an accumulated deficit of approximately \$188.3 million.

The Company has financed its operations to date primarily through the issuance and sale of its common stock in both public and private offerings (see Note 7), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding. The Company expects to continue to incur net losses into the foreseeable future.

As of September 30, 2016, the Company had cash and cash equivalents of \$51.7 million. Although the Company has incurred recurring losses in each year since inception, the Company expects its cash and cash equivalents will be sufficient to fund operations for at least the next twelve months.

Basis of Presentation

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The accompanying unaudited interim condensed financial statements have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC) for reporting on Form 10-Q. Accordingly, certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. These interim condensed financial statements should be read in conjunction with the audited financial statements and related notes included in the Company s annual report on Form 10-K for the year ended December 31, 2015 filed with the SEC.

In the opinion of management, the unaudited interim condensed financial statements reflects all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods have been made. The results of operations for the three and nine months ended September 30, 2016 are not necessarily indicative of the operating results for the full fiscal year or any future period.

2. Summary of Significant Accounting Policies

The Company s complete listing of significant accounting policies are described in Note 2 to the Company s audited financial statements as of December 31, 2015 included in its annual report on Form 10-K filed with the SEC.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2016

(in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for common stock warrants, stock-based compensation, income taxes, and accounting for research and development costs. Actual results could differ from those estimates.

Fair Value of Financial Instruments

In accordance with ASC 825, *Financial Instruments*, disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Cash and cash equivalents are carried at fair value (see Note 3).

Financial instruments, including accounts payable and accrued liabilities, are carried at cost, which approximates fair value given their short-term nature.

Warrants

The Company accounts for its warrants to purchase redeemable convertible stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*. ASC 480 requires that a financial instrument, other than outstanding share, that, at inception, is indexed to an obligation to repurchase

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the issuer's equity shares, regardless of the timing or the probability of the redemption feature, and may require the issuer to settle the obligation by transferring assets be classified as a liability. The Company measures the fair value of its warrant liability using an option pricing model with changes in fair value recognized as increases or reductions to other income (expense) in the statement of operations.

In connection with the completion of the Company's initial public offering in May 2014, the warrants to purchase shares of Series A-1 and Series A-2 preferred stock expired unexercised and the warrants to purchase shares of Series C preferred stock automatically converted into warrants to purchase shares of common stock. Warrants with non-standard anti-dilution provisions (referred to as down round protection) are classified as liabilities and re-measured each reporting period. As of September 30, 2016, there were outstanding 62,505 warrants to purchase common stock at \$6.00 per share. These warrants expire on December 14, 2019.

The warrants issued in connection with the Company's debt financing completed in February 2015 (see Note 6) are classified as a component of stockholders' equity. The value of such warrants was determined using the Black-Scholes option-pricing model.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2016

(in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. The Company grants stock options for a fixed number of shares to employees and non-employees with an exercise price equal to the fair value of the shares at grant date. Compensation cost is recognized for all share-based payments granted and is based on the grant-date fair value estimated using the weighted-average assumption of the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The equity instrument is not considered to be issued until the instrument vests. As a result, compensation cost is recognized over the requisite service period with an offsetting credit to additional paid-in capital.

The Company also awards restricted stock units (RSUs) to employees. RSUs are generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse.

Awards for consultants are accounted for under ASC 505-50, *Equity Based Payments to Non-Employees*. Any compensation expense related to consultants is marked-to-market over the applicable vesting period as they vest.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding plus the effect of dilutive potential common shares outstanding during the period determined using the treasury-stock and if-converted methods. For purposes of diluted net loss per share calculation, common stock warrants, unvested RSUs and stock options are considered to be potentially dilutive securities but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share

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were the same for all periods presented.

Potentially dilutive securities that have been excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2016 and 2015 because to do so would be anti-dilutive are as follows (in common equivalent shares):

	September 30,	
	2016	2015
Common stock warrants	242,779	242,779
Common stock options	2,829,939	2,192,658
Unvested restricted stock units	33,334	
Total	3,106,052	2,435,437

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2016

(in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, which defines management’s responsibility to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The new standard is effective for the annual period ending after December 15, 2016, and for interim periods thereafter. Early adoption is permitted. The Company does not expect the adoption of ASU 2-14-15 to have a material impact on its financial statements.

In April 2015, the FASB issued an amendment to U.S. GAAP to simplify the balance sheet presentation of the costs for issuing debt. The changes were adopted in Accounting Standards Update (ASU) No. 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issue Costs*, or ASU 2015-03. ASU 2015-03 amends current presentation guidance by requiring that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. Prior to the issuance of ASU 2015-03, debt issuance costs were required to be presented as an asset in the balance sheet. The Company adopted the provisions of ASU 2015-03 on January 1, 2016 and prior period balances have been reclassified to conform to the current period presentation. As of December 31, 2015, \$152 of debt issuance costs were reclassified in the balance sheet from deferred financing costs, net to loan payable, current portion and \$139 was reclassified from deferred financing costs, net to loan payable, long-term. The adoption of ASU 2015-03 did not have an impact on the Company’s operations or cash flows.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company will be evaluating the impact of the pending adoption of the new standard on the Company’s financial statements.

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In March 2016, the FASB issued Accounting Standards Update No. 2016-9. This new standard provides guidance on employee share-based payment accounting requiring all tax effects related to share-based payments at settlement or expiration to be recorded through the statement of operations and be reported as operating activities on the statement of cash flows. Further, under the new guidance, entities are permitted to make an accounting policy election for the impact of forfeitures on the recognition of expense for share-based payment awards; whereas forfeitures can be estimated, as required today, or recognized when they occur. The guidance is effective for public business entities for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently evaluating the impact this guidance will have on its financial statements.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2016

(in thousands, except share and per share data)

3. Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures*, describes the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- **Level 1** Quotes prices in active markets for identical assets and liabilities. The Company's Level 1 assets consist of cash and cash equivalents. The Company has no Level 1 liabilities.
- **Level 2** Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets and liabilities. The Company has no Level 2 assets or liabilities.
- **Level 3** Unobservable inputs that are supported by little or no market data and which require internal development of assumptions about how market participant price the fair value of the assets or liabilities. The Company's Level 3 liabilities consist of the warrant liability.

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The Company is required to mark the value of its warrant liability to market and recognize the change in valuation in its statements of operations each reporting period.

The following table sets forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of September 30, 2016 and December 31, 2015.

	Level 1	Level 2	Level 3
September 30, 2016			
Assets:			
Cash equivalents	\$ 51,609	\$	\$
Total assets at fair value	\$ 51,609	\$	\$
Liabilities:			
Common stock warrants			238
Total liabilities at fair value	\$	\$	\$ 238

Table of Contents**Agile Therapeutics, Inc.****Notes to Unaudited Financial Statements****September 30, 2016****(in thousands, except share and per share data)****3. Fair Value Measurements (Continued)**

The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of September 30, 2016 include (i) volatility (75.0%), (ii) risk free interest rate of 0.88% (estimated using treasury bonds with a 3.25 year life), (iii) strike price (\$6.00) for the common stock warrants, (iv) fair value of common stock (\$6.98) and (v) expected life (3.25 years).

The following is a rollforward of the fair value of Level 3 warrants:

Beginning balance at December 31, 2015	\$	406
Change in fair value		(168)
Ending balance at September 30, 2016	\$	238

	Level 1	Level 2	Level 3
December 31, 2015			
Assets:			
Cash equivalents	\$ 34,324	\$	\$
Total assets at fair value	\$ 34,324	\$	\$
Liabilities:			
Common stock warrants			406
Total liabilities at fair value	\$	\$	\$ 406

The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2015 include (i) volatility (75.0%), (ii) risk free interest rate of 1.54% (estimated using treasury bonds with a 4 year life), (iii) strike price (\$6.00) for the common stock warrants, (iv) fair value of common stock (\$9.76) and (v) expected life (four years).

There were no transfers between Level 1, 2 or 3 during 2016 or 2015. If the Company's estimates regarding the fair value of its warrants are inaccurate, a future adjustment to these estimated fair values may be required. Additionally, these estimated fair values could change significantly.

4. Prepaid Expenses

Prepaid expenses consist of the following:

	September 30, 2016		December 31, 2015	
Prepaid clinical trial expense	\$	1,989	\$	2,803
Prepaid insurance		951		780
Other		154		107
Total prepaid expenses	\$	3,094	\$	3,690

Table of Contents**Agile Therapeutics, Inc.****Notes to Unaudited Financial Statements****September 30, 2016****(in thousands, except share and per share data)****5. Accrued Liabilities**

Accrued liabilities consist of the following:

	September 30, 2016		December 31, 2015	
Employee bonuses	\$ 740	\$	938	
Accrued clinical trial costs	407		1,507	
Other	608		208	
Total accrued liabilities	\$ 1,755	\$	2,653	

6. Loan and Security Agreements*Oxford Finance LLC*

In December 2012, the Company entered into a Loan and Security Agreement (the *Oxford Loan*) with Oxford Finance LLC (*Oxford*) pursuant to which the Company borrowed a total of \$15.0 million from Oxford. The Oxford Loan accrued interest at a fixed annual rate equal to 9.20% (Three-month U.S. Libor rate of 0.47% plus 8.73%).

Interest on the Oxford Loan was payable monthly and principal was due in 30 equal consecutive monthly installments beginning on February 1, 2015 and ending on July 1, 2017. In addition, the Company was required to make a final payment of \$675 on the maturity date of the Oxford Loan (July 1, 2017).

In connection with the Oxford Loan, the Company issued Oxford warrants to purchase 62,505 shares of common stock at an exercise price of \$6.00 per share. These warrants expire on December 14, 2019.

In February 2015, the Company terminated and repaid all amounts outstanding under the Oxford Loan and recorded a loss on the extinguishment of the Oxford Loan (see further discussion below).

Hercules Capital, Inc.

In February 2015, the Company entered into a loan and security agreement (the Hercules Loan) with Hercules Capital, Inc. (Hercules) for a term loan of up to \$25.0 million. In August 2016, the Company entered into the First Amendment to Loan and Security Agreement (the First Amendment) with Hercules which amends certain terms of the Hercules Loan. A first tranche of \$16.5 million was funded upon execution of the Hercules Loan, approximately \$15.5 million of which was used to repay the Company's existing term loan with Oxford.

The First Amendment extends the Company's option to draw down the second tranche of \$8.5 million (the Second Term Loan Advance) of the term loan facility provided under the Hercules Loan (the Term Loan) until March 31, 2017, and makes the Second Term Loan Advance subject to the consent of Hercules, among other customary conditions. The First Amendment also extends the interest-only payments until January 31, 2017, in connection with the first tranche of \$16.5 million (the First Term Loan Advance) and together with the Second Term Loan Advance, the Term Loan Advances). The First Amendment also provides the Company the ability to extend further the interest-only payments for two successive periods as follows: (i) until April 30, 2017, subject to the Company successfully completing its SECURE clinical trial, and the Company receiving data that supports the filing of a response to the U.S. Food and Drug Administration's complete response letter relating to the new drug application filed by the Company (First Interest Only Period Extension) and (ii) until July 31, 2017, provided that (x) the Company has received the

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2016

(in thousands, except share and per share data)

6. Loan and Security Agreements (Continued)

First Interest Only Period Extension and (y) the Company has received unrestricted gross cash proceeds in an aggregate amount greater than or equal to \$40.0 million from the issuance and sale by the Company of its equity securities (Second Interest Only Period Extension).

The First Amendment provides the Term Loan will mature on December 1, 2018; provided, however, that if the First Interest Only Period Extension occurs on or prior to January 31, 2017, the Term Loan will mature on March 1, 2019; and provided further, however that if both (a) the First Interest Only Period Extension occurs on or prior to January 31, 2017, and (b) the Second Interest Only Period Extension occurs on or prior to April 30, 2017, the Term Loan will mature on June 1, 2019.

As a result of the First Amendment, and in connection with the extension of the interest-only period from the First Term Loan Advance, Hercules returned to the Company the principal payments paid by the Company in July and August 2016, which such returned payments will once again constitute outstanding Term Loan Advances under the Hercules Loan. In connection with the execution of the First Amendment, the Company paid Hercules a facility fee of \$0.165 million.

The Hercules Loan accrues interest at a rate of the greater of 9.0% or 9.0% plus Prime minus 4.25% and is payable monthly. Principal is due in 23 equal consecutive monthly installments beginning on February 1, 2017 and ending on December 1, 2018. In addition, the Company is required to make a final payment of \$610.5 on the maturity date of the Hercules Loan (December 1, 2018). The final payment is being accrued and recorded to interest expense over the life of the loan.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2016

(in thousands, except share and per share data)

6. Loan and Security Agreements (Continued)

The Company may prepay all, but not less than all, of the Hercules Loan subject to a prepayment premium of 2.0% of the outstanding principal if prepaid during the second year (through February 24, 2017) and 1.0% of the outstanding principal if prepaid after February 24, 2017. The obligations of the Company under the Hercules Loan are secured by a perfected first position lien on all of the assets of the Company, excluding intellectual property assets.

In connection with the Hercules Loan, the Company issued Hercules a warrant to purchase 180,274 shares of the Company's common stock at an exercise price of \$5.89 per share which expires on February 24, 2020 and granted Hercules the right to participate in future equity financings in an amount up to \$2.0 million while the loan and warrant are outstanding.

The Company allocated the proceeds of \$16.5 million in accordance with ASC 470 based on the relative fair values. The relative fair value of the warrants of approximately \$1.2 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in preparing the option pricing model for valuing the Company's warrant issued to Hercules include (i) volatility (75.0%), (ii) risk free interest rate of 1.22% (estimated using treasury bonds with a 4 year life), (iii) strike price (\$5.89) for the common stock warrant, (iv) fair value of common stock (\$9.82) and (v) expected life (four years). The discount on the debt is being amortized to interest expense over the term of the debt.

As a result of the repayment of the Oxford Loan, the Company recorded a loss on the extinguishment of debt of approximately \$1.0 million on the Company's statement of operations for the nine months ended September 30, 2015, representing a prepayment premium, the unamortized discount of the Oxford Loan and the write off of deferred financing costs.

7. Stockholders' Equity

2015 Private Placement of Common Stock

In January 2015, the Company completed a private placement of 3,418,804 shares of common stock at \$5.85 per share. Proceeds from the Company's private placement, net of commissions and other offering costs, were approximately \$19.3 million. Two of the Company's stockholders, who are also affiliated with members of the Company's Board of Directors, purchased a total of 1,623,932 shares of common stock for approximately \$9.5 million in the private placement.

Shelf Registration Statement

On June 19, 2015, the Company filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of \$150.0 million (the 2015 Shelf Registration Statement). On July 1, 2015, the 2015 Shelf Registration Statement was declared effective by the SEC. The Company completed an offering of common stock in February 2016 utilizing the 2015 Shelf Registration Statement (see below). In the future, the Company may also periodically offer one or more of these securities in amounts, prices and terms to be announced when and if the securities are offered. At the time any of the securities covered by the 2015 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

Table of Contents**Agile Therapeutics, Inc.****Notes to Unaudited Financial Statements****September 30, 2016****(in thousands, except share and per share data)****7. Stockholders' Equity (Continued)***2016 Public Offering of Common Stock*

In January 2016, the Company completed an underwritten public offering of 5,511,812 shares of its common stock at a public offering price of \$6.35 per share. In February 2016, the underwriters of the public offering of common stock exercised in full their option to purchase an additional 826,771 shares of common stock at the public offering price of \$6.35 per share, less underwriting discounts and commissions. A total of 6,338,583 shares of common stock were sold in the public offering resulting in total net proceeds of approximately \$37.5 million. One of the Company's stockholders, who is also affiliated with an individual that was at the time a member of the Company's Board of Directors, purchased 393,700 shares of common stock for approximately \$2.5 million in the public offering.

Stock-Based Compensation Expense

Stock-based compensation expense was allocated as follows:

	Three Months Ended September 30,	
	2016	2015
Research and development	\$ 299	\$ 220
General and administrative	641	526
Total stock-based compensation expense	\$ 940	\$ 746

	Nine Months Ended September 30,	
	2016	2015
Research and development	\$ 796	\$ 857

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General and administrative		1,811		1,272
Total stock-based compensation expense	\$	2,607	\$	2,129

8. Related Party Transactions

Between March 17, 2014 and July 6, 2016, one of the Managing Partners of SmartPharma LLC, or SmartPharma, an entity which provides commercial and business development consulting services to the Company, served as Chief Commercial Officer of the Company. In connection with the appointment of this individual as Chief Commercial Officer, the Company amended its consulting agreement with SmartPharma to remove this individual from the list of persons providing service under the consulting agreement. SmartPharma invoiced the Company \$0.6 and \$3.3 of fees for the three and nine months ended September 30, 2016, respectively and \$18 and \$62 of fees for the three and nine months ended September 30, 2015. In connection with the resignation of our Chief Commercial Officer on July 6, 2016, the Company appointed a new Chief Commercial Officer.

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ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the "SEC") on March 9, 2016. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Dollars in tabular format are presented in thousands, except per share data, or as otherwise indicated.

Overview

We are a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. We have developed a proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adherence and stability and patient comfort. Our lead product candidate, Twirla®, also known as AG200-15, is a once-weekly contraceptive patch currently in Phase 3 clinical development.

In addition to Twirla, we are developing a pipeline of other new transdermal contraceptive product candidates, including AG200-SP, which is a regimen designed to provide shorter, lighter periods; AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle; and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. AG200-SP and AG200-ER are intended to be Twirla line extensions that would expand the use of Twirla beyond its initial, approved use. In July 2016, we began preparations for an initial Phase 2 clinical trial examining the use of AG200-SP along with a smaller lower-dose combination ethinyl estradiol/levonorgestrel patch (SmP) in the fourth week of the woman's cycle. The Phase 2 clinical trial is aimed at identifying the optimal dose of the SmP, and will evaluate bleeding profiles, pharmacokinetic parameters, ovulation inhibition and safety over three cycles of treatment with AG200-SP (SmP). We expect to initiate dosing of the AG200-SP (SmP) clinical trial in the first quarter of 2017.

Since our inception in 1997, we have devoted substantial resources to developing Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We incurred research and development expenses of \$25.6 million, \$13.4 million and \$9.2 million during the years ended December 31, 2015, 2014 and 2013, respectively. We incurred research and development expenses of \$4.9 million and \$15.4 million for the three and nine months ended September 30, 2016, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development as we continue to develop Twirla and advance our pipeline of product candidates. We have funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes, and term loans. As of September 30, 2016 and December 31, 2015 respectively, we had \$51.7 million and \$34.4 million in cash and cash equivalents.

In May 2014, we completed our initial public offering whereby we sold 9,166,667 shares of common stock, at a public offering price of \$6.00 per share, before underwriting discounts and expenses. The aggregate net proceeds received by us from the initial public offering were \$49.7 million.

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In January 2015, we completed a private placement of 3,418,804 shares of common stock at \$5.85 per share. Proceeds from our private placement, net of commissions and other offering costs were approximately \$19.3 million.

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In February 2015, we entered into a loan and security agreement with Hercules Capital, Inc., or Hercules, for a term loan of up to \$25.0 million, which we refer to as the Hercules Loan Agreement. A first tranche of \$16.5 million was funded upon execution of the Hercules Loan Agreement, approximately \$15.5 million of which was used to repay our existing term loan. The Hercules Loan Agreement was amended in August 2016 to, among other things, extend the period during which we can draw the second tranche of \$8.5 million and extend the period during which we make interest-only payments. See further discussion in *Funding Requirements and Other Liquidity Matters* below.

In January 2016, we closed an underwritten public offering of 5,511,812 shares of common stock at a public offering price of \$6.35 per share. In February 2016, the underwriters of the public offering of common stock exercised in full their option to purchase an additional 826,771 shares of common stock at the public offering price of \$6.35 per share, less underwriting discounts and commissions. A total of 6,338,583 shares of common stock were sold in the public offering, resulting in total net proceeds of approximately \$37.5 million.

We have not generated any revenue and have never been profitable for any year. Our net loss was \$30.3 million, \$16.1 million and \$14.3 million for the years ended December 31, 2015, 2014 and 2013, respectively. Our net loss was \$7.8 million and \$23.5 million for the three and nine months ended September 30, 2016. We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, Twirla and any other product candidates we advance to clinical development, including the planned Phase 2 clinical trial for AG200-SP. We do not own any manufacturing facilities and rely on our third party manufacturer, Corium International, Inc., or Corium, for all aspects of the manufacturing of Twirla. We will continue to invest in the manufacturing process for Twirla, and incur significant expenses, in order to complete the equipment qualification and validation related to the expansion of Corium's manufacturing capabilities in order to be capable of supplying projected commercial quantities of Twirla, if approved. We continue to plan the process of scaling up the commercial manufacturing capabilities for Twirla with Corium and the associated costs and timelines. We expect the validation to be completed in coordination with our planned commercialization activities. If we obtain regulatory approval for Twirla, we expect to incur significant expenses in order to create an infrastructure to support the commercialization of Twirla, including sales, marketing, distribution, medical affairs and compliance functions.

We are now approaching completion of our Phase 3 clinical trial, the SECURE Phase 3 clinical trial. We enrolled the first subject in our Phase 3 clinical trial in the third quarter of 2014 and completed enrollment in the fourth quarter of 2015. We completed all final subject visits in November 2016 and are now moving forward with data verification and database lock activities, which we anticipate being completed by the end of December 2016. We will then proceed with an initial analysis of the trial data and expect to announce topline data in early January 2017. We expect to announce top-line data in early January 2017 and file our resubmission to the U.S. Food and Drug Administration, or FDA, in the first half of 2017.

We have incurred and will continue to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations and pipeline in addition to Twirla. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. In the future, we may generate revenue from product sales, license fees, milestone payments and royalties from the sale of products developed using our intellectual property. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Twirla and any product candidates that we may advance in the future. If we fail to complete the development of Twirla or any other product candidates we advance in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, will be adversely affected.

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Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities. Research and development expenses consist primarily of costs incurred for the development of Twirla and other current and future product candidates, which include:

- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials and preclinical studies;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expenses;
- the cost of acquiring, developing and manufacturing clinical trial materials, including the supply of our product candidates;
- costs associated with research, development and regulatory activities; and
- costs associated with equipment scale-up required for commercial production.

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our third party vendors.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past and planned expenses have been and will be in support of Twirla. Although we expect the expenses associated with the SECURE clinical trial to decrease as we near completion of the trial, we expect to increase our research and development expenses for the foreseeable future as we initiate further clinical trials and continue equipment qualification and validation of our Twirla commercial manufacturing process.

To date, our research and development expenses have related primarily to the development of Twirla. As we near completion of the SECURE clinical trial, we expect research and development expenses to begin to shift away from costs associated with our SECURE clinical trial and toward the costs associated with preparing the resubmission of our new drug application, or NDA and completing the qualification and validation of our commercial manufacturing process. We began incurring expenses for the clinical development of AG200-SP during the three months ended September 30, 2016. For the three months ended September 30, 2016 and 2015, our research and development expenses were

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approximately \$4.9 million and \$7.2 million, respectively. For the nine months ended September 30, 2016 and 2015, our research and development expenses were approximately \$15.4 million and \$18.7 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
	(In thousands)			
Clinical development	\$ 3,030	\$ 5,436	\$ 9,942	\$ 13,885
Regulatory	72	72	225	203
Personnel related	665	549	1,910	1,500
Manufacturing commercialization	470	782	1,431	1,931
Manufacturing	375	102	1,111	333
Stock-based compensation	299	221	796	857
Total research and development expenses	\$ 4,911	\$ 7,162	\$ 15,415	\$ 18,709

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Although we currently expect to complete our SECURE Phase 3 clinical trial for Twirla in the fourth quarter of 2016, it is difficult to determine with any certainty the exact duration and completion costs of our currently planned or future clinical trials of Twirla and any of our other current and future product candidates we may advance, including AG200-SP. It is also difficult to determine if, when or to what extent we will generate revenue from the commercialization and sale of our product candidates that obtain regulatory approval. Our current business plan contemplates resubmission of our NDA in the first half of 2017 and assumes a six month review by the FDA. We may, however, never succeed in achieving regulatory approval for Twirla or any of our product candidates. The duration, costs and timing of clinical trials and development of our other product candidates in addition to Twirla will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, the slower than expected rate of enrollment we experienced for our SECURE Phase 3 clinical trial for Twirla and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, or experience issues with our manufacturing capabilities we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including insurance, stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs and professional fees for legal, patent review, consulting and accounting services. General and administrative expenses are expensed as incurred.

For the three months ended September 30, 2016 and 2015, our general and administrative expenses totaled approximately \$2.2 million and \$1.8 million, respectively. For the nine months ended September 30, 2016 and 2015, our general and administrative expenses totaled approximately \$6.5 million and \$5.2 million, respectively. We anticipate that our general and administrative expenses will increase in the future with the continued research, development and potential commercialization of Twirla, its planned line extensions, and any of our other product candidates, and as we operate as a public company. These increases will likely include increased legal and accounting services, stock registration and printing fees, addition of new personnel to support compliance and communication needs, increased insurance premiums, outside consultants and investor relations. Additionally, if in the future we believe regulatory approval of Twirla or any of our other product candidates appears likely, we anticipate that we would begin preparations for commercial operations, which would result in an increase in payroll and other expenses, particularly with respect to the sales and marketing of our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures. On an ongoing basis, our actual results may differ significantly from our estimates.

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There have been no material changes to our critical accounting policies and estimates from the information provided discussed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our annual report on Form 10-K.

Table of Contents**Results of Operations***Comparison of the Three Months Ended September 30, 2016 and 2015*

	2016	Three months ended September 30,	2015	Change	
	(In thousands)				
Operating expenses:					
Research and development	\$	4,911	\$	7,162	\$ (2,251)
General and administrative		2,180		1,803	377
Total operating expenses		7,091		8,965	(1,874)
Other income (expenses)					
Interest expense		(784)		(551)	(233)
Interest income		33		1	32
Change in fair value of warrants		38		104	(66)
Loss on extinguishment of debt					
Loss before income taxes		(7,804)		(9,411)	1,607
Benefit from income taxes					
Net loss	\$	(7,804)	\$	(9,411)	\$ 1,607

Research and development expenses. Research and development expenses decreased by \$2.3 million, or 31%, from \$7.2 million for the three months ended September 30, 2015 to \$4.9 million for the three months ended September 30, 2016. This decrease in research and development expenses was primarily due to the following:

- a decrease in clinical development expenses of \$2.4 million for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015. The decrease relates to lower investigator grant payments and related pass-through expenses. Such costs are directly related to the number of subjects enrolled and active in our SECURE clinical trial. Fewer patients were enrolled and active in the three months ended September 30, 2016 as compared to the three months ended September 30, 2015;
- an increase in manufacturing expenses of \$0.3 million for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015. This increase is primarily the results of increased product process testing and additional ongoing method development; and
- a decrease in manufacturing - commercialization expenses of \$0.3 million for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015. This decrease is related to the purchase of a significant quantity of one of the components for the packaging of our Twirla patch, which was expected to be discontinued during the three months ended September 30, 2015 for which there was no comparable purchase

for the three months ended September 30, 2016.

General and administrative expenses. General and administrative expenses increased by \$0.4 million, or 21%, from \$1.8 million for the three months ended September 30, 2015 to \$2.2 million for the three months ended September 30, 2016. This increase in general and administrative expenses was primarily due to the following:

- an increase in stock compensation expense of \$0.1 million for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015 primarily associated with stock options grants and restricted stock unit awards in February 2016;

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- an increase in professional fees expense of \$0.1 million for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015 attributable to increased legal fees associated with our intellectual property and increased search fees and consulting expenses;
- an increase in state franchise tax and property tax of \$0.1 million for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015 associated with the increased amount of outstanding common stock and increased property (equipment) values; and
- an increase in commercialization expenses of \$0.1 million for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015 primarily related to the initiation of certain market research and related consulting costs.

Interest expense. Interest expense is primarily attributable to our term loan with Hercules for the three months ended September 30, 2016 and 2015, respectively. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Hercules, the amortization of the deferred financing costs associated with the term loan and the accrual of the final payment due to Hercules.

Interest income. Interest income comprises interest earned on cash and cash equivalents.

Change in fair value of warrants. Certain of our warrants to purchase shares of our convertible preferred stock (prior to our initial public offering, or IPO) and common stock (post IPO) are recorded at fair value and are subject to re-measurement at each balance sheet date. These liabilities are re-measured at each balance sheet date with the corresponding charge to earnings recorded within change in fair value of warrant liability. The fair value of the convertible preferred stock warrants (prior to the IPO) and common stock warrants with non-standard anti-dilution provisions are determined using the Black-Scholes option pricing model which incorporates a number of assumptions and judgments to estimate the fair value of these warrants including the fair value per share of the underlying stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, credit spread and expected volatility of the price of the underlying stock. During the three months ended September 30, 2016, the fair value of our warrant liability changed by \$66 thousand compared to three months ended September 30, 2015, primarily due to the decrease in the fair value of the underlying common stock.

Comparison of the Nine Months Ended September 30, 2016 and 2015

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	2016	Nine months ended September 30, (In thousands)	2015	Change
Operating expenses:				
Research and development	\$	15,415	\$ 18,709	\$ (3,294)
General and administrative		6,497	5,215	1,282
Total operating expenses		21,912	23,924	(2,012)
Other income (expenses)				
Interest expense		(1,879)	(1,525)	(354)
Interest income		83	4	79
Change in fair value of warrants		168	45	123
Loss on extinguishment of debt			(1,036)	1,036
Loss before income taxes		(23,540)	(26,436)	2,896
Benefit from income taxes				
Net loss	\$	(23,540)	\$ (26,436)	\$ 2,896

Research and development expenses. Research and development expenses decreased by \$3.3 million, or 18%, from \$18.7 million for the nine months ended September 30, 2015 to \$15.4 million for the nine months ended September 30, 2016. This decrease in research and development expenses was primarily due to the following:

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- a decrease in clinical development expenses of \$3.9 million for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015. The decrease relates to costs incurred during the nine months ended September 30, 2015 related to extending the screening period at existing sites as well as increased additional clinical site costs including site selection, recruiting, training, advertising and printing for which there were no comparable costs in during the nine months ended September 30, 2016. In addition, the number of subjects enrolled in our SECURE clinical trial has decreased as the clinical trial nears completion.
- an increase in personnel-related expenses of \$0.4 million for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015 resulting from the addition of clinical and manufacturing employees to assist in the continued development of Twirla;
- an increase in manufacturing expenses of \$0.8 million for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015. This increase is primarily the result of increased product process testing and additional method development; and
- a decrease in manufacturing commercialization expenses of \$0.5 million for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015. The decrease is primarily timing related as manufacturing scale-up activities related to larger scale production of Twirla occurred in 2015 with no comparable activity in 2016.

General and administrative expenses. General and administrative expenses increased by \$1.3 million, or 25%, from \$5.2 million for the nine months ended September 30, 2015 to \$6.5 million for the nine months ended September 30, 2016. This increase in general and administrative expense was primarily due to the following:

- an increase in stock compensation expense of \$0.5 million for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015 primarily associated with stock options grants in February 2016;
- an increase in professional fees of \$0.3 million for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015 attributable to increased legal fees associated with our intellectual property, increased search fees and consulting expenses; and
- an increase in state franchise tax and property tax of \$0.2 million for the nine months ended September 30,

2016 as compared to the nine months ended September 30, 2015 associated with the increased amount of outstanding common stock and increased property (equipment) values.

Interest expense. Interest expense is primarily attributable to our term loan with Hercules for the nine months ended September 30, 2016 and our term loans with Hercules and Oxford for the nine months ended September 30, 2015. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Hercules and Oxford, the amortization of the deferred financing costs associated with the term loans and the accrual of the final payment due to Hercules.

Interest income. Interest income is comprised of interest earned on cash and cash equivalents.

Change in fair value of warrants. Certain of our warrants to purchase shares of our convertible preferred stock (prior to our IPO) and common stock (post IPO) are recorded at fair value and are subject to re-measurement at each balance sheet date. These liabilities are re-measured at each balance sheet date with the corresponding charge to earnings recorded within change in fair value of warrant liability. The fair value of the convertible preferred stock warrants (prior to the IPO) and common stock warrants with non-standard anti-dilution provisions are determined using the Black-Scholes option pricing model which incorporates a number of assumptions and judgments to estimate the fair value of these warrants including the fair value per share of the underlying stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, credit spread and expected volatility of the price of the underlying stock. During the nine months ended September 30, 2016, the fair value of our warrant liability changed by \$123 thousand compared to nine months ended September 30, 2015, primarily due to the increase in the fair value of the underlying common stock.

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Loss on extinguishment of debt. In February 2015, we entered into the Hercules Loan Agreement with Hercules for a term loan of up to \$25.0 million. A first tranche of \$16.5 million was funded upon execution of the Hercules Loan Agreement, approximately \$15.5 million of which was used to repay our existing loan with Oxford. As a result of the repayment of the loan with Oxford, we recorded a loss on the extinguishment of debt of approximately \$1.0 million representing the difference between the amount paid to Oxford and the carrying amount of the Oxford loan. Included in the loss on extinguishment of debt is the prepayment premium, the unamortized discount and the write off of deferred financing costs.

Liquidity and Capital Resources

At September 30, 2016, we had cash and cash equivalents totaling \$51.7 million. We invest our cash equivalents in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

The following table sets forth the primary sources and uses of cash for the periods indicated (in thousands):

	Nine months ended September 30,	
	2016	2015
Cash used in operating activities	\$ (20,381)	\$ (20,410)
Cash used in investing activities	(25)	(288)
Cash provided by financing activities	37,681	19,920
Net increase (decrease) in cash and cash equivalents	\$ 17,275	\$ (778)

Operating Activities

We have incurred significant costs in the area of research and development, including CRO fees, manufacturing, regulatory and other clinical trial costs, as our primary product candidate Twirla was being developed. Net cash used in operating activities was \$20.4 million for the nine months ended September 30, 2016 and consisted primarily of a net loss of \$23.5 million which was offset by non-cash stock-based compensation expense of \$2.6 million and a working capital increase of \$0.3 million. Net cash used in operating activities was \$20.4 million for the nine months ended September 30, 2015 and consisted primarily of a net loss of \$26.4 million which was offset by a loss on the extinguishment of debt of \$1.0 million, an increase in accrued liabilities of \$3.0 million and non-cash stock-based compensation expense of \$2.1 million. We began incurring expenses for the clinical development of AG200-SP in the third quarter of 2016.

Investing Activities

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Net cash used in investing activities for the nine months ended September 30, 2016 and 2015 was \$25 thousand and \$0.3 million, respectively. Cash used in investing activities for these periods primarily represents the acquisition of equipment to be used in the commercialization of Twirla.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2016 was \$37.7 million which included (i) net proceeds of \$37.5 million received from the sale of 6,338,583 shares of common stock and (ii) proceeds of \$0.3 million from the exercise of stock options. Net cash provided by financing activities for the nine months ended September 30, 2015 was \$19.9 million which included (i) net proceeds of \$19.3 million from the private placement of 3,418,804 shares of our common stock, (ii) net proceeds of \$16.3 million from a term loan with Hercules and (iii) the repayment of our loan with Oxford of \$15.8 million.

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Funding Requirements and Other Liquidity Matters

Although Twirla is still in clinical development, we expect the SECURE clinical trial to conclude in the fourth quarter of 2016 and to file the resubmission of our NDA in the first half of 2017. Even as we move toward completion of the SECURE clinical trial, we expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- seek marketing approval for Twirla;
- establish a sales and marketing infrastructure to commercialize Twirla in the United States, if approved;
- continue the equipment qualification and validation related to the expansion of Corium's manufacturing facility;
- seek to identify additional line extensions for Twirla and initiate development of product candidates in addition to Twirla;
- begin clinical development of the line extensions for Twirla, including AG200-SP and AG200-ER;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

Based on our current business plan, we expect that our existing cash and cash equivalents as of September 30, 2016 will enable us to fund our operating expenses and capital expenditures requirements through the end of 2017. In our current business plan, we have assumed completion of our SECURE Phase 3 clinical trial in the fourth quarter of 2016, resubmission of our NDA for Twirla to the FDA in the first half of 2017, a six-month FDA review of our resubmission, completion of validation of our commercial manufacturing process in coordination with our commercialization of Twirla, and initiation of dosing subjects in the initial Phase 2 clinical trial for AG200-SP in the first quarter of 2017. We cannot assure you that the FDA will approve Twirla, that the FDA's timeline for review will be within six months, or that we will timely complete the qualification and validation of our commercial manufacturing process within budget. In addition, the costs of the initial Phase 2 clinical trial for AG200-SP may be greater than we have planned based on all of the factors that can affect clinical development, including

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among other things slower than anticipated enrollment, which we experienced with the SECURE clinical trial. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development, including, among other things, manufacturing scale-up, resubmission of our NDA for Twirla and commercialization of Twirla, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of Twirla. Our future capital requirements will depend on many factors, including:

- the final costs and timing of completion and the outcome of the SECURE Phase 3 clinical trial for Twirla;
- the costs, timing and outcome of regulatory review of Twirla, including for the additional Phase 3 trial for Twirla;
- the timing and costs of the equipment qualification and validation related to the expansion of Corium's manufacturing facility;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for Twirla, if approved;

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- the revenue, if any, received from commercial sales of Twirla, if approved;
- the costs and timing of completion and the outcome of the planned Phase 2 trial for AG200-SP;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish.

Until such time, if ever, as we can generate substantial cash flows from product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market Twirla that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of September 30, 2016 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years (In thousands)	3 - 5 years	More than 5 years
Term loan	\$ 19,499	\$ 5,433	\$ 14,066		
Operating lease	704	162	512	30	
Total	\$ 20,203	\$ 5,595	\$ 14,578	\$ 30	

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. In August 2015, we renewed this lease with the new term to expire in November 2020.

January 2015 Private Placement

In January 2015, we completed a private placement of approximately 3.4 million shares of common stock at \$5.85 per share. Proceeds from our private placement, net of commissions and other offering costs, were \$19.3 million.

February 2015 Loan and Security Agreement Hercules Capital, Inc.

The first tranche of the Hercules Loan was funded in February 2015. In August 2016, we entered into the First Amendment to Loan and Security Agreement, or the First Amendment with Hercules which amends certain terms of the Hercules Loan Agreement.

The First Amendment extends our option to draw down the second tranche of \$8.5 million referred to as the Second Term Loan Advance, of the term loan facility provided under the Hercules Loan, or the Term Loan, until March 31, 2017 and makes the Second Term Loan Advance subject to the consent of Hercules, among other customary conditions. The First Amendment also extends the

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interest-only payments until January 31, 2017, in connection with the first tranche of \$16.5 million, or the First Term Loan Advance, and together with the Second Term Loan Advance, referred to as the Term Loan Advances. The First Amendment also provides us the ability to extend further the interest-only payments for two successive periods as follows: (i) until April 30, 2017, subject to us successfully completing our SECURE clinical trial, and receiving data that supports the filing of a response to the FDA's complete response letter relating to the new drug application filed by us referred to as the First Interest Only Period Extension and (ii) until July 31, 2017, provided that (x) we have received the First Interest Only Period Extension and (y) we have received unrestricted gross cash proceeds in an aggregate amount greater than or equal to \$40.0 million from the issuance and sale of our equity securities referred to as the Second Interest Only Period Extension.

The First Amendment provides that the Term Loan will mature on December 1, 2018; provided, however, that if the First Interest Only Period Extension occurs on or prior to January 31, 2017, the Term Loan will mature on March 1, 2019; and provided further, however, that if both (a) the First Interest Only Period Extension occurs on or prior to January 31, 2017, and (b) the Second Interest Only Period Extension occurs on or prior to April 30, 2017, the Term Loan will mature on June 1, 2019.

The First Amendment also provides that as part of the extension of the interest-only period from the First Term Loan Advance, Hercules returned to us the principal payments paid by us in July and August 2016, which such returned payments will once again constitute Term Loan Advances under the Hercules Loan. In connection with the execution of the First Amendment, we paid Hercules a facility fee of \$0.165 million.

The Hercules Loan accrues interest at a rate of the greater of 9.0% or 9.0% plus Prime minus 4.25% and is payable monthly. Principal is due in 23 equal consecutive monthly installments beginning on February 1, 2017 and ending on December 1, 2018. In addition, we are required to make a final payment of \$610,500 on the maturity date of the Hercules Loan, December 1, 2018. The final payment is being accrued and recorded to interest expense over the life of the Hercules Loan.

We may prepay all, but not less than all, of the Hercules Loan subject to a prepayment premium of 2.0% of the outstanding principal if prepaid during the second year (through February 24, 2017) and 1.0% of the outstanding principal if prepaid after February 24, 2017. Our obligations under the Hercules Loan are secured by a perfected first position lien on all of our assets, excluding intellectual property assets.

In connection with the Hercules Loan, we issued Hercules a warrant to purchase 180,274 shares of our common stock at an exercise price of \$5.89 per share and granted Hercules the right to participate in future equity financings in an amount up to \$2.0 million while the loan and warrant are outstanding.

We allocated the proceeds of \$16.5 million in accordance with ASC 470 based on the relative fair values. The relative fair value of the warrants of approximately \$1.2 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The discount on the debt is being amortized to interest expense over the term of the debt.

In December 2012, we entered into a loan and Security Agreement, the Oxford Loan, with Oxford Finance, LLC, or Oxford, pursuant to which we borrowed a total of \$15.0 million from Oxford.

In February 2015, we terminated and repaid all amounts outstanding under the Oxford Loan. As a result of this repayment, we recorded a loss on the extinguishment of debt of approximately \$1.0 million on our statement of operations for the nine months ended September 30, 2015, primarily representing a prepayment premium and the write off of deferred financing costs.

Shelf Registration Statement

On June 19, 2015, we filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of \$150.0 million, which we refer to as the 2015 Shelf Registration Statement. On July 1, 2015, the 2015 Shelf Registration Statement was declared effective by the SEC. During the first quarter of 2016, we completed an offering of common stock utilizing the 2015 Shelf Registration Statement (see below). In the future, we may periodically offer one or more of these securities in amounts, prices and terms to be announced when and if the securities are offered. At the time any of the securities covered by the 2015 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

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2016 Public Offering of Common Stock

In January 2016, we closed an underwritten public offering of 5,511,812 shares of common stock registered under the 2015 Shelf Registration Statement at a public offering price of \$6.35 per share. In February 2016, the underwriters of the public offering of common stock exercised in full, their option to purchase an additional 826,771 shares of common stock at the public offering price of \$6.35 per share, less underwriting discounts and commissions. A total of 6,338,583 shares of common stock were sold in the public offering resulting in total estimated net proceeds of approximately \$37.5 million. One of our stockholders, who is also affiliated with an individual that was at the time a member of our Board of Directors, purchased 393,700 shares of common stock for approximately \$2.5 million in the public offering.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, which defines management’s responsibility to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The new standard is effective for the annual period ending after December 15, 2016, and for interim periods thereafter. Early adoption is permitted. We do not expect the adoption of ASU 2-14-15 to have a material impact on our financial statements.

In April 2015, the FASB issued an amendment to U.S. GAAP to simplify the balance sheet presentation of the costs for issuing debt. The changes were adopted in Accounting Standards Update (ASU) No. 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issue Costs*, or ASU 2015-03. ASU 2015-03 amends current presentation guidance by requiring that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. Prior to the issuance of ASU 2015-03, debt issuance costs were required to be presented as an asset in the balance sheet. We adopted the provisions of ASU 2015-03 on January 1, 2016 and prior period balances have been reclassified to conform to the current period presentation. As of December 31, 2015, \$152 thousand of debt issuance costs were reclassified in the balance sheet from deferred financing costs, net to loan payable, current portion and \$139 thousand was reclassified from deferred financing costs, net to loan payable, long-term. The adoption of ASU 2015-03 did not have an impact on our operations or cash flows.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. We will be evaluating the impact of the pending adoption of the new standard on our financial statements.

In March 2016, the FASB issued guidance (ASU 2016-09) on employee share-based payment accounting requiring all tax effects related to share-based payments at settlement or expiration to be recorded through the statement of operations and be reported as operating activities on the statement of cash flows. Further, under the new guidance, entities are permitted to make an accounting policy election for the impact of forfeitures on the recognition of expense for share-based payment awards; whereas forfeitures can be estimated, as required today, or recognized when they occur. The guidance is effective for public business entities for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. We are currently evaluating the impact this guidance will have on our financial

statements.

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Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations.

We had cash and cash equivalents of \$51.7 million and \$34.4 million at September 30, 2016 and December 31, 2015, respectively, consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or 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 by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes to Internal Controls Over Financial Reporting

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There has been no change in internal controls over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.

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Part II: Other Information

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors set forth below as well as the other information contained in this Quarterly Report on Form 10-Q and in our other public filings in evaluating our business. Any of the following risks could materially and adversely affect our business, financial condition or results of operations. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently view to be immaterial may also materially adversely affect our business, financial condition or results of operations. In these circumstances, the market price of our common stock would likely decline.

Risks Related to the Clinical Trial Process and Regulatory Approval for Our Product Candidates

We have not obtained regulatory approval for any of our product candidates in the United States or any other country.

We currently do not have any product candidates that have gained regulatory approval for sale in the United States or any other country, and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner. We cannot commercialize product candidates in the United States without first obtaining regulatory approval to market each product candidate from the U.S. Food and Drug Administration, or FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. We are not currently pursuing any regulatory approvals for Twirla or any other product candidate outside the United States.

We have previously conducted two Phase 3 clinical trials for Twirla, and we 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, quality information and chemistry, manufacturing and controls information, which must be addressed before approval can be granted. Accordingly, we are gathering the requested information and are conducting an additional Phase 3 clinical trial for Twirla®, which we refer to as the SECURE clinical trial. The SECURE clinical trial commenced enrollment during the third quarter of 2014, completed enrollment in October 2015, and completed all subject visits in November 2016. We can now move forward with data verification and database lock activities, which we anticipate being completed by the end of December 2016. We will then proceed with an initial analysis of the trial data and expect to announce topline data in early January 2017. The FDA may also re-inspect our manufacturing partner's facilities before approval can be granted. Although we met with the FDA in October 2013 to discuss our new Phase 3 clinical trial and have received substantial written comments from the FDA in subsequent interactions, we have not sought and have not obtained agreement with the FDA on a special protocol

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assessment regarding the new Phase 3 trial. We cannot predict whether our SECURE Phase 3 clinical trial or any future trials we may conduct will be successful or whether regulators will agree with our conclusions regarding the results of these trials or any clinical trials we have conducted to date, including whether our data are reliable and generalizable.

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In the United States, it is necessary to submit an NDA to obtain FDA approval. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication, although we may partially rely on published scientific literature or the FDA's prior approval of similar products. The NDA must also include significant information regarding the chemistry, manufacturing and controls

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for the product. The FDA may further inspect our manufacturing facilities to ensure that the facilities can manufacture our product candidates and our products, if and when approved, in compliance with the applicable regulatory requirements, as well as inspect our clinical trial sites to ensure that our studies are properly conducted. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission of an NDA, the FDA must make an initial determination that the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA, or ultimately be approved. If the application is not accepted for review or approval, the FDA may require that we conduct additional clinical or preclinical trials, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

Regulatory authorities outside of the United States, such as in Europe and Japan and in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in a different jurisdiction. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. Foreign regulatory approval may include all of the risks associated with obtaining FDA approval. For all of these reasons, if we seek foreign regulatory approval for Twirla or any of our other product candidates, we may not obtain such approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the United States, and approval is never guaranteed. Even if our product candidates were to successfully obtain approval from regulatory authorities, any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, risk evaluation and mitigation strategies, or REMS, or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that we may make, which may impede the successful commercialization of our product candidates. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, will be subject to additional FDA notification, or review and approval. Also, regulatory approval for any of our product candidates may be withdrawn. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue or complete the development of any of our current or future product candidates.

Failure can occur at any stage of clinical development. If the clinical trials for Twirla or any of our current or future product candidates are unsuccessful, we could be required to abandon development.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more clinical trials can occur at any stage of testing for a variety of reasons. The outcome of preclinical testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in or adherence to trial protocols, differences in size and type of the subject populations and the rates of dropout among clinical trial subjects. Our future clinical trial results therefore may not demonstrate safety and efficacy sufficient to obtain regulatory approval for our product candidates. For example, we received a CRL from the FDA with respect to an NDA previously filed for Twirla, in which the FDA requested, among other items, additional Phase 3 clinical data to support the

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application. The SECURE Phase 3 clinical trial was designed in consultation with the FDA and is different than the design of our previous clinical trials of Twirla and it is possible that there could be significant variability in the safety and efficacy results of these trials. Additionally, while our SECURE Phase 3 clinical trial was designed and implemented in a manner to address the FDA's comments and guidance, it is possible that the trial may not be successful or the FDA could conclude the data are not reliable or generalizable. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trials may not be successful.

Flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. We have limited experience in designing contraceptive clinical trials and may be unable to design and execute clinical trials to support regulatory approval of our product candidates. In addition, clinical trials often reveal that it is not practical or feasible to continue development efforts for a product candidate.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to subjects. Furthermore, regulatory agencies, Institutional Review Boards, or IRBs, or data safety monitoring boards, if utilized in our clinical trials, may at any time order the temporary or permanent discontinuation of our clinical trials or request that we cease using certain investigators in the clinical trials if such regulatory agencies or boards believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to subjects. Since our inception, we have not voluntarily or involuntarily suspended or terminated a clinical trial due to unacceptable safety risks to subjects.

If the results of the clinical trials for our current product candidates or clinical trials for any future product candidates do not achieve the primary efficacy endpoints or demonstrate unexpected safety issues, the prospects for approval of our product candidates will be materially adversely affected. For example, in the CRL that we received from the FDA in connection with the NDA previously filed for Twirla, one of the FDA's comments was that acceptable evidence of efficacy was not demonstrated, as measured by Pearl Index, or PI. Specifically, in our two completed Phase 3 trials, the PI was higher than that seen in registration trials for previously approved hormonal contraceptives. Experts seem to agree that inconsistent or incorrect use is a major contributor to the increased PI seen in more recent contraceptive trials. The PI values from clinical trials are also affected by additional factors, including differences in study design, increased sensitivity of early pregnancy tests, weight and body mass index, or BMI, of the study population and user experience. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to achieve similar results in later clinical trials, including longer-term trials, or have failed to obtain regulatory approval of their product candidates. Many compounds that initially showed promise in clinical trials or earlier preclinical studies have later been found to cause undesirable or unexpected adverse effects that have prevented further development of the compound. Our SECURE Phase 3 clinical trial for our primary product candidate, Twirla, may not produce the results that we expect, or the FDA may interpret the data differently than we do.

In addition to the circumstances noted above, we may experience numerous unforeseen events that could cause our clinical trials to be delayed, suspended or terminated, or which could delay or prevent our ability to receive regulatory approval for or commercialize our product candidates, including:

- Clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or implement a clinical hold;

- The number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate. For instance, we experienced a high withdrawal rate in our two completed Phase 3 clinical trials for Twirla and we experienced slower than anticipated enrollment in our current Phase 3 trial;
- Our third party contract research organization, or CRO, or study sites may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all. For instance, investigator compliance with study procedures was an issue that we encountered in our two completed Phase 3 clinical trials for Twirla;

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- Regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or amend a trial protocol;
- We may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CRO;
- We may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- We may elect or be required to suspend or terminate clinical trials of our product candidates based on a finding that the subjects are being exposed to health risks, or due to other reasons;
- The cost of clinical trials for our product candidates may be greater than we anticipate;
- The supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- There may be changes in government regulations or administrative actions;
- Our product candidates may have undesirable adverse effects or other unexpected characteristics;
- We may not be able to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- We may not be able to demonstrate that a product candidate provides an advantage over current standards of care or future competitive therapies in development; and
- There may be changes in the approval policies or regulations that render our data insufficient for approval.

If we elect or are required to suspend or terminate a clinical trial for any of our product candidates, or our product candidate development is otherwise delayed, our development costs may increase, our commercial prospects will be adversely impacted, any periods during which we may have the exclusive right to commercialize our product candidates may be shortened and our ability to generate product revenues may be delayed or eliminated.

We are currently in the final stages of our SECURE Phase 3 clinical trial for Twirla and, as we have previously announced, we expect to conduct additional clinical trials in the future for our other product candidates subject to available funding. Subject enrollment for our future clinical trials, which is a significant factor in the timing of clinical trials, is affected by a variety of factors, including the following:

- Size and nature of the subject population;
- Proximity of subjects to clinical sites and the number of sites;
- Effectiveness of publicity created by clinical trial sites regarding the trial;
- Eligibility and exclusion criteria for the trial;
- Design of the clinical trial, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- Competing clinical trials;
- Clinician and subject perceptions as to the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for the indications we are investigating;

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- Subjects' ability to comply with the specific instructions related to the trial protocol, proper documentation and use of the drug product. For instance, in our completed Phase 3 clinical trials, there was a high rate of subject noncompliance;
- Inability to obtain or maintain subject informed consents;
- Risk that enrolled subjects will drop out before completion;
- Subject's relationship with her partner; and
- Other events that may occur and are beyond our control.

Furthermore, we plan to rely on a CRO and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we may have agreements governing their committed activities, we have limited influence over their actual performance. Additionally, the CRO and clinical trial sites may have business, regulatory, personnel or other issues that keep us from satisfactorily completing our clinical trials. Any delays or unanticipated problems during clinical trials, such as additional monitoring of clinical trial sites, slower than anticipated enrollment in our clinical trials or subjects dropping out of or being excluded from participation in our clinical trials at a higher rate than we anticipate, could increase our costs, slow down our product development and approval process and harm our business. For example, we experienced a slower than expected rate of enrollment for our SECURE Phase 3 clinical trial of Twirla and, as a result, now expect the clinical trial to be completed in the fourth quarter of 2016.

Regulatory approval may be substantially delayed or may not be obtained for one or all of our product candidates if regulatory authorities require additional time or studies to assess the safety and efficacy of our product candidates.

We may be unable to initiate or complete development of our product candidates on schedule, if at all. The timing for the completion of the studies for our product candidates other than Twirla will require funding beyond our existing cash and cash equivalents. In addition, if regulatory authorities require additional time or studies to assess the safety or efficacy of Twirla, we may not have or be able to obtain adequate funding to complete the necessary steps for approval for any or all of our product candidates. Additional delays may result if the FDA, an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. Studies required to demonstrate the safety and efficacy of our product candidates are time consuming, expensive and together take several years or more to complete. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Delays in regulatory approvals or rejections of applications for regulatory approval in the United States, Europe, Japan or other markets may result from many factors, including:

- Our inability to obtain sufficient funds required for a clinical trial;
- Regulatory requests for additional analyses, reports, data, non- clinical and preclinical studies and clinical trials;
- Regulatory questions regarding interpretations of data and results and the emergence of new information regarding our product candidates or other products;
- Clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- Failure to reach agreement with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- Our inability to enroll or retain a sufficient number of subjects who meet the inclusion and exclusion criteria in our clinical trials;

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- Our inability to conduct our clinical trials in accordance with regulatory requirements or our clinical trial protocols;
- Unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding safety or efficacy of our product candidates during clinical trials;
- Failure to meet the level of statistical significance required for approval;
- Any determination that a clinical trial presents unacceptable health risks to subjects;
- Lack of adequate funding to commence or continue our clinical trials due to unforeseen costs or other business decisions;
- Our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- Our inability to identify and maintain a sufficient number of sites, many of which may already be engaged in other clinical trial programs, including other clinical trials for the same indications targeted by our product candidates;
- Our inability to obtain approval from IRBs to conduct clinical trials at their respective sites;
- Our inability to timely obtain from our third party manufacturer sufficient quantities or quality of the product candidate or other materials required for a clinical trial;
- Our inability to validate our commercial manufacturing process;
- We may be unable to obtain approval for the manufacturing processes or facilities of the third party manufacturer with whom we contract for clinical and commercial supplies;

- We may be unable to obtain agreement from the FDA on product labeling;
- We may have insufficient funds to pay the significant user fees required by the FDA upon the filing of any future NDAs; and
- We may have difficulty in maintaining contact with subjects, resulting in incomplete data.

We have completed all subject visits in our Phase 3 SECURE clinical trial and are now moving forward with data verification, database lock activities which we anticipate being completed by the end of December 2016. We will then proceed with an initial analysis of the trial data and expect to announce topline data in early January 2017. We plan to resubmit our NDA for Twirla in the first half of 2017. The FDA's review of our NDA is subject to all the risks described above in addition to, among other things, the FDA's assessment of our specific response to the 2013 CRL and the efficacy and safety of Twirla as demonstrated in the final SECURE clinical trial results. The lengthy and unpredictable approval process, as well as the unpredictability of future clinical trial results, may result in our failure to obtain regulatory approval to market Twirla or any of our other product candidates, which would significantly harm our business, results of operations and prospects.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities or conduct additional studies to reflect these changes. Amendments and additional studies may require us to resubmit clinical trial protocols to Institutional Review Boards and regulatory authorities for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If we are required to conduct additional clinical trials or other studies with respect to any of our product candidates beyond those that we contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these studies are not positive or are only modestly positive, we may be delayed in obtaining regulatory approval for our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. For example, the FDA issued a CRL in response to our NDA for Twirla requesting, among other items, an additional Phase 3 clinical study, which will delay our ability to obtain regulatory approval for that product candidate. We may also experience delays due to

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changes in regulatory requirements and guidance, which may require protocol amendments or the conduct of additional studies. These amendments and additional studies may require regulatory or IRB approval. The approval and conduct of these studies may delay, limit or preclude regulatory approval for our product candidates. Our product development costs will also increase if we experience delays in testing or approvals and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business will be materially harmed.

Our product candidates may have undesirable adverse effects, which may delay or prevent regulatory approval or, if approval is received, require our products to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen adverse effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. In the combined safety population of our completed Phase 3 trials, there were a total of 22 serious adverse events, or SAEs, of which 16 occurred in the Twirla cohort, which had approximately 2.3 times as many subjects as the oral contraceptive comparator cohort. Three of the 16 SAEs in the Twirla cohort (0.2% of the overall Twirla safety population) were considered to be possibly related to Twirla, and included one drug overdose with Benadryl, one case of uncontrollable nausea and vomiting and one instance of deep vein thrombosis. In addition to the SAEs described above, some subjects taking Twirla experienced non-serious adverse events, such as nausea, headache, application site irritation and breast tenderness. Subjects receiving the oral contraceptive comparator also experienced non-serious adverse events such as nausea, headache and breast tenderness, though at different rates.

Any undesirable adverse effects that may be caused by our product candidates could interrupt, delay or halt clinical trials and could result in more restrictive labeling or the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. Adverse effects could also impact subject recruitment or the ability or willingness of enrolled subjects to complete the trial, or result in product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if any of our product candidates receive regulatory approval and we or others later identify undesirable adverse effects caused by the product, we could face one or more of the following consequences:

- We may suspend marketing of, withdraw or recall the product;

- Regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication, or other labeling changes;

- Regulatory authorities may withdraw their approval of the product;

- Regulatory authorities may seize or detain the product or seek an injunction against its manufacture or distribution;
- The FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- The FDA may require the establishment or modification of a REMS or a comparable foreign authority may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such adverse effects for distribution to patients, or restrict distribution of the product, if and when approved, and impose burdensome implementation requirements on us;
- We may be required to conduct additional trials;
- We may be required to change the way that the product is administered;

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- We may be subject to litigation or product liability claims, fines, injunctions or criminal penalties;
- Regulatory authorities may impose additional restrictions on marketing and distribution of the product; and
- Our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its sale.

Our development and commercialization strategy for Twirla depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products containing Ethinyl Estradiol and Levonorgestrel based on data not developed by us, but upon which the FDA may rely in reviewing our NDA.

The Hatch-Waxman Act added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA may also require companies to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions. We have submitted an NDA for Twirla under Section 505(b)(2) and as such the NDA relied, in part, on the FDA's previous findings of safety and efficacy from investigations for approved products containing ethinyl estradiol, or EE, and levonorgestrel, or LNG and published scientific literature for which we have not received a right of reference. We received a CRL in response to our Section 505(b)(2) NDA for Twirla, in which the FDA requested, among other things, that we conduct an additional Phase 3 clinical trial. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for Twirla, the FDA may require us to perform additional clinical trials or measurements to support approval over and above the clinical trials that we have already completed and the additional clinical trial we are currently conducting. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of our product candidates, including Twirla.

Risks Related to Our Financial Position and Need for Capital

We have never been profitable. Currently, we have no products approved for commercial sale, no source of revenue and we may never become profitable.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have no products approved for commercial sale and to date have not generated any revenue from product sales. Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of and obtain the necessary regulatory approvals for our product candidates. We have been engaged in developing Twirla and our Skinfusion® technology since our inception. To date, we have not generated any revenue from Twirla, and we may never be able to obtain regulatory approval for the marketing of Twirla. Further, even if we are able to gain approval for and commercialize Twirla or any other product candidate, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our ability to generate product revenue depends on a number of factors, including our ability to:

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- Successfully complete clinical development of, and receive regulatory approval for, our product candidates;
- Set an acceptable price for our products, if approved, and obtain adequate coverage and reimbursement from third party payors;
- Obtain commercial quantities of our products, if approved, at acceptable cost levels; and
- Successfully market and sell our products, if approved, in the United States and abroad.

In addition, because of the numerous risks and uncertainties associated with product candidate development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or other regulatory authorities to perform studies in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these products.

Our ability to become and remain profitable depends on our ability to generate revenue. Even if we are able to generate revenues from the sale of our products, if approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or obtain additional funding, or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future.

We have incurred losses in each year since our inception in December 1997. Our net loss was \$30.3 million, \$16.1 million and \$14.3 million for the years ended December 31, 2015, 2014 and 2013, respectively. Our net loss was \$7.8 million and \$23.5 million for the three and nine month periods ended September 30, 2016. As of September 30, 2016, we had an accumulated deficit of \$188.3 million.

Specialty pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. We expect to incur expenses without corresponding revenues until we are able to obtain regulatory approval and subsequently sell Twirla in significant quantities, which may not happen. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We expect to incur increased expenses as we conduct our additional Phase 3 clinical trial for Twirla, respond to the CRL and supplement our NDA with the results of the trial, complete the qualification and validation of our commercial manufacturing process, advance our other product candidates and expand our research and development programs. To date, we have

financed our operations primarily through sales of common stock, convertible preferred stock and convertible promissory notes and to a lesser extent, through term loans and government grants. Our product candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue.

Assuming we obtain FDA approval, we expect that our expenses will increase as we prepare for the commercial launch of Twirla. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses may increase. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

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If we fail to obtain the capital necessary to fund our operations, we may be unable to obtain regulatory approval of or commercialize Twirla in the United States and we could be forced to share our rights to commercialize Twirla with third parties on terms that may not be favorable to us.

We need large amounts of capital to support our development and commercialization efforts for Twirla. If we are unable to secure sufficient capital to fund our operations, we will not be able to continue these efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to Twirla with third parties in ways that we currently do not intend or on terms that may not be favorable to us. Our cash and cash equivalents were \$51.7 million as of September 30, 2016. Based on our current business plan, we believe that our cash and cash equivalents as of September 30, 2016 will be sufficient to meet our anticipated operating needs through the end of 2017. We anticipate requiring additional capital to fund operating needs thereafter. We may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate or we encounter any unforeseen events that affect our current business plan.

Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our loan agreement and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

In February 2015, we entered into a loan and security agreement, referred to herein as the Hercules Loan Agreement, with Hercules Capital, Inc., or Hercules, for a term loan of up to \$25.0 million. The Hercules Loan Agreement was amended effective August 25, 2016. A first tranche of \$16.5 million was funded upon execution of the Hercules Loan Agreement, approximately \$15.5 million of which was used to repay our term loan with Oxford. Under terms of the Hercules Loan Agreement, we may, but are not obligated to, draw an additional tranche of up to \$8.5 million through March 31, 2017, subject to the achievement of certain clinical milestones

The Hercules Loan Agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, change our line of business, liquidate or dissolve, enter into any change in control transaction, merge or consolidate with any other entity or acquire all or substantially all the capital stock or property of another entity, incur additional indebtedness, incur certain types of liens on our property, including our intellectual property, pay any dividends or other distributions on our capital stock other than dividends payable solely in capital stock or redeem our capital stock. Our business may be adversely affected by these restrictions on our ability to operate our business.

The Hercules Loan Agreement is secured by substantially all of our property other than our intellectual property. As a result of the amendment to the Hercules Loan Agreement, we are currently required to make interest-only payments through January 2017. The Hercules Loan Agreement currently bears interest at rate of 9.0% per annum and matures on December 1, 2018.

Additionally, we may be required to repay the outstanding indebtedness under the term loan if an event of default occurs under the Hercules Loan Agreement. Under the Hercules Loan Agreement, an event of default will occur if, among other things, we fail to make payments under the Hercules Loan Agreement we breach any of our covenants under the Hercules Loan Agreement, subject to specified cure periods with respect to certain breaches; Hercules determines in good faith that we are unable to satisfy our obligations under the Hercules Loan Agreement as they become due and that our principal investors do not intend to fund amounts necessary to satisfy such obligations; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit Hercules to accelerate the maturity of such indebtedness or that could have a material adverse effect on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our product candidate development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise

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prefer to develop and market ourselves. Hercules could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit, which collateral includes all of our property other than our intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

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We will need to obtain additional financing to fund our operations and, if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. From our inception to September 30, 2016, we have cumulative net cash flows used by operating activities of \$167.2 million. We will need to obtain additional financing to fund our future operations, including completing the development and commercialization of our product candidates. We will need to obtain additional financing to conduct additional trials for the approval of our product candidates if requested by regulatory authorities, and to complete the development of any additional product candidates we might acquire. Moreover, our fixed expenses such as rent, interest expense and other contractual commitments are substantial and are expected to increase in the future.

Our future funding requirements will depend on many factors, including, but not limited to:

- Progress, timing, scope and costs of our clinical trials, including the ability to timely enroll subjects in our ongoing, planned and potential future clinical trials;
- Time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities;
- Our ability to successfully commercialize our product candidates, if approved;
- Our ability to have commercial product successfully manufactured consistent with FDA regulations;
- Amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement;
- Sales and marketing costs associated with commercializing our products, if approved, including the cost and timing of expanding our marketing and sales capabilities;
- Terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;

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- Cash requirements of any future acquisitions or the development of other product candidates;
- Costs of operating as a public company;
- Time and cost necessary to respond to technological and market developments;
- Costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
and
- Costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish.

Until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

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Based on our current business plan, we believe that our existing cash and cash equivalents as of September 30, 2016 will be sufficient to fund our projected operating requirements through the end of 2017. We expect that these funds will not be sufficient to enable us to complete all necessary development of our product candidates other than Twirla, complete validation of our commercial manufacturing process or commercially launch Twirla or our other current product candidates. Accordingly, we will be required to obtain further funding through other public or private offerings, debt financing, collaboration or licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward- looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this Risk Factors section. We have based this estimate on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. Our inability to obtain additional funding when we need it could seriously harm our business.

Raising additional capital may cause dilution to our existing stockholders or restrict our operations.

We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. The sale of additional equity or convertible debt securities could result in the issuance of additional shares of our capital stock and could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing research and development efforts. This could harm our business, operating results and financial condition and cause the price of our common stock to fall.

We are a development stage company which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a development stage company. We were incorporated and commenced active operations in 1997. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital and developing our product candidates. We have not yet demonstrated our ability to successfully complete a Phase 3 registration trial for, obtain regulatory approval of, or manufacture on a commercial scale any of our product candidates, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a development stage company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a focus on product candidate development to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Relating to the Commercialization of Our Product Candidates

We are substantially dependent on the commercial success of Twirla.

Assuming FDA approval, Twirla will be the first product that we commercialize. The rest of our pipeline of products are in earlier stages of clinical development and will require additional clinical and product development and funding in order to advance towards commercialization, which could take considerable time. If Twirla is not approved, our ability to advance our pipeline would be significantly adversely affected. Our ability to generate revenues and become profitable will depend in large part on the commercial success of Twirla. Potential prescribers of Twirla include physicians, nurse practitioners (NPs), physician s assistants (PAs) and pharmacists. Registered Pharmacists (RPh) are authorized to prescribe contraceptives in some states currently, and others have pending legislation that would allow pharmacists to prescribe contraceptives. If Twirla or any other product that we

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commercialize in the future does not gain an adequate level of acceptance among prescribers, patients and third parties, we may not generate significant product revenues or become profitable. Market acceptance of Twirla, and any other product that we commercialize, by prescribers, patients and third party payors will depend on a number of factors, some of which are beyond our control, including:

- Efficacy, safety and other potential advantages of our product candidates in relation to alternative treatments;
- Relative convenience and ease of administration of our product candidates;
- Availability of adequate coverage or reimbursement of our product candidates by third parties, such as insurance companies and other payors, and by government healthcare programs, including Medicare, Medicaid and state health insurance exchanges;
- Prevalence and severity of adverse events associated with our product candidates;
- Cost of our product candidates in relation to alternative treatments, including generic products;
- Extent and strength of our third-party manufacturer and supplier support;
- Extent and strength of our marketing and distribution support;
- Limitations or warnings contained in our product's FDA approved labeling; and
- Distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan.

For example, if Twirla is approved by the FDA, prescribers and patients may not be immediately receptive to a transdermal contraceptive system, as opposed to a pill or any other method, and may be slow to adopt it as an accepted treatment for the prevention of pregnancy. In addition, even though we believe Twirla has significant advantages over other treatment options, because no head-to-head trials comparing Twirla to the competing approved patch product have been conducted, the prescribing information approved by the FDA may not contain claims

that Twirla is safer or more effective than the currently approved patch product, or other claims that may be necessary for successful marketing of Twirla. Accordingly, we will not be permitted to promote Twirla, if approved, for any comparative advantages to the currently marketed contraceptive patch. The availability of numerous inexpensive generic forms of contraceptive products may also limit acceptance of Twirla among prescribers, patients and third party payors. If Twirla does not achieve an adequate level of acceptance among prescribers, patients and third party payors, we may not generate significant product revenues or become profitable.

It will be difficult for us to profitably sell Twirla, if approved, or any other product that we obtain marketing approval for in the future if coverage and reimbursement for such product is limited.

Market acceptance and sales of Twirla, if approved, or any other product that we obtain marketing approval for in the future, will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for approved medications. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and these third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage or reimbursement will be available for Twirla, if approved, or any other product that we obtain marketing approval for in the future and, if coverage is available, we cannot be sure of the level of reimbursement. Reimbursement may impact the demand for, or the price of, Twirla, if approved, and any other products that we obtain marketing approval for and commercialize. Numerous generic products may be available at lower prices than branded therapy products, such as Twirla, which may also reduce the likelihood and level of reimbursement for Twirla or other products. If coverage and reimbursement are not available

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or are available only at limited levels, we may not be able to successfully commercialize Twirla, if approved, or any other product for which we obtain marketing approval.

If we are unable to establish effective marketing and sales capabilities for Twirla, if approved, or enter into agreements with third parties to market and sell Twirla, we may be unable to generate product revenues.

We are seeking approval for Twirla from the FDA for a contraception indication. Following our original submission of the NDA, we received a CRL from the FDA requesting, among other things, additional Phase 3 data. Our ability to commercialize Twirla, and the timing of Twirla commercialization, is dependent on timely and successful completion of this additional Phase 3 study and other items such as timely and successful completion of validation of equipment for commercial manufacturing, and ultimate FDA approval. In our current business plan, we have assumed completion of our SECURE Phase 3 clinical trial in the fourth quarter of 2016, resubmission of our NDA for Twirla to the FDA in the first half of 2017, a six-month FDA review of our resubmission and completion of validation of our commercial manufacturing process in coordination with our commercialization of Twirla. We cannot assure you that the FDA will approve Twirla or that the FDA's timeline for review will be within six months.

At present, we have no sales personnel and a limited number of marketing personnel. We do not intend to begin to hire additional marketing personnel until shortly prior to the final submission to our NDA or establish our own sales force or engage a contract sales organization in the United States until shortly prior to FDA approval of Twirla. At the time of our anticipated commercial launch of Twirla, assuming regulatory approval by the FDA, our sales and marketing team will have worked together for only a limited period of time. We cannot guarantee that we will be successful in marketing Twirla in the United States.

We may not be able to establish our own sales force or a contract sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize Twirla, if approved, in the United States without strategic partners or licensees include:

- Our inability to timely recruit and retain adequate numbers of effective sales and marketing personnel;

- The inability of sales personnel to obtain access to or persuade adequate numbers of prescribers to prescribe Twirla;

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

- The costs associated with training sales and marketing personnel on legal and regulatory compliance matters

and monitoring their actions;

- Liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements; and
- Unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty commercializing Twirla, which would adversely affect our business, operating results and financial condition.

If we intend to commercialize Twirla outside the United States, we will likely enter into collaboration agreements with pharmaceutical partners, and we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend on the success of the efforts of these third parties.

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To the extent that we rely on, or partner with, third parties to commercialize Twirla, if approved, or any other product candidate for which we obtain marketing approval in the future, we may receive less revenue than if we commercialized these products ourselves. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts. We, however, will remain responsible for the conduct of any contract sales force, which could expose us to legal and regulatory enforcement actions and liability. In the event that we are unable to partner with a third party marketing and sales organization, our ability to generate product revenues may be limited in the United States, internationally or both.

A variety of risks associated with potential international business relationships could materially adversely affect our business.

We may enter into agreements with third parties for the development and commercialization of Twirla and possibly other product candidates in international markets. If we do so, we would be subject to additional risks related to entering into international business relationships, including:

- Differing regulatory requirements in foreign countries including, among others, requirements relating to drug approvals, reimbursement and sales and marketing practices;
- Potentially reduced protection for intellectual property rights;
- The potential for so-called parallel importing, which is when a local seller, faced with higher local prices, opts to import goods from a foreign market with lower prices, rather than buying them locally;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- Economic weakness, including inflation, or political instability in foreign economies and markets;
- Compliance with tax, employment, immigration and labor laws for employees traveling and working abroad;
- Foreign taxes;
- Foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other risks incident to doing business in another country;

- Workforce uncertainty in countries where labor unrest is more common than in the United States;
- Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- Business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, tsunamis, hurricanes and fires.

These and other risks may materially adversely affect our ability to develop and commercialize products in international markets and may harm our business.

Even if we receive regulatory approval for Twirla, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited.

The commercial success of Twirla in any indication for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the contraceptive market landscape as well as acceptance and uptake of Twirla by prescribers, patients and third-party payors.

Risks related to the contraceptive market landscape include:

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- The prescription contraceptive market could experience a decrease in growth or negative growth if fewer women choose to use hormonal contraception;
- The perceived safety of hormonal contraceptives could be negatively affected by media reports of adverse effects and advertisements for class action lawsuits due to adverse effects;
- Price pressures from third party payors, including managed care organizations and government-sponsored health systems, could limit our revenue;
- The proportion of the contraceptive market comprised of generic products continues to increase, making introduction of a branded contraceptive difficult and expensive;
- Competition in the contraceptive market could increase, with the introduction of new contraceptives, including the potential of a new generic or branded competitive contraceptive patch;
- Competition from generic contraceptive products could increase as additional generic contraceptives receive FDA approval;
- Implementation of the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010 or, collectively, the Affordable Care Act, or ACA, and its effect on pharmaceutical coverage, reimbursement and pricing could limit our revenue; and
- Access to the prescriber universe, particularly obstetrics and gynecology physicians, could be limited, decreasing our ability to promote Twirla efficiently.
- Our ability to access pharmacists in states where they are authorized by law to prescribe contraceptives could be limited, decreasing our ability to promote Twirla

The degree of acceptance and uptake of Twirla, if approved, by prescribers, patients and third-party payors will depend upon a number of factors, including:

- The level of contraceptive effectiveness of Twirla demonstrated in our clinical trials;
- The incidence and severity of adverse effects associated with Twirla;
- Limitations on use or warnings contained in FDA-approved labeling;
- Acceptability to patients of the appearance and feel of Twirla;
- Willingness of patients to try a new contraceptive and to use a transdermal patch as their form of contraception;
- Willingness of prescribers to prescribe a contraceptive patch in light of safety issues and restrictive labeling of the currently marketed contraceptive patch;
- The cost of Twirla to the patient, as compared to other contraceptive products and methods;
- Our ability to obtain and maintain sufficient third party coverage or reimbursement for Twirla from private health insurers, government healthcare programs (including Medicare, Medicaid and 340B Clinics) and other third party payors; and
- The effectiveness of our or any future collaborators sales and marketing strategies.

In addition, even if we obtain regulatory approval, the timing of an approval may reduce our ability to commercialize Twirla successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render Twirla not commercially viable. For example, regulatory authorities may grant approval contingent on the performance of

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costly post-marketing clinical trials or other post-marketing commitments, including REMS, or may approve Twirla with a label that contains fewer, or more limited, indications than requested, warnings, precautions or contraindications, including black box warnings, and the label may not include the claims necessary or desirable for the successful commercialization of Twirla. Any of the foregoing scenarios could materially harm the commercial prospects for Twirla.

Moreover, we may face additional generic or other drug product competition sooner than we anticipate for Twirla or our other product candidates, which would potentially limit their commercial success. We believe that we may be eligible for three years of FDA marketing exclusivity for Twirla and our other product candidates. The FDCA provides a period of three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA for a drug product that contains a previously approved active moiety, if new clinical investigations, other than bioavailability or bioequivalence studies, were conducted or sponsored by the applicant and are determined by the FDA to be essential to the approval of the application. This three year marketing exclusivity, however, does not protect drug products from all competition. For instance, it does not protect against the approval of a full NDA. It also would only protect against the approval of a product that contains the same conditions of approval as our product candidates. We may not receive the three year exclusivity for any of our product candidates, and, even if we do, it may not adequately protect us from competition. Competition that our product candidates may face from generic or similar versions of our product candidates could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

If Twirla is approved, but does not achieve an adequate level of acceptance by prescribers, third-party payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate prescribers, patients and third party payors on the benefits of Twirla may require significant resources and may never be successful. Even if we are able to demonstrate and maintain a competitive advantage over our competitors and become profitable, if the market for hormonal contraceptives fails to achieve expected future growth or decreases, we may not generate sufficient revenue or sustain profitability.

The proportion of the contraceptive market that is made up of generic products continues to increase, making introduction of a branded contraceptive difficult and expensive.

The proportion of the U.S. market that is made up of generic products has been increasing over time. In 2005, generic contraceptive products held 47% of prescription volume and 34% of sales and, by 2011, those values had risen to 68% and 44%, respectively. For the six months ended June 30, 2016, approximately 83% of the prescription volume and approximately 43% of sales of combined hormonal contraceptives, or CHCs, in the U.S. were generated by generic products. If this trend continues, it may be more difficult to introduce Twirla, if approved, as a branded contraceptive, at a price that will maximize our revenue and profits. Also, there may be additional marketing costs to introduce Twirla in order to overcome the trend towards generics and to gain access to reimbursement by payors. If we are unable to introduce Twirla at a price that is commensurate with that of current branded contraceptive products, or we are unable to gain reimbursement from payors for Twirla, or if patients are unwilling to pay any price differential between Twirla and a generic contraceptive, our revenues will be limited. For example, in light of the introduction of the generic version of the Ortho Evra product by Mylan Inc. in April 2014, and the subsequent discontinuation of distribution of Ortho Evra in October 2014 by Janssen in order to be competitive and gain market share, we may increase the rebates available to commercial payors or we may provide incentives to consumers covered by non-governmental payors, such as coupons or rebates, in order to make up for the difference in the co-payment for Twirla and the generic patch product.

Prescribers, patients and payors may not adopt a new contraceptive patch due to concerns based upon the prior experience with or perception of the currently marketed contraceptive patch.

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The following is a brief history of the Evra market experience:

- Evra had rapid uptake in the contraceptive market, achieving a 10% share of the CHC market by September 2003. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms.

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- Following the approval of Evra, users of Evra began to report thrombotic and thromboembolic events to the FDA.
- A pharmacokinetic study was conducted in 2005 and later published in the Journal of Clinical Pharmacology comparing Evra to an oral contraceptive, which demonstrated that Evra was delivering higher serum concentrations of EE compared to an oral contraceptive with an EE dose of 35 micrograms. A pharmacokinetic study evaluates how the body handles a given drug over time; these studies are conducted by measuring the amount of time it takes for the drug to be absorbed, distributed and eliminated throughout the body.
- Johnson & Johnson, the manufacturer of Evra, revised the Evra labeling in November 2005 to include information that EE exposure with Evra is 60% higher than that of an oral contraceptive containing EE of 35 micrograms, based on area under the curve, a commonly-used metric for measuring EE exposure in contraceptives. This information was ultimately included in a unique black box warning and bolded warning in the Evra labeling.
- The FDA held a Joint Meeting of the Advisory Committees for Reproductive Health Drugs and Drug Safety and Risk Management on December 9, 2011. The Committees concluded that users of Evra have an increased risk of venous thromboembolism, or VTE compared to users of second generation contraceptives, such as those containing LNG. The Committees, through a vote, concluded that the benefits of Evra outweighed the risks, but that the current package insert did not adequately reflect the risk/benefit profile.
- A subsequent change to the labeling for Evra was implemented in August 2012.
- The Evra market share declined rapidly following the labeling changes, from a peak share of 11% in 2005, to 4% by the end of 2006, to 1.4% by the end of 2013.
- In April 2014, the Evra label was revised to provide revised dosage form and strength information. However, this revision did not affect the unique black box warning and bolded warning in the Evra label.
- The approval of a generic equivalent to Evra, Xulane® was announced by Mylan Inc. in April 2014. Subsequently, in October 2014, Janssen discontinued distribution of Evra and currently over 99% of patch prescriptions are filled with the generic.

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We have conducted pharmacokinetic studies of Twirla to demonstrate that it delivers a daily EE dose of approximately 30 micrograms, comparable to a low-dose oral contraceptive. However, because none of our completed or planned clinical trials studied or expect to study Twirla in a head-to-head comparison with Evra, if Twirla is approved by the FDA, we will not be able to make direct comparative claims regarding the safety and efficacy of Twirla as compared to Evra. While we expect Twirla, if approved, to have the same black box warning currently required for all CHCs, we cannot predict whether the FDA will require that we include information in the Twirla labeling or black box warning regarding the additional risks associated with the Evra patch. Assuming approval, if we are not able to convince prescribers, patients and payors that Twirla delivers a low daily dose of EE, this may limit uptake and usage of Twirla and our revenue will be limited.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We would have significant competition with contraceptive products already in the marketplace, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Any new product that competes with a previously approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability or safety to be commercially successful. In addition, new products developed by

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others could emerge as competitors to Twirla, if approved. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. These companies include Merck & Co., Inc., or Merck, which markets Nuvaring®, Allergan, Inc., or Allergan, which markets several branded and generic contraceptives including Loestrin® 24, Minastrin® 24 and LoLoestrin®, Teva Pharmaceutical Industries Ltd., or Teva, which markets several branded and generic contraceptives including Gianvi® and Quartette®, Bayer AG, or Bayer, which markets Beyaz® and Mirena®, Johnson & Johnson, which markets Ortho-Tri-Cyclen® Lo, Pfizer Inc., which markets Alesse® and Mylan Inc. which markets Xulane , a generic version of Ortho Evra. Additionally, several generic manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz International GmbH, Glenmark Pharmaceuticals Ltd., Lupin Pharmaceuticals, Inc., and Amneal Pharmaceuticals LLC.

There are other contraceptive product candidates in development that, if approved, would potentially compete with Twirla. Specifically, Bayer has a contraceptive patch approved in the European Union, or E.U. Bayer entered into a license and distribution agreement for the sale of this contraceptive patch in Europe with Gedeon Richter Ltd. Other companies that have new contraceptive product candidates in various stages of development include Teva (oral contraceptive in Phase 3), Merck (oral contraceptive in Phase 3), Allergan (vaginal ring and oral contraceptive in Phase 2) and Antares Pharma, Inc. (transdermal gel contraceptive in Phase 2).

Sales of our products, if approved, may be adversely affected by the consolidation among wholesale drug distributors and the growth of large retail drug store chains.

The network through which we will sell our products, if and when approved, has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large distributors control a significant share of the market. In 2012, three companies generated about 85% of all revenues from drug distribution in the United States, and in 2010, four chain pharmacy companies owned about 30% of all retail pharmacy outlets. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and to commercialize Twirla and our other product candidates and may affect the prices we may obtain.

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

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Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will change, or what the impact of such changes on the potential marketing approval of Twirla, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the healthcare industry and impose additional healthcare policy reforms. The ACA, among other things, increased the Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs, extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, addressed new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are line extension products and expanded the 340B drug discount program (excluding orphan drugs) to other entities. Further, the ACA imposed a significant annual tax on companies that manufacture or

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import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with regard to healthcare practitioners.

Of particular relevance to our business is the ACA requirement that all health plans, with limited exceptions, cover certain preventive services for women with no cost-sharing, which means no deductible, no co-insurance and no co-payments by the patient. Contraceptive methods and counseling, including all FDA-approved contraceptive methods as prescribed, are included in the ACA mandate, and this has come to be known as the contraceptive mandate. Under the ACA, payors are only required to cover one favored product within each contraceptive method without imposing any cost-sharing obligations on the patient. For example, the introduction of a generic contraceptive patch product with a price that will likely be lower than the price of Twirla makes it less clear that Twirla would have a preferred position, such as coverage without a co-insurance payment, under the ACA contraceptive mandate. Other products within the same method may also be covered, but payors are allowed to use reasonable medical management techniques, such as the application of cost-sharing obligations. An amendment was issued that provided an exemption to the contraceptive mandate for group health plans established or maintained by religious employers. However, the contraceptive mandate has remained controversial, with several legal challenges filed around the country. In June 2014, the U.S. Supreme Court ruled that owners of certain private companies can object to the contraceptive mandate on religious grounds and in November 2015, the Court agreed to hear arguments from non-profit organizations requesting similar treatment. Although it is too early to determine the full effect of the contraceptive mandate and other provisions of the ACA on our business, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA 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 of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or ATRA, which among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional 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, and in turn could significantly reduce the projected value of our product candidates and reduce our profitability.

Moreover, the recently enacted Drug Quality and Security Act imposes new obligations related to product tracking and tracing on manufacturers of pharmaceutical products. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug products they produce to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' drug products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Third party coverage and reimbursement and healthcare cost containment initiatives and treatment guidelines may constrain our future revenues.

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Our ability to successfully market Twirla and other product candidates, if approved, will depend in part on the level of coverage and reimbursement that government authorities, private health insurers and other organizations provide for Twirla or our other product candidates and contraceptives in general. Countries in which Twirla or our other product candidates are sold through reimbursement schemes under national health insurance programs

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frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell Twirla or our other product candidates profitably if adequate prices are not approved or coverage and reimbursement are unavailable or limited in scope. Increasingly, third party payors attempt to contain healthcare costs in ways that are likely to impact our development of products including:

- Failing to approve or challenging the prices charged for healthcare products;
- Introducing reimportation schemes from lower-priced jurisdictions;
- Limiting both coverage and the amount of reimbursement for new therapeutic products;
- Denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third party payors; and
- Refusing to provide coverage when an approved product is used for off-label indications.

Risks Related to Manufacturing and Our Reliance on Third Parties

We have no manufacturing capacity and anticipate continued reliance on Corium, our third party manufacturer, for the development and commercialization of our product candidates in accordance with manufacturing regulations.

We rely on Corium International, Inc., or Corium, our third party manufacturer, to produce clinical supplies of Twirla and our other product candidates, and we plan to continue relying on them for commercial supplies and samples of our product candidates, if approved. We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We lack the resources and the capabilities to manufacture Twirla or any of our product candidates on a clinical or commercial scale. The facilities used by Corium to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after submission of an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as Current Good Manufacturing Practices, or cGMPs, for manufacture of our product candidates and our products, if and when approved. If Corium or other contract manufacturers that we may use cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturer to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities that would also require FDA approval and which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Moreover, if our contract manufacturer cannot successfully manufacture materials

that conform to our specifications and the strict regulatory requirements of the FDA or others, we may be subject to other regulatory enforcement action such as adverse inspectional findings, Warning Letters, Untitled Letters, recall requests, withdrawal of product or investigational approvals, clinical holds or termination, disgorgement, restitution, exclusion from federal healthcare programs product seizures and detention, consent decrees, corporate integrity agreements, criminal and civil penalties, including imprisonment, refusal to permit import or export of the product and injunction against or restriction of manufacture or distribution. If our contract manufacturer experiences issues in its manufacturing process or is unable to produce clinical supplies in adequate quantity and quality, our clinical trial could be delayed or our ability to receive regulatory approval of our product candidates could be negatively affected. Additionally, if there are changes to the manufacturing process for Twirla or to our formulation for Twirla that require a change in the manufacturing process, we could experience significant additional cost and our ability to receive regulatory approval could be delayed.

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The machinery to produce the commercial supply of Twirla must be qualified and validated, which is time-consuming and expensive, and this machinery is located within one manufacturing site and is customized to the particular manufacturing specifications of Twirla. If Corium is unable to qualify and validate this equipment in a timely manner, our ability to launch and commercialize Twirla will be compromised. If this customized equipment malfunctions at any time during the production process, the time it may take Corium to secure replacement parts, to undertake repairs and to revalidate the equipment and process could limit our ability to meet the commercial demand for Twirla. Similar manufacturing conditions may also apply to our other product candidates. This may increase the risk that the third party manufacturer may not manufacture Twirla in accordance with the applicable regulatory requirements, that we may not have sufficient quantities of Twirla or our product candidates or that we may not have such quantities at an acceptable cost, any of which could delay, prevent, or impair the commercialization of Twirla, if approved, and the development of our product candidates.

Although we have manufacturing agreements with Corium for the clinical and commercial supply of Twirla, Corium and several of its suppliers of raw materials will be single source providers to us for a significant period of time. In particular, Corium manufactures Twirla using EE and LNG and components that it purchases from third parties, most of which are single source suppliers of the applicable material. We do not have any control over the process or timing of the acquisition of these raw materials by Corium. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Because we outsource all of our manufacturing processes, there is no guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Although Corium intends to enter into agreements with critical manufacturers, component fabricators and secondary service providers to secure commercial supply of Twirla, not all of such suppliers and service providers will be under contract. Any delays in obtaining adequate supplies of our product candidates could limit our ability to meet commercial demand for Twirla.

In addition, in the event Twirla is approved and achieves significant market share, Corium may not possess adequate manufacturing capabilities to meet market demand for Twirla. If it becomes necessary to engage an additional third party manufacturer to produce Twirla, we may need to license certain manufacturing know-how from Corium, or our commercial supply will be limited while the new third party manufacturer develops the necessary know-how to manufacture Twirla and while we obtain regulatory approval for the addition of a new manufacturer.

Reliance on a third party manufacturer subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including:

- Reliance on the third party for regulatory compliance and quality assurance;
- Reduced control over the manufacturing process for our product candidates;
- The possible breach of the manufacturing agreements by the third party because of factors beyond our control;

- The possibility of termination or nonrenewal of the agreements by the third party because of our breach of the manufacturing agreement or based on their own business priorities; and
- The disruption and costs associated with changing suppliers.

Our product candidates may compete with other products and product candidates for access to manufacturing resources and facilities. There are a limited number of manufacturers that operate under cGMP requirements and that are both capable of manufacturing for us and willing to do so. If our existing third party manufacturer, or the third parties that we may engage in the future to manufacture a product for commercial sale or

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for our clinical trials, should cease to continue to manufacture our product candidates for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our third party manufacturer is subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. In addition to the above-described regulatory actions, failures by our third party manufacturer to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another third party manufacturer that meets all regulatory requirements.

We are dependent on numerous third parties in Corium's supply chain for the supply of our product candidates, and if Corium fails to maintain supply relationships with these third parties, develop new relationships with other third parties or suffers disruptions in supply, we may be unable to continue to develop our product candidates, or, assuming FDA approval, commercialize Twirla.

We, through our manufacturing partner Corium, rely on a number of third parties for the supply of active ingredients, other raw materials and laboratory services for the supply of our product candidates and, assuming FDA approval, commercialization of Twirla. Our ability to develop our product candidates depends, in part, on Corium's ability to successfully obtain the active pharmaceutical ingredients used in our product candidates, in accordance with regulatory requirements and in sufficient quantities for clinical testing and later commercialization. If Corium fails to develop and maintain supply relationships with these third parties, we may be unable to continue to develop our product candidates or commercialize any approved products in the future.

We, through Corium, 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 get regulatory approval to use alternative suppliers, and this process of approval could delay development of our product candidates and, assuming FDA approval, commercial production of Twirla, indefinitely. For example, the sole manufacturer of one of the components of the packaging of our Twirla patch notified us that it would be discontinuing manufacture of the component in 2016. In conjunction with Corium, we were able to secure an amount of inventory of the packaging component that we believe will last until 2019. We are currently evaluating sources for a replacement for this discontinued component and, assuming FDA approval of this replacement material, we plan to use the replacement material in connection with the commercial production of Twirla.

If Corium's third party suppliers fail to deliver the required quantities of sub-components and starting materials, in accordance with all regulatory requirements, and on a timely basis and at commercially reasonable prices, and we and Corium 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 development of our product candidates, and assuming FDA approval, commercialization of Twirla, would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

If the manufacturing facilities of Corium are not maintained in a manner that is compliant with cGMP requirements, we may need to find alternative manufacturers and suppliers, which could result in supply interruptions of Twirla and our other product candidates, additional costs and lost revenues.

Corium's facilities used for the manufacture of our product candidates must be maintained in a manner compliant with cGMP requirements, including obtaining favorable inspection reports. We do not control the manufacturing process and are dependent on Corium for compliance with the FDA's requirements for manufacture of Twirla and our other product candidates. If Corium cannot successfully manufacture material components and finished products that conform to our specifications and the FDA's strict regulatory requirements, they and we may be subject to regulatory action, including adverse inspectional findings, Warning Letters, Untitled Letters, product

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recall requests, withdrawal of product or investigational approvals, clinical holds or termination, disgorgement, restitution, exclusion from federal healthcare programs, detentions or seizures, refusal to allow the import or export of a product, injunction against or restriction of manufacture or distribution, consent decrees, corporate integrity agreements, criminal and civil penalties, including imprisonment, and Corium may not be able to maintain FDA approval for its manufacturing facilities or acceptance of its manufacturing data in regulatory filings. If Corium's facilities cannot maintain compliance with FDA requirements, we may need to find and successfully qualify alternative manufacturing facilities, which could result in supply interruptions of Twirla and our other product candidates and substantial additional costs as a result of such delays, including costs with respect to finding alternative manufacturing facilities, and lost revenues.

We rely on third parties to conduct aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with applicable regulatory requirements, we may be delayed in obtaining or ultimately not be able to obtain marketing approval for our product candidates.

We currently rely on CROs for most aspects of our clinical trials, including trial conduct, data management, statistical analysis and electronic compilation of our NDA. We may enter into agreements with CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to new or ongoing clinical and preclinical programs. Entering into relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period between engagement of a CRO and the time the CRO commences work. As a result, delays may occur, which may materially impact our ability to meet our desired clinical development timelines and ultimately have a material adverse impact on our operating results, financial condition or future prospects.

As CROs are not our employees, we cannot control whether or not they devote sufficient time and resources to our clinical trials for which they are engaged to perform, and whether they comply with the applicable regulatory requirements, known as Current Good Clinical Practices, or cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our product candidates in clinical development, which include requirements related to the conduct of the study, subject informed consent, and IRB approval. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. Although we may rely on third parties for the execution of our trials, we are nevertheless responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, European Medicines Agency or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, in addition to the additional Phase 3 clinical trial that we are conducting in response to the CRL that we received from the FDA in February 2013. 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 cGCP regulations. In addition, our clinical trials must be conducted with product candidate materials produced under cGMP regulations. Our failure to comply with these regulations may require us to discontinue or repeat clinical trials, which would delay the regulatory approval process. If the CROs we engage do not successfully carry out their contractual duties or obligations, conduct the clinical trials in accordance with all regulatory requirements, or meet expected deadlines, or if they need to be replaced, or the quality or accuracy of the data they provide is compromised due to the failure to adhere to regulatory requirements or for other reasons, then our development programs may be extended, delayed or terminated, or we may not be able to obtain marketing approval for or successfully commercialize our product candidates. Failure to comply with clinical trial regulatory requirements may further subject us to regulatory action, including Warning Letters, Untitled Letters, adverse inspectional findings, clinical holds or termination, criminal and civil penalties, including imprisonment, injunction against manufacture or distribution and debarment. As a result, our financial results and the commercial prospects for our product candidates would be harmed and our costs would increase.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may seek partnerships, collaborations and other strategic transactions to maximize the commercial potential of Twirla, our other product candidates and our proprietary technologies in the United States and territories

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throughout the world. We may enter into such arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for Twirla and each of our other product candidates and technologies, both in the United States and internationally. We face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters could lead to delays in the development process or commercialization of our product candidates and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

If we fail to establish an effective distribution process our business may be adversely affected.

We do not currently have the infrastructure necessary for distributing pharmaceutical products. We intend to contract with third party logistics wholesalers to warehouse these products and distribute them to pharmacies. This distribution network will require significant coordination with our sales and marketing and finance organizations. Failure to secure contracts with wholesalers could negatively impact the distribution of our products, if and when approved, and failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively establish and manage the distribution process, the commercial launch and sales of our products, if and when approved, will be delayed or severely compromised and our results of operations may be harmed. Distribution practices will also need to comply with the applicable regulatory requirements. If our distributors do not comply with the applicable regulatory requirements, we could be exposed to potential enforcement actions.

Risks Related to Regulatory Matters Following Approval

Even if we obtain marketing approval for Twirla or other product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, Twirla or other product candidates could be subject to labeling and other restrictions, including withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems.

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Even if we obtain U.S. regulatory approval of Twirla or other product candidates, the FDA may still impose significant restrictions on their indicated uses, including more limited patient populations, require that precautions, contraindications, or warnings be included on the product labeling, including black box warnings, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Claims that we may make may also be restricted through our approved labeling. Twirla and our other product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, import, export, safety surveillance, advertising, marketing promotion, recordkeeping, reporting of adverse events and other post-market information, and further development. These requirements include registration with the FDA, listing of our drug products, payment of annual fees, as well as continued compliance with cGCPs for any clinical trials that we conduct post-approval. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product manufacturing changes. 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

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compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Should the inspectional findings not be resolved to the FDA's satisfaction or should the finding rise to a sufficient level, the FDA and other government authorities may issue a Warning Letter or Untitled Letter, or take other regulatory action such as a product seizure and detention, withdrawal of product approval, request for a recall, refusal to allow the import or export of the product, criminal or civil penalties, injunction against or restriction of manufacture or distribution, consent decrees, disgorgement, restitution, clinical holds or terminations, exclusion from federal healthcare programs, corporate integrity agreements, or imprisonment.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the information that patients must be provided, distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring treated patients to enroll in a registry.

With respect to sales and marketing activities by us or any future collaborative partner, advertising and promotional materials must comply with the FDA's rules in addition to other applicable federal and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws, which impact, among other things, our proposed sales, marketing and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if Twirla and our other product candidates are approved, our product labeling, advertising and promotional materials would be subject to regulatory requirements and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, a practice known as off-label promotion. If we receive marketing approval for Twirla or our other product candidates, physicians may nevertheless prescribe the products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. 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 sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. For example, we believe that Twirla, if approved, will have a label consistent with all other marketed hormonal contraceptive products, which include class labeling that warns of risks of certain serious conditions, including venous and arterial blood clots, such as heart attacks, thromboembolism and stroke, as well as liver tumors, gallbladder disease, and hypertension, and a black box warning regarding risks of smoking and CHC use, particularly in women over 35 years old that smoke. However, regulatory authorities may require the inclusion of additional statements about adverse events in the label, including additional black box warnings or contraindications.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute drug products through, for example, corporate integrity agreements, and debarment, suspension or exclusion from participation in federal and state healthcare programs. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines

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or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines that are as much as \$3.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or a regulatory agency discover previously unknown problems with a product candidate, once approved, such as adverse events of unanticipated severity or frequency, data integrity issues with regulatory filings, problems with the facility where the product is manufactured or we or our manufacturers or others working on our behalf fail to comply with applicable regulatory requirements before or after marketing approval, we may be subject to reporting obligations as well as the following administrative or judicial sanctions:

- Restrictions on the marketing, distribution or manufacturing of the product, withdrawal of the product from the market, or requests for product recalls;
- Issuance of Warning Letters, Cyber Letters or Untitled Letters;
- Mandate modification to promotional materials and labeling or require us to provide corrective information to healthcare providers;
- FDA or regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings and other safety information about the product;
- Require us to enter into a consent decree or corporate integrity agreement, which can include imposition of various fines, reimbursement for inspection costs, required due dates for specific actions and penalties for noncompliance;
- Clinical holds or termination;
- Injunctions or the imposition of civil or criminal penalties, imprisonment, monetary fines disgorgement or restitution;

- Suspension or withdrawal of regulatory approval;

- Suspension of any ongoing clinical trials;

- Refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- Debarment;

- Exclusion from participation in federal healthcare programs or refusal of government contracts;

- Suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or

- Product seizure or detention or refusal to permit the import or export of product.

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The occurrence of any event or penalty described above may inhibit our ability to commercialize Twirla or our other product candidates, if approved, and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Moreover, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if Twirla receives marketing approval by the FDA in the United States, we may never receive marketing approval for or commercialize Twirla or any other product candidates outside the United States.

In order to market Twirla or any other product candidate outside the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the United States, as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FDCA in the United States, which relates to the ability of an NDA applicant to use published data not developed by such applicant, may not exist in other countries. In territories where data is not freely available, we may not have the ability to commercialize our products, when and if approved, without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. Further, we may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety and efficacy dossiers. In addition, in many countries outside the United States, it is required that a product receive pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries. Further, the product labeling requirements outside the United States may be different and inconsistent with the U.S. labeling and to the detriment to the product, and therefore negatively affect the ability to market in countries outside the United States.

Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we fail to comply with applicable foreign regulatory requirements. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

We have received conditional approval from the FDA for the use of Twirla as the proprietary name for our lead product candidate, AG200-15. However, this approval is conditional upon a further and final review by the FDA at the time of NDA approval. Additionally, any name we intend to use for our other product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names,

we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any product candidates that we commercialize. Our arrangements with third-party payors, including government healthcare programs, and customers will expose us to broadly-applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute Twirla, if approved, and any other product candidates we commercialize. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, impose obligations on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates that create receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- The federal physician payment transparency requirements under the ACA and applicable regulations require manufacturers of drugs, devices, biologics and medical supplies to report certain information to the Department of Health and Human Services including information related to payments and other transfers of value made to physicians and teaching hospitals and the ownership and investment interests held by physicians and their immediate family members; and

- Analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing; 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 often are not preempted by HIPAA, thus complicating compliance efforts.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the relevant government or regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes; such that a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the ACA provided that the government may assert that a claim

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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 statutes.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations are costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities conducted by our sales team in the sale of Twirla or our other product candidates, if approved, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to a variety of different consequences, depending upon which law we are found to have violated, including significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, corporate integrity agreements, refusal of government contracts, contract debarment and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Intellectual Property Rights

We may not be able to protect our proprietary technology in the marketplace.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any future licensee's ability to maintain our patents and to obtain additional patent protection in the United States and other countries with respect to our proprietary technology and products. We believe we will be able to obtain, through prosecution of our pending patent applications, additional patent protection for our proprietary technology. If we are compelled to spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed. If we are unable to effectively protect the intellectual property that we own, other companies may be able to offer for sale the same or similar products containing the generically available active pharmaceutical ingredients in our product candidates, which could materially adversely affect our competitive business position and harm our business prospects. Our patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our product candidates. Even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the United States and many jurisdictions outside of the United States is not consistent. For example, in many jurisdictions the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or create uncertainty. In addition, publication of information related to our current product candidates and potential products may prevent us from obtaining or enforcing patents relating to these product candidates and potential products, including without limitation transdermal delivery systems and methods of using such transdermal delivery systems. Our product candidates contain generically available active pharmaceutical ingredients. As a result, composition-of-matter patents directed to the active pharmaceutical ingredients in our product candidates, which are generally believed to offer the strongest form of patent protection, are not available for our product candidates.

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Patents that we own or may license in the future do not necessarily ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

- The active pharmaceutical ingredients in our product candidates are generic and therefore our patents do not include claims directed solely to the active pharmaceutical ingredients;

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- Our patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates using the same active pharmaceutical ingredients;
- There can be no assurance that the term of a patent protection will be long enough for our company to realize sufficient economic value under the patents following commercialization of our product candidates;
- We do not expect, upon approval of our NDA, to receive patent term restoration under the Hatch-Waxman Act for the patents that have been, or will be, submitted to the FDA for listing in the Orange Book;
- Our issued patents and pending patent applications that may issue as patents in the future may not prevent entry into the U.S. market or other markets of generic versions of our Twirla and AG890 product candidates;
- Our patents may face paragraph IV challenges from potential generic of 505(b)(2) applicants, asserting that our applicable patents are invalid, enforceable, or will not be infringed by the manufacture, use, or sale of the competitive drug product;
- We do not at this time own or control issued foreign patents in all markets that would prevent generic entry into some markets for our product candidates;
- We may be required to disclaim part of the term of one or more patents;
- There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- There may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- There may be other patents issued to others that will affect our freedom to operate;

- If our patents are challenged, a patent office or a court could determine that they are invalid or unenforceable;
- There might be changes in the law that governs patentability, validity and infringement of our patents that adversely affects the scope or enforceability of our patent rights;
- A court could determine that a competitor's technology or product that is the same as or similar to, our product candidates does not infringe our patents; and
- Our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or government agency with jurisdiction may find our

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patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In that regard, third parties may challenge our patents in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire or be held invalid or unenforceable before our company can realize sufficient economic value following commercialization of our product candidates.

Our intellectual property portfolio is currently comprised of issued patents and pending patent applications. If our issued patents are found to be invalid, not enforceable or not infringed by competitor products, or pending patent applications fail to issue or fail to issue with a scope that is meaningful to our product candidates, our business will be adversely affected.

There can be no assurance that our pending patent applications will result in issued patents in the United States or foreign jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity or enforceability, or that we will obtain sufficient claim scope or term in those patents to prevent a third party from competing successfully with our product candidates.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. To the extent that we have obtained or are able to obtain patents or other intellectual property rights in any foreign jurisdictions, it may be difficult for us to stop the infringement of our patents or the misappropriation of other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the availability of certain types of patent rights and enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and product candidates, and the enforcement of intellectual property.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a first to file system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent

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rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. However, the full impact of the Leahy-Smith Act and the courts' review of any appeals to related proceedings, is in its early stages. Accordingly, the full impact that the Leahy-Smith Act will have on the operation of our business is not clear. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, as well as our ability to bring about timely favorable resolution of any disputes involving our patents and the patents of others.

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

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

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our products, when and if approved.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or future product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. There may be currently pending applications of which we are unaware that may later result in issued patents that our current or future product candidates infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our current or future product candidates infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

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Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement or misappropriation. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that

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any third-party patents are valid, enforceable and cover our product candidates or their use, the holders of any of these patents may be able to block our ability to commercialize our product candidates unless we acquire or obtain a license under the applicable patents or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our product candidates or lead to prohibition of the manufacture or sale of product candidates by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information, know-how or trade secrets could have a similar negative impact on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or that claim ownership of what we regard as our own intellectual property.

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

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary technological advances and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, contractors, outside scientific collaborators, sponsored researchers and other advisors, including the third parties we rely on to manufacture our product candidates, to protect our trade secrets and other proprietary information. However, any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets. Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope

of our proprietary rights. In addition, others may independently discover our trade secrets and proprietary information. Further, the FDA, as part of its Transparency Initiative, a proposal to increase disclosure and make data more accessible to the public, is

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currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

Any lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely impact the price of our common stock.

We may be required to initiate litigation to enforce or defend our intellectual property rights. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information and trade secrets could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our patents and patent applications could face other challenges, such as interference proceedings, opposition proceedings, reissue, inter partes review, re-examination proceedings, third-party submissions of prior art, and other forms of post-grant review. In the United States, for example, post-grant review has recently been expanded. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope or preventing the issuance of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of our common stock.

Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive

these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings.

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Risks Related to the Development of Our Additional Product Candidates

If we fail to develop and commercialize Twirla and our current pipeline of additional product candidates, our prospects for future growth and our ability to reach or sustain profitability may be limited.

A key element of our strategy is to develop, obtain regulatory approval for and commercialize our portfolio of product candidates in addition to Twirla. To do so, we plan to utilize our proprietary transdermal delivery technology, Skinfusion, to develop additional product candidates. We may not be successful in our efforts to develop our portfolio of additional product candidates, and any product candidates we do develop may not produce commercially viable products that safely and effectively treat their indicated conditions. To date, our efforts have identified three additional product candidates in addition to Twirla, including AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle, AG200-SP, which is a regimen designed to provide shorter, lighter periods, and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. AG200-SP and AG200-ER are intended to be Twirla line extensions that would expand the use of Twirla beyond its initial approved use. In July 2016, we began preparations for an initial Phase 2 clinical trial examining the use of AG200-SP along with a smaller lower dose combination ethinyl estradiol/levonorgestrel patch (SmP) in the fourth week of the woman's cycle. The Phase 2 clinical trial is designed to identify the optimal dose of the SmP, and will evaluate bleeding profiles, pharmacokinetic parameters, ovulation inhibition and safety over 3 cycles of treatment with AG200-SP. We expect to initiate dosing of the AG200-SP (SmP) clinical trial in the first quarter of 2017. Our planned Phase 2 clinical trial of AG200-SP (SmP) is only the initial clinical trial in this program and AG200-SP (SmP) may require additional clinical trials to establish the safety and efficacy of this product candidate. The other product candidates in our pipeline will likely require additional product development efforts to optimize patch formulations and dosing. In addition, we will need to conduct additional clinical trials to establish the safety and efficacy of these product candidates which will require additional capital. Our ability to develop these product candidates, in particular AG200-SP and AG200-ER could be significantly affected by our inability to get Twirla approved.

Our development programs may initially show promise in identifying potential product leads, yet fail to produce product candidates for clinical development. In addition, identifying new treatment needs and product candidates requires substantial technical, financial and human resources on our part. If we are unable to obtain development partners or additional development program funding, or to continue to devote substantial technical and human resources to such programs, we may have to delay or abandon these programs. Any product candidate that we successfully identify may require substantial additional development efforts prior to commercial sale, including preclinical studies, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are susceptible to the risks of failure that are inherent in pharmaceutical product development.

We may be unable to license or acquire suitable additional product candidates or technologies from third parties for a number of reasons.

The licensing and acquisition of pharmaceutical products is competitive. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, we expect competition in acquiring product candidates to increase, which may lead to fewer suitable acquisition opportunities for us as well as higher acquisition prices.

Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates include the following:

- We may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return on our investment in such product;
- Companies that perceive us to be their competitor may be unwilling to assign or license their product rights to us;

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- We may be unable to identify suitable products or product candidates within our areas of expertise; or
- We may not have sufficient funds to acquire, develop or commercialize additional product candidates or technologies.

Risks Related to Our Business Operations and Industry

In order to establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of November 4, 2016, we had a total of 18 full-time employees, and we use third-party consultants to assist with our current sales and marketing functions. As our development and commercialization plans and strategies develop, we expect to need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Twirla, if approved, and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. In order to induce valuable employees to remain with us, we have provided these employees with stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. Competition for skilled personnel in our market is intense and competition for experienced personnel may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have an employment agreement with only one of our employees, Alfred Altomari, our President and Chief Executive Officer. The employment agreement provides for at-will employment, which means that Mr. Altomari or any of our other employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of Mr. Altomari, or Dr. Elizabeth Garner, our Chief Medical Officer, may have a material adverse effect on our business. We do not currently carry key person insurance on the lives of members of executive management. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than those that we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate of and success with which we can develop and commercialize product candidates would be limited.

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If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Twirla or our other product candidates, if approved.

We face a potential risk of product liability as a result of the clinical testing of Twirla and our other product candidates and will face an even greater risk if we commercialize Twirla or our other product candidates, if approved or any other current or future product candidate. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of the product candidate subject to such claims. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- Decreased demand for Twirla or any future product candidates that we may develop;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Costs to defend any related litigation;
- A diversion of management's time and our resources;
- Substantial monetary awards to trial participants or patients;
- Product recalls, withdrawals or labeling, marketing or promotional restrictions;
- Loss of revenue;
- The inability to commercialize Twirla or our other product candidates, if approved;

- A decline in our stock price; and
- Exposure to adverse publicity.

We have obtained limited product liability insurance coverage for our products and our clinical trials with a \$10.0 million annual aggregate coverage limit. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses or products, or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We

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cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Our business is affected by macroeconomic conditions.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions and uncertainties, including those resulting from political instability and the current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass through price increases to patients. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations, if necessary.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payors and distributors to purchase, pay for and effectively distribute our products if and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future contract manufacturers, sole-source or single-source suppliers, or licensees to remain in business or otherwise manufacture or supply our product candidates. Failure by any of them to remain in business could affect our ability to manufacture product candidates.

We continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Global Market, impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure controls and internal control over financial reporting and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. We estimate that we will annually incur approximately \$2.0 million in expenses in response to these requirements.

Section 404(a) of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting, starting with the second annual report that we would expect to file with the SEC. However, for as long as we remain an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. 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 \$1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than \$1.0 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.

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Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. We will incur substantial accounting expense and expend significant management efforts to comply with internal control over financial reporting requirements. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with these requirements in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the NASDAQ Global Market, the SEC or other regulatory authorities, which would require additional financial and management resources.

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Business interruptions could delay us in the process of developing our product candidates and could disrupt our sales.

Our headquarters are located in Princeton, New Jersey, and Corium, our contract manufacturer, is located in Grand Rapids, Michigan. We are vulnerable to natural disasters, such as severe storms and other events that could disrupt our or Corium's operations. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned 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 and the further development of our product candidates could be delayed.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk that employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in fraudulent or other illegal activity, fraud or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the law and regulations of the FDA and non-U.S. regulators, including those laws that require the reporting of true, complete and accurate information to the FDA and non-U.S. regulators, (ii) healthcare fraud and abuse laws and regulations in the United States and abroad and (iii) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct in violation of these laws may also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these 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 regulatory enforcement actions, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, corporate integrity agreements, 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.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of our initial public offering.

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on

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ownership changes involving stockholders owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability.

In addition, it is possible that the transactions relating to our initial public offering, either on a standalone basis or when combined with future transactions, has caused us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustained.

In May 2014, we closed our initial public offering. Prior to our initial public offering, there was no public market for shares of our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on The NASDAQ Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares.

We expect that our stock price may fluctuate significantly.

Prior to our initial public offering, you could not buy or sell our common stock publicly. The trading price of our common stock is highly volatile and is subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this quarterly report, these factors include:

- Any delay in filing our response to the CRL received from the FDA with respect to Twirla and any adverse development or perceived adverse development with respect to the FDA's review of our response;
- Adverse results in our SECURE Phase 3 clinical trial for Twirla;

- Our failure to commercialize Twirla, if approved, or develop and commercialize additional product candidates;
- Unanticipated efficacy, safety or tolerability concerns related to the use of Twirla;
- Regulatory actions with respect to Twirla;
- Inability to obtain adequate product supply of Twirla or inability to do so at acceptable prices;
- Adverse results or delays in our clinical trials for our other product candidates;
- Changes in laws or regulations applicable to Twirla or any future product candidates, including but not limited to clinical trial requirements for approvals;

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- Actual or anticipated fluctuations in our financial condition and operating results;
- Actual or anticipated changes in our growth rate relative to our competitors;
- Competition from existing products or new products that may emerge;
- Announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- Failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- Issuance of new or updated research or reports by securities analysts;
- Fluctuations in the valuation of companies perceived by investors to be comparable to us;
- Share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- Additions or departures of key management or scientific personnel;
- Disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- Announcement or expectation of additional debt or equity financing efforts;
- Sales of our common stock by us, our insiders or our other stockholders; and

- General economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and the NASDAQ Global Market and the stock prices of pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

Future sales of shares of our common stock by existing stockholders could cause our stock price to decline.

If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

As of November 4, 2016, we had 28,757,719 shares of common stock outstanding. Of these shares, 25,148,671 shares of common stock are freely tradeable, without restriction, in the public market. Moreover, a relatively small number of our stockholders own large blocks of shares. We cannot predict the effect, if any, that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock

In addition, the 2,870,481 shares subject to outstanding options under our stock option plans and the 615,225 shares reserved for future issuance under our stock option plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations.

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We may be subject to securities litigation, which is expensive and could divert management attention.

Our market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our existing principal stockholders, executive officers and directors own a significant percentage of our common stock and will be able to exert a significant control over matters submitted to our stockholders for approval.

As of September 30, 2016, our executive officers, directors, director nominees, holders of 5% or more of our capital stock and their respective affiliates together beneficially owned approximately 68.1% of our outstanding voting stock.

This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, if they acted together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. These stockholders may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that other stockholders may feel are in their best interest and our large stockholders may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We will have broad discretion in how we use the net proceeds from our initial public offering, our private placement and our recently completed public offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds from our initial public offering, our private placement and our recently completed public offering. We intend to use the majority of the net proceeds from our initial public offering, our private placement and our recently completed public offering to conduct a Phase 3 clinical trial for Twirla, obtain marketing approval and begin preparations for the U.S. commercial launch of Twirla, continue the equipment qualification and validation related to the expansion of Corium's manufacturing capabilities, develop our product pipeline, and for working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, validation of capital equipment and the costs of operating as a public company. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds from our initial public offering, our private placement and our recently completed public offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from our initial public offering, our private placement and our recently completed public offering in a manner that does not produce income or that loses value.

We are an emerging growth company 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 are 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 not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. 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

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of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date we completed our initial public offering; (iii) the date on which we have issued more than \$1.0 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.

Our status as an emerging growth company under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements allowed to us as an emerging growth company we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

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. In addition, any 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. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ Global Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

We have never paid dividends on our common stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have not paid dividends on our common stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future,

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you will likely only experience a gain from your investment in our common stock if the price of our common stock increases.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- Authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of our common stock;

- Provide for a classified board of directors, with each director serving a staggered three-year term;

- Prohibit our stockholders from filling board vacancies, calling special stockholder meetings or taking action by written consent;

- Provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors;

- Require advance written notice of stockholder proposals and director nominations; and

- Require any action instituted against our officers or directors in connection with their service to the Company to be brought in the state of Delaware.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our company. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

Use of Proceeds

On May 22, 2014, the Company's registration statement on Form S-1 (File No. 333-194621) for our IPO was declared effective by the Securities and Exchange Commission, or SEC. On May 29, 2014, we completed our IPO whereby we sold 9,166,667 shares of common stock, at a public offering price of \$6.00 per share, before underwriting discounts and expenses. The aggregate net proceeds received by us from the offering were \$49.7 million after deducting the underwriting discounts and commissions and offering expenses paid by us.

As of September 30, 2016, we have used all of our net proceeds from the IPO primarily to fund the Phase 3 clinical trial for Twirla and for general working capital purposes; and, to a lesser extent, for activities related to the completion of the equipment qualification related to the expansion of Corium's manufacturing capabilities

There was no material change in the planned use of proceeds from our IPO as described in our prospectus dated May 22, 2014, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, as revised in our Quarterly Report on Form 10-Q for the period ended June 30, 2014, filed with the SEC on August 14, 2014.

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Item 6. Exhibits.

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

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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.

Date: November 7, 2016

Agile Therapeutics, Inc.

By:

/s/ Alfred Altomari
Alfred Altomari
President and Chief Executive Officer (Principal
Executive Officer)

Date: November 7, 2016

By:

/s/ Scott M. Coiante
Scott M. Coiante
Vice President and Chief Financial Officer (Principal
Financial and Accounting Officer)

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Exhibit Index

Exhibit Number	Description of Document
10.1	First Amendment to Loan and Security Agreement, dated August 25, 2016, by and among Agile Therapeutics, Inc. and Hercules Capital, Inc. and the several banks and other financial institutions or entities from time to time parties to the loan agreement, dated August 25, 2016 (incorporated by reference, Exhibit 10.1 to Company's 8-K, file number 001-36464, filed on August 26, 2016).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2016.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2016.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2016.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2016.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders' Equity, (v) Statements of Cash Flows, and (vi) the Notes to Financial Statements.

September

December

2016

2015

MCh\$

MCh\$

Short-term personnel benefits

28,676

34,307

Vacation accrual

26,291

25,480

Pension plan- defined benefit plan

9,225

10,728

152

Other benefits

6,852

4,276

Total

71,044

74,791

61

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

24. Provisions, continued:

(d) Pension plan Defined benefit plan:

(i) Movement in the defined benefit obligations are as follow:

	September 2016 MCh\$	September 2015 MCh\$
Opening defined benefit obligation	10,728	11,471
Increase in provisions	285	496
Benefit paid	(1,788)	(1,395)
Actuarial gains		
Total	9,225	10,572

(ii) Net benefits expenses:

	September 2016 MCh\$	September 2015 MCh\$
Current service cost	(126)	54
Interest cost of benefits obligations	411	442
Effect of change in actuarial factors		
Net benefit expenses	285	496

(iii) Assumptions used to determine pension obligations:

The principal assumptions used in determining pension obligations for the Bank's plan are shown below:

September 2016	December 2015
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	%	%
Discount rate	4.60	4.60
Annual salary increase	5.41	5.41
Payment probability	99.99	99.99

The most recent actuarial valuation of the present value of the benefit plan obligation was carried out as of December 31, 2015.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

24. Provisions, continued:

(e) Movements in provisions for incentive plans:

	September 2016 MCh\$	September 2015 MCh\$
Balances as of January 1,	34,307	29,678
Provisions established	27,669	24,063
Provisions used	(33,300)	(30,162)
Provisions release		
Total	28,676	23,579

(f) Movements in vacations accruals:

	September 2016 MCh\$	September 2015 MCh\$
Balances as of January 1,	25,480	23,727
Provisions established	5,100	4,318
Provisions used	(4,289)	(3,337)
Provisions release		
Total	26,291	24,708

(g) Employee share-based benefits provision:

As of September 30, 2016 and 2015, the Bank and its subsidiaries do not have a stock-based compensation plan.

(h) Contingent loan provisions:

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As of September 30, 2016 and December 31, 2015, the Bank and its subsidiaries maintain contingent loan provisions by an amount of Ch\$50,831 million (Ch\$59,213 million as of December 31, 2015). See Note No. 26 (d).

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

25. Other Liabilities:

At the end of each period, other liabilities are detailed as follows:

	September 2016 MCh\$	December 2015 MCh\$
Accounts and notes payable (*)	153,173	121,419
Unearned income	5,989	6,644
Dividends payable	1,447	1,255
Other liabilities		
Cobranding	47,748	54,006
Documents intermediated (**)	42,379	39,735
Securities unliquidated	27,778	3,429
VAT debit	12,445	13,235
Leasing deferred gains	5,801	6,040
Transactions in progress	515	767
Insurance payments	232	634
Others	12,163	12,148
Total	309,670	259,312

(*) It comprises obligations that do not correspond to transactions in the line of business, such as withholding tax, pension and healthcare contributions, insurance payable, balances of prices for the purchase of materials and provisions for expenses pending payment.

(**) This item mainly includes financing of simultaneous operations performed by subsidiary Banchile Corredores de Bolsa S.A.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

26. Contingencies and Commitments:

(a) Commitments and responsibilities accounted for in off-balance-sheet accounts:

In order to satisfy its customers' needs, the Bank entered into several irrevocable commitments and contingent obligations. Although these obligations are not recognized in the Interim Condensed Consolidated Statement of Financial Position, they contain credit risks and, therefore, form part of the Bank's overall risk.

The Bank and its subsidiaries record the following balances related to such commitments and responsibilities, which fall within its line of business, in off-balance-sheet accounts:

	September 2016 MCh\$	December 2015 MCh\$
Contingent loans		
Guarantees and surety bonds	321,840	389,727
Confirmed foreign letters of credit	47,229	33,871
Issued letters of credit	155,395	122,060
Bank guarantees	2,201,268	2,058,813
Immediately available credit lines	7,388,184	7,224,242
Other commitments	374,905	204,862
Transactions on behalf of third parties		
Collections	129,769	217,479
Third-party resources managed by the Bank:		
Financial assets managed on behalf of third parties	11,845	18,563
Other Financial assets managed on behalf of third parties		
Financial assets acquired on its own behalf	186,194	151,375
Other Financial assets acquired on its own behalf		
Fiduciary activities		
Securities held in safe custody in the Bank	9,324,976	8,248,416
Securities held in safe custody in other entities	5,574,414	5,006,510
Total	25,716,019	23,675,918

The prior information only includes the most significant balances.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

26. **Contingencies and Commitments, continued:**

(b) **Lawsuits and legal proceedings:**

(b.1) **Legal contingencies within the ordinary course of business:**

At the date of issuance of these consolidated financial statements, there are actions filed against the Bank and its subsidiaries related with the ordinary course operations. As of September 30, 2016 the Bank has established provisions for this concept in the amount of Ch\$21,666 million (Ch\$14,877 million as of December 31, 2015), recorded within Provisions in the Interim Condensed Consolidated Statement of Financial Position.

Among these actions, there is the following:

- Collective action filed by the National Consumer Service (Servicio Nacional del Consumidor) in accordance with Law No. 19,496. This action seeks to challenge some clauses of the Person Products Unified Agreement (Contrato Unificado de Productos de Personas) regarding fees on credit lines for overdraft and validity of the tacit consent to changes in fees, charges and other conditions in consumer contracts.
- Collective action filed by the National Corporation of Consumers and Users of Chile (Corporación Nacional de Consumidores y Usuarios de Chile) that challenge some clauses of the Person Products Unified Agreement (Contrato Unificado de Productos de Personas) regarding fees on credit lines for overdraft and validity of the tacit consent to changes in fees, charges and other conditions in consumer contracts, along with the outsourcing of certain services related to our clients' current account data.
- Collective action filed by the National Organization of Consumers and Users of Chile (Organización de Consumidores y Usuarios de Chile) that requests the Court to declare abusive and void certain provisions of the Person Products Unified Agreement regarding the use of self-service channels (internet, ATMs, telephone banking) and Credit Cards. Such provisions refer to the user's duty to act with diligence and care with respect to passwords as

well as the responsibility they have in case of disclosure to third parties, and the use by such third parties of them.

The following table presents estimated date of completion of the respective litigation:

	2016	2017	As of September 30, 2016		Total
	MCh\$	MCh\$	2018	2019	
	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$
Legal contingencies	21,269	6	391		21,666

(b.2) Contingencies for significant lawsuits:

As of September 30, 2016 and December 31, 2015 there are not any significant lawsuits, where the Bank is involved, that affect or may affect these consolidated financial statements.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

26. **Contingencies and Commitments, continued:**

(c) **Guarantees granted:**

i. **In subsidiary Banchile Administradora General de Fondos S.A.:**

In compliance with Article No, 12 of Law No, 20,712, Banchile Administradora General de Fondos S.A., has designated Banco de Chile as the representative of the beneficiaries of the guarantees it has established and in that character the Bank has issued bank guarantees totaling UF 2,642,000, maturing January 10, 2017 (UF 2,603,000, maturing on January 8, 2016 as of December 31, 2015). The subsidiary took a policy with Mapfre Seguros Generales S.A. for the Real State Funds by a guaranteed amount of UF 273,000.

As of September 30, 2016 and December 31, 2015 the Bank has not guaranteed mutual funds.

In compliance to stablish by the Superintendence of Securities and Insurance in letter f) of Circular 1,894 of September 24, 2008, the entity has constituted guarantees, by management portfolio, in benefit of investor. Such guarantee corresponds to a bank guarantee for UF 250,000, with maturity on January 10, 2017.

ii. **In subsidiary Banchile Corredores de Bolsa S.A.:**

For the purposes of ensuring correct and complete compliance with all of its obligations as Stock Brokerage entity, in conformity with the provisions of Article 30 and subsequent Articles of Law 18,045 on Securities Markets, the subsidiary established a guarantee in an insurance policy for UF 20,000, insured by HDI Seguros de Garantía y Créditos S.A., that matures April 22, 2018, whereby the Securities Exchange of the Santiago Stock Exchange was appointed as the subsidiary's creditor representative.

September 2016 MCh\$	December 2015 MCh\$
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Guarantees:

Shares to secure short-sale transactions in:

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Securities Exchange of the Santiago, Stock Exchange	15,949	14,628
Securities Exchange of the Electronic, Stock Exchange of Chile	13,630	27,981
Fixed income securities to ensure system CCLV, Securities Exchange of the Santiago, Stock Exchange	2,965	2,995
Fixed income securities to secure loans of shares, Chilean Electronic Stock Exchange, Stock Exchange		80
Shares delivered to ensure equity loan, Chilean Electronic Stock Exchange, Stock Exchange		
Total	32,544	45,684

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, *continued*

26. Contingencies and Commitments, continued:

(c) Guarantees granted, continued:

ii. In subsidiary Banchile Corredores de Bolsa S.A., continued:

In conformity with the provisions of internal stock market regulations, and for the purpose of securing the broker's correct performance, the company established a pledge on its share of the Santiago Stock Exchange in favor of that institution, as recorded in Public Deed on September 13, 1990, signed before Santiago public notary Mr. Raul Perry Pefaur, and on its share in the Electronic Stock Exchange of Chile in favor of that institution, as recorded in a contract entered into by both parties on May 16, 1990.

Banchile Corredores de Bolsa S.A. keeps an insurance policy current with AIG Chile Compañía de Seguros Generales S.A. that expires January 2, 2017, and that covers employee fidelity, physical losses, falsification or adulteration, and currency fraud with a coverage amount equivalent to US\$10,000,000.

According to disposition of Chilean Central Bank, it was constituted a bank guarantee corresponding to UF 10,500, with purposes to comply with the contract SOMA (Contract for Service System Open Market Operations) of Chilean Central Bank. This bank guarantee is revaluated in UF to fixed term, not endorsable with maturity of July 20, 2017.

It was constituted a bank guarantee No. 379031-1 corresponds to UF 215,000, in benefits of investors with contracts of portfolio management. This bank guarantee is revaluated in UF to fixed term, not endorsable with maturity of January 10, 2017.

It was constituted a cash guarantee for an amount of US\$122,494.32, whose purpose is to comply obligations with Pershing, by operations made through this broker.

iii. In subsidiary Banchile Corredores de Seguros Ltda.:

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According to established in article No. 58, letter D of D.F.L. 251, as of September 30, 2016 the entity maintains two insurance policies that protect it in the face of possible damages that it could affect it, due to infractions of the law, regulations and complementary rules that regulate insurance brokers, and when the non-compliance is from acts, mistakes or omissions of the brokers, its represents, agent or dependent that participate in the intermediation.

The policies contracted are the following:

Matter insured	Amount Insured (UF)
Responsibility for errors and omissions policy	60,000
Civil responsibility policy	500

Table of ContentsNOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, *continued***26. Contingencies and Commitments, continued:**

(d) Provisions for contingencies loans:

Established provisions for credit risk from contingencies operations are the followings:

	September 2016 MCh\$	December 2015 MCh\$
Free credit lines available (*)	28,070	36,743
Bank guarantees	18,402	18,474
Guarantees and surety bonds	3,086	3,314
Letters of credit	905	393
Other commitments	368	289
Total	50,831	59,213

(*) See Note No.2 c).

(e) Before the Eleventh Civil Court of Santiago, Banchile Corredores de Bolsa S.A., claimed against Exempt Resolution No. 270 of October 30, 2014 of the Superintendency of Securities and Insurance (SVS), under which the SVS fined the Company to pay a fine of 50,000 UF, considering that it would have violated paragraph 2 of Article 53 of the Securities Act by acting as an intermediary in a share purchase operations SQM-A. To make such a claim Banchile appropriated 25% of the amount of the fine. Under the claim is intended to annul the fine. That complaint was accumulated trial Case No. 25.795-2014, of the 22nd Civil Court of Santiago, issued the order test. To date the replacement resources submitted have not been resolved by the parties on the resolution that received the case to trial. The procedure is suspended by the application for joinder filed by another claimant.

According to the provisioning policy, the company has not made provisions because this trial has not yet been ruled as also considering that the legal position of the same advisers estimate that there are solid grounds for that hosting the claim.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

27. Equity:

(a) Capital:

(i) Authorized, subscribed and paid shares:

As of September 30, 2016, the paid-in capital of Banco de Chile is represented by 97,624,347,430 registered shares (96,129,146,433 shares as of December 31, 2015), with no par value, fully paid and distributed.

(ii) Shares:

(ii.1) On June 23, 2016, Banco de Chile informs regarding the capitalization of 30% of the distributable net income obtained during the fiscal year ending the 31st of December, 2015, through the issuance of fully paid-in shares, agreed in the Extraordinary Shareholders Meeting held on the 24th of March, 2016, where it was agreed to increase the Bank's capital in the amount of \$96,874,072,595 through the issuance of 1,495,200,997 fully paid-in shares, of no par value, payable under the distributable net income for the year 2015 that was not distributed as dividends as agreed at the Ordinary Shareholders Meeting held on the same day.

The issuance of fully in paid shares was registered in the Superintendency of Banks and Financial Institutions of Chile (SBIF) with the No.4/2016, on June 16, 2016.

The Board of Directors of Banco de Chile, at the meeting No.2,840, dated June 23, 2016, set July 7, 2016, as the date for issuance and distribution of the fully paid in shares.

(ii.2) The following table shows the share movements from December 31, 2014 to September 30, 2016:

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	Total Ordinary Shares
As of December 31, 2014	94,655,367,544
Capitalization of earning Issue fully paid-in shares (*)	1,473,778,889
Total shares as of September 30, 2015	96,129,146,433
Total shares as of December 31, 2015	96,129,146,433
Capitalization of earning Issue fully paid-in shares (**)	1,495,200,997
Total shares as September 30, 2016	97,624,347,430

(*) Capitalization on July 23, 2015.

(**) See Note No.5 g) (a).

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

27. Equity, continued:

(b) **Distributable income:**

For purposes of Law No. 19,396 (in particular Articles 24, 25 and 28 of such law) and the Central Bank Contract between Banco de Chile and Sociedad Matriz del Banco de Chile S.A.- Banco de Chile's distributable net income will be determined by subtracting or adding to net income the correction of the value of the paid-in capital and reserves according to the variation of the Consumer Price Index between November of the fiscal year prior to the one in which the calculation is made and November of the fiscal year in which the calculation is made. Provisional Article four shall be in force until the obligation of Law No. 19,396 owed by Sociedad Matriz del Banco de Chile S.A., directly or through its subsidiary SAOS has been fully paid. The above described agreement was subject to the consideration of the Council of the Central Bank of Chile, and such entity approved, in ordinary meeting that took place on December 3, 2009.

The distributable income for the nine-month period ended as of September 30, 2016 ascend to Ch\$361,872 million (Ch\$463,528 million as of December 31, 2015).

As stated, the retention of earnings for the year ended as of December 31, 2015, made in March of 2016, ascend to Ch\$95,467 million (Ch\$127,383 million of income for the year ended as of December 31, 2014, retained in March of 2015).

(c) **Approval and payment of dividends:**

At the Ordinary Shareholders Meeting held on March 24, 2016, the Bank's shareholders agreed to distribute and pay dividend No. 204 amounting to Ch\$3.37534954173 per common share of Banco de Chile, with charge to distributable net income for the year ended as of December 31, 2015. The dividend of period 2016 amounted Ch\$366,654 million.

At the Ordinary Shareholders Meeting held on March 26, 2015, the Bank's shareholders agreed to distribute and pay dividend No. 203 amounting to Ch\$3.42915880220 per common share of Banco de Chile, with charge to distributable net income for the year ended as of December 31, 2014. The dividend of period 2015 amounted Ch\$367,444 million.

(d) **Provision for minimum dividends:**

According to established in Note No. 5 Relevant events, the Board of Directors established that since 2016, a minimum dividend, where the Bank has to record a provision of 60% of distributable net income. Accordingly, the Bank recorded a liability under the line item Provisions for an amount of Ch\$217,123 million (Ch\$324,469 million as of December 31, 2015, corresponding to 70%) against Retained earnings .

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

27. **Equity, continued:**

(e) Earnings per share:

(i) Basic earnings per share:

Basic earnings per share are determined by dividing the net income attributable to the Bank shareholders in a period by the weighted average number of shares outstanding during the period, excluding the average number of own shares maintained at the long period.

(ii) Diluted earnings per share:

Diluted earnings per share are determined in the same way as Basic Earnings, but the weighted average number of outstanding shares is adjusted to take into account the potential diluting effect of stock options, warrants, and convertible debt.

The following table shows the income and share data used in the calculation of EPS:

	September 2016	September 2015
Basic earnings per share:		
Net profits attributable to ordinary equity holders of the bank (in millions)	428,215	418,897
Weighted average number of ordinary shares	97,624,347,430	97,624,347,430
Earning per shares (in Chilean pesos) (*)	4.39	4.29
Diluted earnings per share:		
Net profits attributable to ordinary equity holders of the bank (in millions)	428,215	418,897
Weighted average number of ordinary shares	97,624,347,430	97,624,347,430
Assumed conversion of convertible debt		
Adjusted number of shares	97,624,347,430	97,624,347,430
Diluted earnings per share (in Chilean pesos) (*)	4.39	4.29

(*) As of September 30, 2015 earning per shares considers the effect of fully paid-in shares, no par value, issued in 2016.

As of September 30, 2016 and 2015, the Bank did not have any instruments that could lead to a dilution of its ordinary shares.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

27. Equity, continued:

(f) Other comprehensive income:

The cumulative translation adjustment is generated from the Bank's translation of its investments in foreign companies, as it records the effects of foreign currency translation for these items in equity. During the period 2016 there were made a charge to equity to Ch\$59 million of cumulative translation adjustment (credit to equity for Ch\$1 in 2015).

The fair market value adjustment for available-for-sale instruments is generated by fluctuations in the fair value of that portfolio, with a charge or credit to equity, net of deferred taxes. During the period of 2016 it was made a net debit to equity for an amount of Ch\$38,629 million (net credit to equity for Ch\$2,734 million as of September 30, 2015).

Cash flow hedge adjustment it consists in the portion of income of hedge instruments registered in equity produced in a cash flow hedge, During the period of 2016 it was made a net debit to equity for an amount of Ch\$17,127 million (charge to equity for Ch\$3,970 million as of September 30, 2015).

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

28. Interest Revenue and Expenses:

(a) On the Interim Condensed Consolidated Financial Statement closing date, the composition of income from interest and adjustments, not including the net loss from hedge accounting, is as follows:

	September 2016			September 2015			Total MCh\$
	Interest MCh\$	Adjustment MCh\$	Prepaid fees MCh\$	Interest MCh\$	Adjustment MCh\$	Prepaid fees MCh\$	
Commercial loans	529,760	118,537	1,893	487,379	133,964	2,810	624,153
Consumer loans	448,396	1,225	7,018	416,631	2,386	7,032	426,049
Residential mortgage loans	194,674	149,560	2,992	172,648	162,693	3,528	338,869
Financial investment	20,168	4,981		36,664	12,076		48,740
Repurchase agreements	1,161			996			996
Loans and advances to banks	24,793			21,146			21,146
Other interest revenue	1,122	1,511		491	1,787		2,278
Total	1,220,074	275,814	11,903	1,135,955	312,906	13,370	1,462,231

The amount of interest revenue recognized on a received basis for impaired portfolio as of September 30, 2016 was Ch\$3,812 million (Ch\$6,973 million in September 2015).

(b) At the each period end, the stock of interest income not recognized in income is the following:

	September 2016			September 2015		
	Interest MCh\$	Adjustment MCh\$	Total MCh\$	Interest MCh\$	Adjustment MCh\$	Total MCh\$
Commercial loans	8,019	1,263	9,282	9,581	3,024	12,605
Residential mortgage loans	2,456	2,056	4,512	1,944	2,014	3,958
Consumer loans	70	14	84	272	4	276
Total	10,545	3,333	13,878	11,797	5,042	16,839

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

28. Interest Revenue and Expenses, continued:

(c) At the each period end, interest and adjustment expenses (not including hedge gain) are detailed as follows:

	Interest MCh\$	September 2016 Adjustment MCh\$	Total MCh\$	Interest MCh\$	September 2015 Adjustment MCh\$	Total MCh\$
Savings accounts and time deposits	238,660	47,137	285,797	200,785	47,430	248,215
Debt issued	139,836	102,205	242,041	124,357	112,204	236,561
Other financial obligations	1,230	243	1,473	1,313	373	1,686
Repurchase agreements	4,543		4,543	5,321	266	5,587
Borrowings from financial institutions	10,012		10,012	7,108		7,108
Demand deposits	470	4,930	5,400	533	4,304	4,837
Other interest expenses		413	413		665	665
Total	394,751	154,928	549,679	339,417	165,242	504,659

(d) As of September 30, 2016 and 2015, the Bank uses cross currency and interest rate swaps to hedge its position on the fair value of corporate bonds and commercial loans and cross currency swaps to hedge its obligations with foreign banks and bonds issued abroad.

	Income MCh\$	September 2016 Expense MCh\$	Total MCh\$	Income MCh\$	September 2015 Expense MCh\$	Total MCh\$
Gain from fair value accounting hedges	54		54			
Loss from fair value accounting hedges	(6,937)		(6,937)	(2,852)		(2,852)
Gain from cash flow accounting hedges	266,092	285,867	551,959	20,390	25,790	46,180
Loss from cash flow accounting hedges	(322,009)	(267,073)	(589,082)	(82,074)	(10,845)	(92,919)
Net gain on hedge items	1,152		1,152	(1,429)		(1,429)
Total	(61,648)	18,794	(42,854)	(65,965)	14,945	(51,020)

(e) At the each period end, the detail of income from suspended interest is as follows:

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	September 2016 MCh\$	September 2015 MCh\$
Interest revenue	1,507,791	1,462,231
Interest expense	(549,679)	(504,659)
Subtotal interest income	958,112	957,572
Net gain (loss) from accounting hedges	(42,854)	(51,020)
Total net interest income	915,258	906,552

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

29. Income and Expenses from Fees and Commissions:

At the each period end, the income and expenses for fees and commissions shown in the Interim Consolidated Statements of Comprehensive Income refer to the following items:

	September 2016 MCh\$	September 2015 MCh\$
Income from fees and commission		
Card services	106,657	95,615
Investments in mutual funds and others	59,373	56,971
Collections and payments	36,646	39,048
Portfolio management	31,400	29,135
Fees for insurance transactions	20,754	16,294
Guarantees and letters of credit	15,643	15,108
Use of distribution channel	13,998	15,337
Usage Banchile s brand	10,625	10,175
Trading and securities management	10,362	11,376
Lines of credit and overdrafts	4,505	11,616
Financial advisory services	3,499	5,968
Other fees earned	14,186	13,877
Total income from fees and commissions	327,648	320,520
Expenses from fees and commissions		
Credit card transactions	(72,118)	(75,506)
Interbank transactions	(7,282)	(10,270)
Collections and payments	(4,759)	(4,905)
Securities transactions	(2,540)	(2,362)
Sales force fees	(442)	(949)
Other fees	(360)	(3,369)
Total expenses from fees and commissions	(87,501)	(97,361)

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

30. Net Financial Operating Income:

The gains (losses) from trading and brokerage activities are detailed as follows:

	September 2016 MCh\$	September 2015 MCh\$
Sale of available-for-sale instruments	65,226	9,509
Financial assets held-for-trading	46,461	14,124
Trading derivative	10,910	8,599
Sale of loan portfolios	4,930	2,690
Net income on other transactions	1,047	2,001
Total	128,574	36,923

31. Foreign Exchange Transactions, net:

Net foreign exchange transactions are detailed as follows:

	September 2016 MCh\$	September 2015 MCh\$
Indexed foreign currency, net	83,056	(174,869)
Translation difference, net	(7,400)	19,540
Gain from accounting hedges	(68,525)	199,927
Total	7,131	44,598

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

32. Provisions for Loan Losses:

The movement during the nine-month period ended as of September 2016 and September 2015 is the following:

	Loans and advance to banks		Commercial Loans		Loans to customers Mortgage Loans		Consumer Loans		Subtotal		Contingent Loans	
	September 2016 MCh\$	September 2015 MCh\$	September 2016 MCh\$	September 2015 MCh\$	September 2016 MCh\$	September 2015 MCh\$	September 2016 MCh\$	September 2015 MCh\$	September 2016 MCh\$	September 2015 MCh\$	September 2016 MCh\$	September 2015 MCh\$
Provisions established:												
- Individual provisions		(277)		(38,245)					(38,245)			(3,366)
- Group provisions			(32,388)	(31,680)	(2,384)	(6,186)	(182,750)	(156,298)	(217,522)	(194,164)		(1,689)
Provisions established, net		(277)	(32,388)	(69,925)	(2,384)	(6,186)	(182,750)	(156,298)	(217,522)	(232,409)		(5,055)
Provisions released:												
- Individual provisions	125		5,825						5,825		2,030	
- Group provisions											6,352	
Provisions released, net	125		5,825						5,825		8,382	
Provision, net	125	(277)	(26,563)	(69,925)	(2,384)	(6,186)	(182,750)	(156,298)	(211,697)	(232,409)	8,382	(5,055)
Additional provision			(52,075)	(30,921)					(52,075)	(30,921)		
Recovery of written-off assets			8,359	13,927	1,514	1,358	22,938	24,326	32,811	39,611		
Provision for loan losses, net	125	(277)	(70,279)	(86,919)	(870)	(4,828)	(159,812)	(131,972)	(230,961)	(223,719)	8,382	(5,055)

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According to the management, the provisions constituted by credit risk, cover all the possible losses that could arise from the non-recovery of assets.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

33. **Personnel Expenses:**

At the each period end personnel expenses are detailed as follows:

	September 2016 MCh\$	September 2015 MCh\$
Salaries	171,216	160,801
Bonuses and incentives	38,319	28,751
Variable compensation	29,424	25,912
Lunch and health benefits	21,079	18,926
Gratifications	18,624	17,686
Staff severance indemnities	12,676	9,591
Training expenses	2,137	1,960
Other personnel expenses	17,759	14,759
Total	311,234	278,386

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

34. Administrative Expenses:

At the each period end, administrative expenses are detailed as follows:

	September 2016 MCh\$	September 2015 MCh\$
General administrative expenses		
Information technology and communications	50,677	43,318
Maintenance and repair of property and equipment	26,758	23,468
Office rental and equipment	19,201	18,183
Securities and valuables transport services	9,802	8,542
External advisory services and professional fees and services	6,927	6,193
Office supplies	6,478	5,344
Rent ATM area	5,736	4,863
P,O, box mail , postage and home delivery services	4,908	3,559
Energy, heating and other utilities	4,316	3,914
Insurance premiums	3,674	3,098
Representation and transferring of personnel	3,248	3,647
Legal and notary	2,638	3,331
External service of financial information	2,444	2,132
Outsourcing of custody and filing	2,109	2,002
Donations	1,487	1,583
Other general administrative expenses	15,520	13,167
Subtotal	165,923	146,344
Outsources services		
Credit pre-evaluation services	12,188	14,970
Data processing	8,047	7,439
External technological developments expenses	6,057	5,471
Certification and testing technology	4,410	3,782
Other	2,476	2,568
Subtotal	33,178	34,230
Board expenses		
Board remunerations	1,867	1,710
Other Board expenses	496	386
Subtotal	2,363	2,096
Marketing expenses		
Advertising	25,591	22,214
Subtotal	25,591	22,214

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Taxes, payroll taxes and contributions		
Contribution to the Superintendency of Banks	6,624	6,033
Real estate contributions	2,051	1,884
Patents	972	984
Other taxes	951	386
Subtotal	10,598	9,287
Total	237,653	214,171

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

35. Depreciation, Amortization and Impairment:

(a) At the each period end, the amounts charged to income for depreciation and amortization are detailed as follows:

	September 2016 MCh\$	September 2015 MCh\$
Depreciation and amortization		
Depreciation of property and equipment (Note No. 16 (b))	18,461	15,698
Amortization of intangibles assets (Note No. 15 (b))	6,454	6,301
Total	24,915	21,999

(b) As of September 30, 2016 and 2015 the composition of impairment expenses is the following:

	September 2016 MCh\$	September 2015 MCh\$
Impairment		
Impairment of financial instruments		
Impairment of properties and equipment (Note No. 16 (b))	4	85
Impairment of intangible assets (Note No. 15 (b))		59
Total	4	144

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

36. Other Operating Income:

At the each period end, the Bank and its subsidiaries present the following under other operating income:

	September 2016 MCh\$	September 2015 MCh\$
Income for assets received in lieu of payment		
Income from sale of assets received in lieu of payment	3,698	2,568
Other income	33	15
Subtotal	3,731	2,583
Release of provisions for contingencies		
Country risk provisions		
Other provisions for contingencies	84	290
Subtotal	84	290
Other income		
Rental income	6,485	6,289
Credit card income	4,898	1,987
Expense recovery	2,378	3,138
Recovery from external branches	2,187	2,113
Revaluation of prepaid monthly payments	666	1,023
Income from differences sale leased assets	289	737
Fiduciary and trustee commissions	184	155
Income from sale of leased assets	110	465
Gain on sale of property and equipment	101	124
Others	2,361	1,838
Subtotal	19,659	17,869
Total	23,474	20,742

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

37. Other Operating Expenses:

At the each period end, the Bank and its subsidiaries incurred the following other operating expenses:

	September 2016 MCh\$	September 2015 MCh\$
Provisions and expenses for assets received in lieu of payment		
Charge-off assets received in lieu of payment	2,935	1,220
Provisions for assets received in lieu of payment	695	231
Expenses to maintain assets received in lieu of payment	331	307
Subtotal	3,961	1,758
Provisions for contingencies		
Country risk provisions	1,684	6,524
Other provisions for contingencies	6,879	1,007
Subtotal	8,563	7,531
Other expenses		
Credit cards administration	3,160	2,483
Write-offs for operating risks	2,375	3,319
Provisions and charge-offs of other assets	2,305	4,368
Provision for leased assets recoveries	782	618
Operations expenses and charge-offs leasing	637	986
Contribution to other organisms	195	181
Credit life insurance	187	136
Civil lawsuits	90	412
Others	1,359	1,799
Subtotal	11,090	14,302
Total	23,614	23,591

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

38. Related Party Transactions:

It is considered as related to the Bank and its subsidiaries, the natural or legal persons who are related by ownership or management of the Bank, directly or through third parties.

According to the above, the Bank has considered related natural or legal persons parties that have a direct participation or through third parties on bank ownership, where such participation exceeds (1% or 5%) of the shares, and people who, regardless of ownership, have authority and responsibility for planning, management and control of the activities of the entity or its subsidiaries. They are also considered related, the companies in which the parties related by ownership or management of the bank have a share which reaches or exceeds 5% or has the position of director, general manager or equivalent.

The article 89 of the Law on Corporations, which also applies to banks, provides that any transaction with a related party must take place in conditions of equity similar to those normally prevailing in the market.

The article 147 of the Corporations Law, provides that a public company may only enter into transactions with related when they have to contribute to the social interest, they adjust in price, terms and conditions to those prevailing in the market at the time of their approval and comply with the requirements and procedure pointing the same norm.

Moreover, Article 84 of the General Banking Law establishes limits for credits granted to related parties and the prohibition on granting loans to directors, managers or general representatives of the bank.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

38. Related Party Transactions, continued:

(a) Loans to related parties:

The following table details loans accounts receivable, contingent loans and assets related to trading and investments securities, corresponding to related entities.

	Production Companies (*)		Investment Companies (**)		Individuals (***)		Total	
	September 2016 MCh\$	December 2015 MCh\$	September 2016 MCh\$	December 2015 MCh\$	September 2016 MCh\$	December 2015 MCh\$	September 2016 MCh\$	December 2015 MCh\$
Loans and accounts receivable:								
Commercial loans	279,729	289,803	20,467	40,916	8,218	7,570	308,414	338,289
Residential mortgage loans					30,620	27,678	30,620	27,678
Consumer loans	14				5,751	5,682	5,765	5,682
Gross loans	279,743	289,803	20,467	40,916	44,589	40,930	344,799	371,649
Provision for loan losses	(963)	(921)	(30)	(79)	(243)	(248)	(1,236)	(1,248)
Net loans	278,780	288,882	20,437	40,837	44,346	40,682	343,563	370,401
Off balance sheet accounts:								
Guarantees	13,334	11,501	43	46			13,377	11,547
Letters of credits	176	487					176	487
Foreign letters of credits								
Banks guarantees	66,404	63,247	490	2,473			66,894	65,720
Immediately available credit lines	65,859	60,002	3,743	24,470	15,884	15,319	85,486	99,791
Total off balance sheet account	145,773	135,237	4,276	26,989	15,884	15,319	165,933	177,545
Provision for contingencies loans	(115)	(117)		(1)			(115)	(118)
Off balance sheet account, net	145,658	135,120	4,276	26,988	15,884	15,319	165,818	177,427
Amount covered by Collateral								
Mortgage	83,791	88,140	7,139	7,619	47,099	39,657	138,029	135,416
Warrant								
Pledge	2,900				3	3	2,903	3

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Others(****)	74,365	84,913	8,997	11,873	1,714	1,704	85,076	98,490
Total collateral	161,056	173,053	16,136	19,492	48,816	41,364	226,008	233,909
Acquired Instruments								
For trading purposes								
For investing purposes	7,629	7,454					7,629	7,454
Total acquired instruments	7,629	7,454					7,629	7,454

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

38. Related Party Transactions, continued:

(a) Loans with related parties, continued:

(*) Production companies are legal entities which comply with the following conditions:

- i) They engage in productive activities and generate a separable flow of income.
- ii) Less than 50% of their assets are trading securities or investments.

(**) Investment companies include those legal entities that do not comply with the conditions for production companies and are profit-oriented.

(***) Individuals include key members of the management, who directly or indirectly possess the authority and responsibility of planning, administrating and controlling the activities of the organization, including directors. This category also includes their family members who are expected to have an influence or to be influenced by such individuals in their interactions with the organization.

(****) These guarantees correspond mainly to shares and other financial guarantees.

(b) Other assets and liabilities with related parties:

	September 2016 MCh\$	December 2015 MCh\$
Assets		
Cash and due from banks	31,677	222

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Transactions in the course of collection	9,487	
Cash collateral on securities borrowed and reverse repurchase agreements		
Derivative instruments	164,480	112,370
Other assets	51,181	32,028
Total	256,825	144,620

Liabilities

Demand deposits	145,843	139,313
Transactions in the course of payment	12,489	
Cash collateral on securities lent and repurchase agreements	12,402	
Savings accounts and time deposits	346,038	300,868
Derivative instruments	158,547	101,433
Borrowings from financial institutions	271,544	321,374
Other liabilities	78,415	11,617
Total	1,025,278	874,605

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

38. Related Party Transactions, continued:

(c) Income and expenses from related party transactions (*):

Type of income or expense recognized	September 2016		September 2015	
	Income MCh\$	Expense MCh\$	Income MCh\$	Expense MCh\$
Interest and revenue expenses	14,082	10,117	17,490	10,667
Fees and commission income	47,936	32,862	38,723	31,905
Financial operating (**)	389,094	395,587	165,928	138,951
Released or established of provision for credit risk	368			3
Operating expenses		64,510		60,775
Other income and expenses	347	27	363	19

(*) This detail do not correspond a Statement of Comprehensive Income for related party transactions, so assets with these parties are not necessarily equal to liabilities and each item reflects total income and expense and does not correspond to exact transactions.

(**) The increase is explained by derivatives operations that are affected by the clearing through Comder Contraparte Central S.A. (related entity), which began to work in July 2015, this process that has implied that a portion of derivative contracts that are closed with a local banking counterparty (not related) have been novated to that entity, with the purpose of make a centralized clearing of them.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

38. Related Party Transactions, continued:

(d) Payments to key management personnel:

	September 2016 MCh\$	September 2015 MCh\$
Remunerations	2,921	2,685
Short-term benefits	4,422	3,420
Severance pay	2,434	
Paid based on shares		
Total	9,777	6,105

Composition of key personnel:

Position	NO. of executives	
	September 2016	September 2015
CEO	1	1
CEOs of subsidiaries	7	7
Division Managers	14	11
Total	22	19

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

38. Related Party Transactions, continued:

(e) Directors' expenses and remunerations:

Name of Directors	Remunerations		Fees for attending Board meetings		Fees for attending Committees and Subsidiary Board meetings (1)		Consulting		Total	
	September 2016	September 2015	September 2016	September 2015	September 2016	September 2015	September 2016	September 2015	September 2016	September 2015
	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$
Pablo Granifo Lavín	406(*)	295(*)	37	36	298	266			741	597
Andrónico Luksic Craig	126	121	7	9					133	130
Jorge Awad Mehech	42	40	20	18	74	76			136	134
Gonzalo Menéndez Duque	42	40	19	17	89	94	20	19	170	170
Jaime Estévez Valencia	42	40	20	19	109	91			171	150
Rodrigo Manubens Moltedo	42	40	18	19	34	41			94	100
Jorge Ergas Heymann	42	40	12	13	43	32			97	85
Francisco Pérez Mackenna	42	40	14	17	47	54			103	111
Thomas Fürst Freiwirth	42	40	15	16	30	33			87	89
Jean-Paul Luksic Fontbona	42	40	5	9					47	49
Other directors of subsidiaries					108	114			108	114
Total	868	736	167	173	832	801	20	19	1,887	1,729

(1) It includes fees paid to members of the Advisory Committee of Banchile Corredores de Seguros Ltda, of Ch\$12 million (Ch\$12 million as of September 30, 2015).

(*) It includes a provision of Ch\$279 million (Ch\$174 million as of September 30, 2015) for an incentive subject to achieving the Bank's forecasted earnings.

Fees paid for advisory services to the Board of Directors amount to Ch\$387 million (Ch\$304 million as of September 30, 2015).

Travel and other related expenses amount to Ch\$74 million (Ch\$63 million as of September 30, 2015).

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities:

Banco de Chile and its subsidiaries have defined a corporate framework for valorization and control related with the process to the fair value measurement.

One of the most important definitions in this framework is the Product Control Unit (PCU), hereinafter PCU, function. This area is independent from both the principal management and the business unit, and reports to the CFO of Banco de Chile. This area is responsible for the independent verification of Profit and Losses, and Fair Value measurement and control for all Treasury transactions; Trading, Funding and gapping and Investments deals.

To accomplish the measurements and controls, Banco de Chile and its subsidiaries, take into account at least the following aspects:

(i) **Industry standards of fair value measurements**

In the fair value calculation process, standard methodologies are used; closing prices, discounted cash flows and option models. In the options case, Black-Scholes model is used. The input parameters are rates, prices and volatility levels for each term and market factor that trade in the local and international markets.

(ii) **Quoted prices in active markets**

The fair value for instruments with quoted prices in active markets is determined using daily quotes from electronic systems information such as Bloomberg, Bolsa de Comercio de Santiago, LVA and Risk America terminals. This quote represents the price at which instruments are frequently bought and sold in financial markets.

(iii) **Valuation techniques**

If there is no market quotes in active markets for the financial instrument, valuation techniques will be used to determine the fair value.

Due to the fact that fair value models require a set of market parameters as inputs, it is part of the fair value process to maximize the utilization based on observable quoted prices or derived from similar instruments in active markets. Nevertheless there are some cases for which neither quoted prices nor derived prices are available; in these cases external data from specialized providers, price for similar transactions and historical information it is used for validate the parameters that will be used as inputs.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

(iv) Fair value adjustments

Part of the fair value process consists of adjustment, to take into account bid/offer spreads. This adjustment is calculated and analyzed by the PCU and Risk Market areas.

The bid/offer spread adjustment reflects the expected impact on fair value due to close long or short positions in a specific market factor and term, valued at midpoint. For example, long positions in an asset will be impacted in order to reflect the fact that when selling the position it will be quoted at bid instead at midpoint. For the bid/offer spread adjustment, market quotes or indicative prices for each position, instrument, currency and term are used, Bid, mid and offer market quotes are considered.

(v) Fair value control

To ensure that the market input parameters that Banco de Chile is using for fair value calculations represent the state of the market and the best estimate of fair value, the PCU unit runs on a daily basis an independent verification of prices and rates. This process aims to set a preventive control on the official market parameters provided by the respective business area. A comparative control based on Mark-to-Market differences, using one set of inputs prepared by the business area and one set prepared by the PCU, is conducted before fair value calculations. The output of this process is a set of differences in fair value by currency, product and portfolio. These differences are compared with specific ranges by grouping level; currency, product and portfolio.

In the event that significant differences are detected, these differences are measured and scaled according to the amount of materiality for each grouping level, ranging from a single report to the trader to a report presented to the Board. These ranges of materiality control are approved by the Assets and Liabilities Committee (ALCO).

Complementary and in parallel, the PCU generates daily reports of P&L and risk market exposure. These two kinds of reports allows for adequate control and consistency in the parameters used in valuations and backwards looking revisions.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

(vi) **Judgmental analysis and information to Management**

In particular, in cases where there are no market quotations for the instrument, similar transaction prices, nor indicative parameters, a reasoned analysis and specific controls should be made to estimate the fair value of the operation or transaction. Within the Banco de Chile's framework for fair value, described in the Fair Value Policy approved by the Board of Banco de Chile, the approval level required to operate this kinds of instruments, there is no market information or cannot be inferred from prices or rates, is established.

(a) **Fair value hierarchy:**

Banco de Chile and subsidiaries, classify all the financial instruments among the following levels:

Level 1: Observable, quoted price in an active markets for the same instrument or specific type of transaction to be evaluated (return internal rates, quote value, price).

In this level, the following instruments are considered: currency futures, Chilean Central Bank and Treasury securities, mutual fund investments and equity.

For the Chilean Central Bank and Treasury securities, all instruments that belong to one of the following benchmark groups will be considered as Level 1: Pesos-02, Pesos-05, Pesos-07, Pesos-10, UF-02, UF-05, UF-07, UF-10, UF-20, UF-30. A benchmark group is composed by a number of instruments that have similar duration and share the same quoted price within the group. This condition allows for a greater depth of market, assuring daily observable quotes.

For currency futures as well as mutual funds and equity, to determine fair value, the multiplication of closing prices by the number of instruments is used. For Chilean Central Bank and Treasury securities the internal rate of return is used to discount every cash flow and obtain the fair value of each instrument. For mutual funds and equity, the current price multiplied by the quantity of instruments is used to calculate the fair value.

The preceding described methodology corresponds to the one utilized for the Bolsa de Comercio de Santiago (Santiago's main Exchange) and is recognized as the standard in the market.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

Level 2: Valuation techniques whose inputs are those other than quoted prices included within Level 1 and that are observable for assets or liabilities, either directly or indirectly. For instruments in this level, the valuation is performed based on an inference from observable market parameters; such quoted prices for similar instruments in active markets. In this level the following inputs are included:

- a) Quoted prices for similar assets or liabilities in active markets.
- b) Quoted prices for identical or similar assets or liabilities in markets that are not active.
- c) Inputs other than quoted prices that are observable for the asset or liability.
- d) Inputs that are derived principally from or corroborated by observable market data.

This level is composed mostly of currency and rate derivatives, bank's debt securities, debt of Chilean and foreign companies, mortgage claims, money market instruments and less liquid Chilean Central Bank and Treasury securities.

For derivatives the fair value process depends upon whether this value is impacted by volatility as a relevant market factor; if that is the case, the Black-Scholes-Merton type of formula is used. For the rest of the derivatives, namely swaps and forwards, net present value through discounted cash flows is used. For securities classified as level 2, the obtained internal rate of return is used to discount every cash flow and obtain the fair value of each instrument, for each currency.

In the event that there is no observable price for an instrument in a specific term, the price will be inferred from the interpolation between periods that have observable quoted price in active markets. These models incorporate various market variables, including foreign exchange rates and interest rate curves.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

Valuation Techniques and Inputs:

Type of Financial Instrument	Valuation Method	Description: Inputs and Sources
------------------------------------	---------------------	---------------------------------

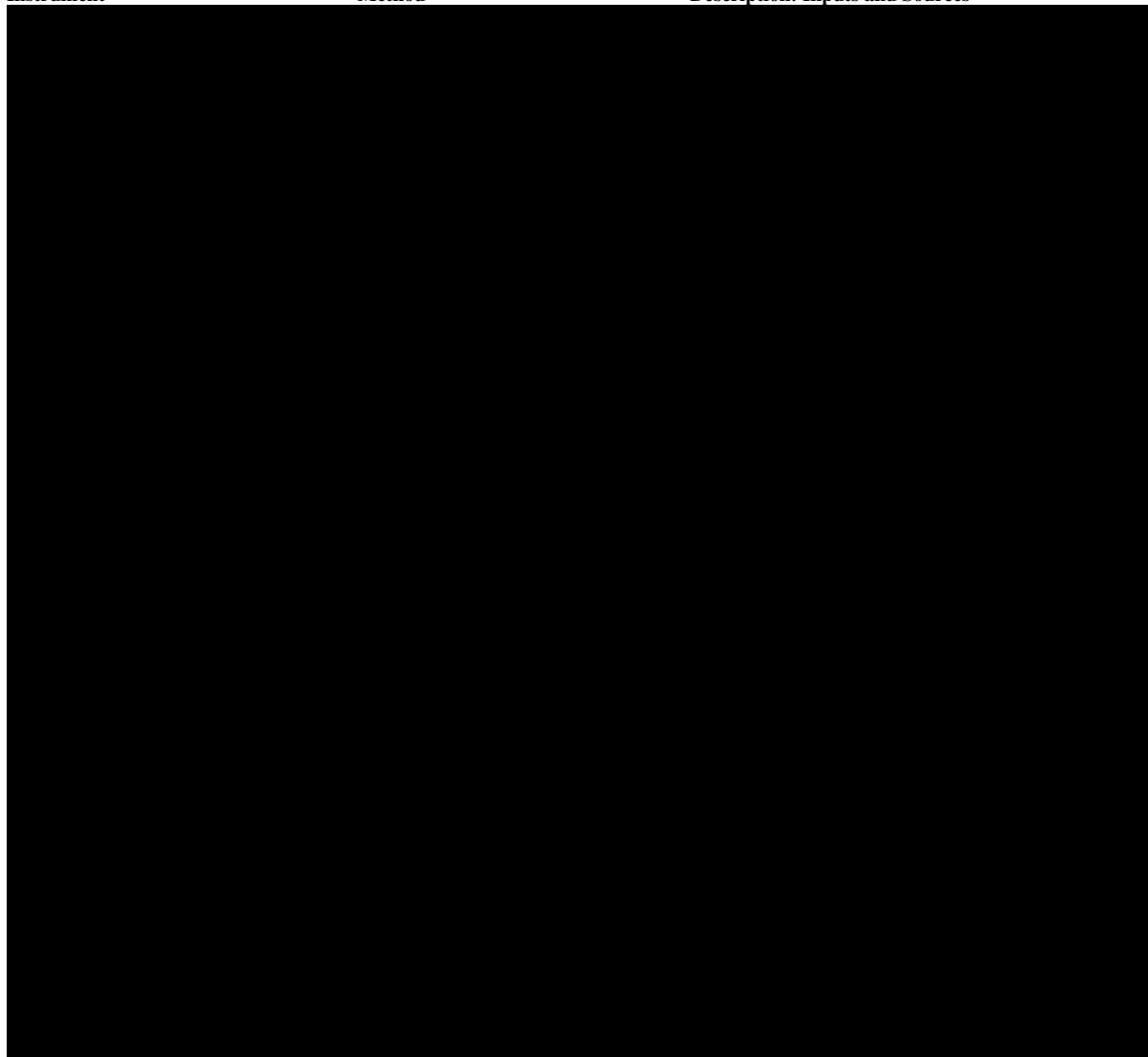




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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

Level 3: These are financial instruments whose fair value is determined using unobservable inputs. An adjustment to an input that is significant to the entire measurement can result in a fair value measurement classified within Level 3 of the fair value hierarchy if the adjustment is using significant unobservable data entry.

Instruments classified as level 3 correspond to Corporate Debt issued mainly by Chilean and foreign companies, issued both in Chile and abroad.

Valuation Techniques and Inputs:

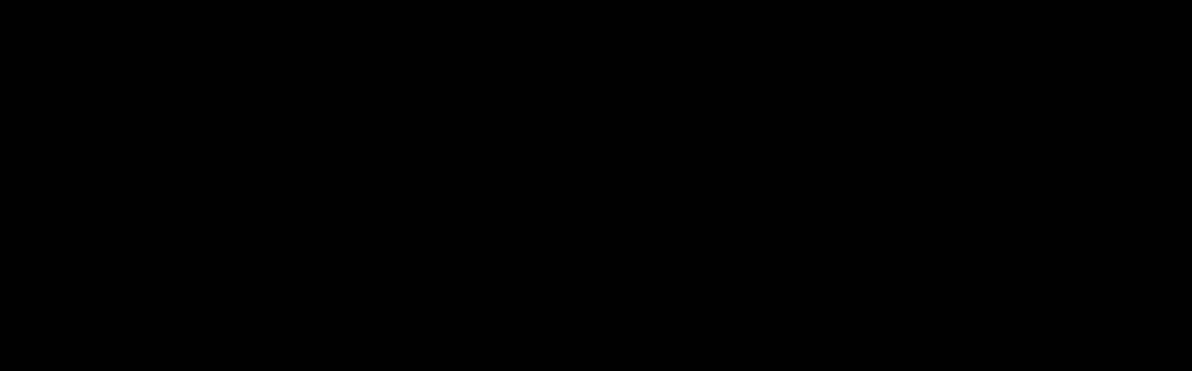
Type of Financial Instrument	Valuation Method	Description: Inputs and Sources
		

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

(b) Level chart:

The following table shows the classification by levels, for financial instruments registered at fair value.

	Level 1		Level 2		Level 3		Total	
	September 2016 MCh\$	December 2015 MCh\$	September 2016 MCh\$	December 2015 MCh\$	September 2016 MCh\$	December 2015 MCh\$	September 2016 MCh\$	December 2015 MCh\$
Financial Assets								
Financial assets held-for-trading								
From the Chilean Government and Central Bank								
	32,628	122,920	480,518	126,996			513,146	249,916
Other instruments issued in Chile	7	10,420	868,795	565,210	13	18,028	868,815	593,658
Instruments issued abroad	340						340	
Mutual fund investments	28,944	23,080					28,944	23,080
Subtotal	61,919	156,420	1,349,313	692,206	13	18,028	1,411,245	866,654
Derivative contracts for trading purposes								
Forwards			199,364	180,616			199,364	180,616
Swaps			754,272	739,777			754,272	739,777
Call Options			868	1,878			868	1,878
Put Options			3,087	680			3,087	680
Futures								
Subtotal			957,591	922,951			957,591	922,951
Hedge accounting derivative contracts								
Fair value hedge (Swap)			12	279			12	279
Cash flow hedge (Swap)			97,971	203,892			97,971	203,892
Subtotal			97,983	204,171			97,983	204,171
Financial assets available-for-sale (1)								
From the Chilean Government and Central Bank								
		15,321	67,486	71,187			67,486	86,508
Other instruments issued in Chile			255,588	735,724	76,443	96,125	332,031	831,849
Instruments issued abroad		81,644						81,644
Subtotal		96,965	323,074	806,911	76,443	96,125	399,517	1,000,001
Total	61,919	253,385	2,727,961	2,626,239	76,456	114,153	2,866,336	2,993,777
Financial Liabilities								
Derivative contracts for trading purposes								
Forwards			180,084	207,961			180,084	207,961
Swaps			845,099	897,513			845,099	897,513
Call Options			1,123	3,689			1,123	3,689

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Put Options	1,268	549	1,268	549
Futures				
Subtotal	1,027,574	1,109,712	1,027,574	1,109,712
Hedge derivative contracts				
Fair value hedge (Swap)	13,988	14,549	13,988	14,549
Cash flow hedge (Swap)	25,999	3,666	25,999	3,666
Subtotal	39,987	18,215	39,987	18,215
Total	1,067,561	1,127,927	1,067,561	1,127,927

(1) As of September 30, 2016 a 88% of instruments of level 3 have denomination Investment Grade . Also, 100% of total of these financial instruments correspond to domestic issuers.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

(c) Level 3 reconciliation:

The following table shows the reconciliation between stock at the beginning and the end of balance periods for instruments classified in Level 3:

	As of September 30, 2016							Balance as of September 30, 2016 MCh\$
	Balance as of January 1, 2016 MCh\$	Gain (Loss) Recognized in Income (1) MCh\$	Gain (Loss) Recognized in Equity (2) MCh\$	Purchases MCh\$	Sales MCh\$	Transfer from Level 1 and 2 MCh\$	Transfer to Level 1 and 2 MCh\$	
Financial Assets								
Financial assets held-for-trading								
Other instruments issued in Chile	18,028	27			(18,042)			13
Subtotal	18,028	27			(18,042)			13
Available-for-Sale Instruments								
Other instruments issued in Chile	96,125	(5,360)	985	4,802	(17,405)		(2,704)	76,443
Instruments issued abroad								
Subtotal	96,125	(5,360)	985	4,802	(17,405)		(2,704)	76,443
Total	114,153	(5,333)	985	4,802	(35,447)		(2,704)	76,456

	As of December 31, 2015							Balance as of December 31, 2015 MCh\$
	Balance as of January 1, 2015 MCh\$	Gain (Loss) Recognized in Income (1) MCh\$	Gain (Loss) Recognized in Equity (2) MCh\$	Purchases MCh\$	Sales MCh\$	Transfer from Level 1 and 2 MCh\$	Transfer to Level 1 and 2 MCh\$	
Financial Assets								
Financial assets held-for-trading								
Other instruments issued in Chile	1,401	(26)		18,055	(51)		(1,351)	18,028
Subtotal	1,401	(26)		18,055	(51)		(1,351)	18,028
Available-for-Sale Instruments								

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Other instruments issued in Chile	179,378	11,230	(775)	213	(101,213)	13,336	(6,044)	96,125
Instruments issued abroad	1,938	103	56		(2,097)			
Subtotal	181,316	11,333	(719)	213	(103,310)	13,336	(6,044)	96,125
Total	182,717	11,307	(719)	18,268	(103,361)	13,336	(7,395)	114,153

(1) Recorded in income under item Net financial operating income

(2) Recorded in equity under item Other Comprehensive Income .

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

(d) Sensitivity of level 3 instruments to changes in key assumptions of the input parameters for the valuation model:

The following table shows the impact on the fair value of Level 3 financial instruments using alternative assumptions that are reasonably possible. It is believed that the positive and negative impacts are similar:

	As of September 30, 2016		As of December 31, 2015	
	Sensitivity to changes in key assumptions of		Sensitivity to changes in key assumptions of	
	Level 3	models	Level 3	models
	MCh\$	MCh\$	MCh\$	MCh\$
Financial Assets				
Financial assets held-for-trading				
Other instruments issued in Chile	13		18,028	(445)
Total	13		18,028	(445)
Available-for- Sale Instruments				
Other instruments issued in Chile	76,443	(1,326)	96,125	(1,969)
Instruments issued abroad				
Total	76,443	(1,326)	96,125	(1,969)
Total	76,456	(1,326)	114,153	(2,414)

With the purpose to determine the sensitivity of the financial investments to changes in significant market factors, the Bank has made alternative calculations at fair value, changing those key parameters for the valuation and which are not directly observable in screens, In the case of financial assets presented table above, which corresponds to bank bonds and corporate bonds, input prices, prices based on broker quotes or runs were used, considering that these instruments do not have current prices or observable. Prices are generally calculated as a base rate plus a spread. For local bonds, this was determined by applying only a 10% impact on the price, while for offshore bonds this was determined by applying only a 10% impact on the spread because the base rate is hedged with instruments on interest rate swaps so-called hedge accounting. The impact of 10% is considered a reasonable move considering the market performance of these instruments and comparing it against the adjustment bid/offer that is provided for by these instruments.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

(e) Other assets and liabilities:

The following table summarizes the fair values of the Bank's main financial assets and liabilities that are not recorded at fair value in the Statement of Financial Position. The values shown in this note do not attempt to estimate the value of the Bank's income-generating assets, nor forecast their future behavior. The estimated fair value is as follows:

	Book Value		Estimated Fair Value	
	September 2016 MCh\$	December 2015 MCh\$	September 2016 MCh\$	December 2015 MCh\$
Assets				
Cash and due from banks	1,161,938	1,361,222	1,161,938	1,361,222
Transactions in the course of collection	485,580	526,046	485,580	526,046
Cash collateral on securities borrowed and reverse repurchase agreements	46,534	46,164	46,534	46,164
Subtotal	1,694,052	1,933,432	1,694,052	1,933,432
Loans and advances to banks				
Domestic banks	128,230	45,186	128,230	45,186
Central Bank of Chile	640,222	1,000,433	640,222	1,000,433
Foreign banks	313,493	349,576	313,493	349,576
Subtotal	1,081,945	1,395,195	1,081,945	1,395,195
Loans to customers, net				
Commercial loans	14,043,563	14,046,119	13,861,298	13,859,949
Residential mortgage loans	6,722,456	6,370,034	7,148,720	6,625,557
Consumer loans	3,648,862	3,540,122	3,613,823	3,525,034
Subtotal	24,414,881	23,956,275	24,623,841	24,010,540
Total	27,190,878	27,284,902	27,399,838	27,339,167
Liabilities				
Current accounts and other demand deposits	7,629,008	8,327,048	7,629,008	8,327,048
Transactions in the course of payment	297,673	241,842	297,673	241,842
Cash collateral on securities lent and repurchase agreements	221,271	184,131	221,271	184,131
Savings accounts and time deposits	10,572,835	9,907,692	10,584,567	9,902,468
Borrowings from financial institutions	1,123,190	1,529,627	1,118,086	1,522,667
Other financial obligations	165,436	173,081	165,436	173,081
Subtotal	20,009,413	20,363,421	20,016,041	20,351,237
Debt Issued				
Letters of credit for residential purposes	31,496	39,568	33,808	41,849
Letters of credit for general purposes	4,607	6,813	4,945	7,206

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Bonds	5,405,951	5,270,214	5,653,672	5,302,742
Subordinate bonds	723,290	785,613	737,540	788,883
Subtotal	6,165,344	6,102,208	6,429,965	6,140,680
Total	26,174,757	26,465,629	26,446,006	26,491,917

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

(e) Other assets and liabilities, continued:

Other financial instruments not measured at fair value in our statement of financial position, but for which the fair value is disclosed, are not managed on a fair value basis. These instruments include assets and liabilities such as loans and deposits to customers, bank borrowings, debt issued, and other financial assets and obligations with diverse maturities and features. Fair values of these assets/liabilities are estimated by applying the traditional Discounted Cash Flows model and using diverse valuation inputs such as yield curves, credit risk spreads, etc. Also, since some of these assets/liabilities are not traded in the market, judgmental analysis is required in determining the adequacy of the inputs and fair values.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial assets and liabilities, continued:

(f) Levels of other assets and liabilities:

The following chart shows fair value of financial assests and liabilites not valued at their fair value, as of September 30th 2016 and December 2015:

	Level 1		Level 2		Level 3		Total	
	September 2016	December 2015	September 2016	December 2015	September 2016	December 2015	September 2016	December 2015
	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$
Assets								
Cash and due from banks	1,161,938	1,361,222					1,161,938	1,361,222
Transactions in the course of collection	485,580	526,046					485,580	526,046
Receivables from repurchase agreements and security borrowing	46,534	46,164					46,534	46,164
Subtotal	1,694,052	1,933,432					1,694,052	1,933,432
Loans and advances to banks								
Domestic banks	128,230	45,186					128,230	45,186
Central bank	640,222	1,000,433					640,222	1,000,433
Foreign banks	313,493	349,576					313,493	349,576
Subtotal	1,081,945	1,395,195					1,081,945	1,395,195
Loans to customers, net								
Commercial loans					13,861,298	13,859,949	13,861,298	13,859,949
Residential mortgage loans					7,148,720	6,625,557	7,148,720	6,625,557
Consumer loans					3,613,823	3,525,034	3,613,823	3,525,034
Subtotal					24,623,841	24,010,540	24,623,841	24,010,540
Total	2,775,997	3,328,627			24,623,841	24,010,540	27,399,838	27,339,167
Liabilities								
Current accounts and other demand deposits								
Transactions in the course of payment	297,673	241,842					297,673	241,842
Payables from repurchase agreements and security lending	221,271	184,131					221,271	184,131
Savings accounts and time deposits					10,584,567	9,902,468	10,584,567	9,902,468
Borrowings from financial institutions					1,118,086	1,522,667	1,118,086	1,522,667

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Other financial obligations	165,436	173,081				165,436	173,081
Subtotal	8,313,388	8,926,102		11,702,653	11,425,135	20,016,041	20,351,237
Debt Issued							
Letters of credit for residential purposes		33,808	41,849			33,808	41,849
Letters of credit for general purposes		4,945	7,206			4,945	7,206
Bonds		5,653,672	5,302,742			5,653,672	5,302,742
Subordinate bonds				737,540	788,883	737,540	788,883
Subtotal		5,692,425	5,351,797	737,540	788,883	6,429,965	6,140,680
Total	8,313,388	8,926,102	5,692,425	5,351,797	12,440,193	12,214,018	26,446,006

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, *continued*

39. **Fair Value of Financial Assets and Liabilities, continued:**

(f) Levels of other assets and liabilities, continued:

The Bank determines the fair value of these assets and liabilities according to the following:

- **Short-Term Financial Assets/Liabilities:** For assets and liabilities with no specific maturity (on demand) or terms of less than three months we use the carrying or book values as proxies of their fair value, since their tenors are not believed to significantly affect their valuation. As a result, these assets/liabilities are categorized in Level 1. This assumption is applied to the following assets/liabilities:

- | | |
|--|--|
| • Cash and due from banks | • Current accounts and other demand deposits |
| • Transactions in the course of collection | • Transactions in the course of payments |
| • Cash collateral on securities borrowed and reverse repurchase agreements | • Cash collateral on securities lent and repurchase agreements |
| • Loans and advance to banks | • Other financial obligations |

- **Loans to Customers:** Fair value is determined by using the DCF model and internally generated discount rates, based on internal transfer rates derived from our internal transfer price policy. After we calculate the present value, we deduct the related loan loss allowances in order to incorporate the credit risk associated with each contract or loan. As we use internally generated parameters for valuation purposes, we categorize these instruments in Level 3.

- **Letters of Credit and Bonds:** In order to determine the present value of contractual cash flows, we apply the DCF model by using market interest rates that are available in the market, either for the instruments under valuation or instruments with similar features that fit valuation needs in terms of currency, maturities and liquidity. Market interest rates are obtained from third party price providers widely used by the market. As a result of the valuation technique and the quality of inputs (observable) used for valuation, we categorize these financial liabilities in Level 2.

- Saving Accounts, Time Deposits, Borrowings from Financial Institutions and Subordinated Bonds: The DCF model is used to obtain the present value of committed cash flows by applying a bucket approach and average adjusted discount rates that are derived from both market rates for instruments with similar features and our internal transfer price policy. As we use internally generated parameters and/or apply significant judgmental analysis for valuation purposes, we categorize these financial assets/liabilities in Level 3.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

39. Fair Value of Financial Assets and Liabilities, continued:

(g) Offsetting of financial assets and liabilities:

The Bank trades financial derivatives with foreign counterparties using ISDA Master Agreement (International Swaps and Derivatives Association, Inc.), under legal jurisdiction of the City of New York USA or London United Kingdom. Legal framework in these jurisdictions, along with documentation mentioned, it allows to Banco de Chile the right to anticipate the maturity of the transaction and then, offset the net value of those transactions in case of default of counterparty. The Bank has negotiated with these counterparties an additional annex (CSA Credit Support Annex), including other credit mitigating, such as margins about a certain threshold, early termination (optional or mandatory), coupon adjustment transaction over a certain threshold amount, etc.

Below are detail contracts susceptible to offset:

	Fair Value		Negative Fair Value of contracts with right to offset		Positive Fair Value of contracts with right to offset		Financial Collateral		Net Fair Value	
	September 2016	December 2015	September 2016	December 2015	September 2016	December 2015	September 2016	December 2015	September 2016	December 2015
	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$	MCh\$
Derivative financial assets	1,055,574	1,127,122	(341,956)	(258,213)	(301,429)	(244,064)	(87,306)	(148,023)	324,883	476,822
Derivative financial liabilities	1,067,561	1,127,927	(341,956)	(258,213)	(301,429)	(244,064)	(151,480)	(190,563)	272,696	435,087

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

40. Maturity of Assets and Liabilities:

The table below shows details of loans and other financial assets and liabilities grouped in accordance with their remaining maturity, including accrued interest as of September 30, 2016 and December 31, 2015, respectively. Trading and available-for-sale instruments are included at their fair value:

Assets	As of September 30, 2016						Total MCh\$
	Up to 1 month MCh\$	Over 1 month and up to 3 months MCh\$	Over 3 month and up to 12 months MCh\$	Over 1 year and up to 3 years MCh\$	Over 3 year and up to 5 years MCh\$	Over 5 years MCh\$	
Cash and due from banks	1,161,938						1,161,938
Transactions in the course of collection	485,580						485,580
Financial Assets held-for-trading	1,411,245						1,411,245
Cash collateral on securities borrowed and reverse repurchase agreements	20,138	23,232	3,164				46,534
Derivative instruments	49,057	66,930	218,685	195,881	158,733	366,288	1,055,574
Loans and advances to banks (*)	801,055	164,733	97,000	19,734			1,082,522
Loans to customers (*)	2,938,753	3,134,584	4,284,773	4,872,532	2,961,510	6,812,101	25,004,253
Financial assets available-for-sale	7,034	43,450	42,149	73,839	69,064	163,981	399,517
Financial assets held-to-maturity							
Total assets	6,874,800	3,432,929	4,645,771	5,161,986	3,189,307	7,342,370	30,647,163

Assets	As of December 31, 2015						Total MCh\$
	Up to 1 month MCh\$	Over 1 month and up to 3 months MCh\$	Over 3 month and up to 12 months MCh\$	Over 1 year and up to 3 years MCh\$	Over 3 year and up to 5 years MCh\$	Over 5 years MCh\$	
Cash and due from banks	1,361,222						1,361,222
Transactions in the course of collection	526,046						526,046
Financial Assets held-for-trading	866,654						866,654
Cash collateral on securities borrowed and reverse repurchase agreements	35,909	8,704	1,551				46,164

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Derivative instruments	74,809	75,895	160,886	323,580	171,498	320,454	1,127,122
Loans and advances to banks (*)	1,063,248	78,056	224,943	29,650			1,395,897
Loans to customers (*)	2,670,006	2,935,330	4,586,126	4,873,871	2,843,390	6,649,318	24,558,041
Financial assets available-for-sale	124,174	73,409	343,350	76,834	121,680	260,554	1,000,001
Financial assets held-to-maturity							
Total assets	6,722,068	3,171,394	5,316,856	5,303,935	3,136,568	7,230,326	30,881,147

(*) The respective provisions, which amount to Ch\$589,372 million (Ch\$601,766 million as of December 31, 2015) for loans to customers and Ch\$577 million (Ch\$702 million as of December 31, 2015) for borrowings from financial institutions, have not been deducted from these balance.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

40. Maturity of Assets and Liabilities, continued:

Liabilities	As of September 30, 2016						
	Up to 1 month MCh\$	Over 1 month and up to 3 months MCh\$	Over 3 month and up to 12 months MCh\$	Over 1 year and up to 3 years MCh\$	Over 3 year and up to 5 years MCh\$	Over 5 years MCh\$	Total MCh\$
Current accounts and other demand deposits	7,629,008						7,629,008
Transactions in the course of payment	297,673						297,673
Cash collateral on securities lent and repurchase agreements	211,621	9,650					221,271
Savings accounts and time deposits (**)	4,786,313	1,959,763	3,278,174	332,841	505	197	10,357,793
Derivative instruments	35,839	74,945	193,742	191,984	164,027	407,024	1,067,561
Borrowings from financial institutions	151,133	284,881	535,147	152,029			1,123,190
Debt issued:							
Mortgage bonds	2,572	3,091	6,036	12,356	7,067	4,981	36,103
Bonds	74,190	303,836	402,868	785,358	959,572	2,880,127	5,405,951
Subordinate bonds	10,069	25,982	18,650	54,145	42,057	572,387	723,290
Other financial obligations	127,991	4,556	8,081	20,547	3,567	694	165,436
Total liabilities	13,326,409	2,666,704	4,442,698	1,549,260	1,176,795	3,865,410	27,027,276

Liabilities	As of December 31, 2015						
	Up to 1 month MCh\$	Over 1 month and up to 3 months MCh\$	Over 3 month and up to 12 months MCh\$	Over 1 year and up to 3 years MCh\$	Over 3 year and up to 5 years MCh\$	Over 5 years MCh\$	Total MCh\$
Current accounts and other demand deposits	8,327,048						8,327,048
Transactions in the course of payment	241,842						241,842
Cash collateral on securities lent and repurchase agreements	170,451	13,680					184,131
Savings accounts and time deposits (**)	4,575,625	1,687,604	2,975,070	463,454	557	211	9,702,521
Derivative instruments	84,043	97,292	193,171	289,987	135,760	327,674	1,127,927
Borrowings from financial institutions	340,856	126,034	905,878	156,859			1,529,627
Debt issued:							
Mortgage bonds	3,226	3,220	8,157	15,035	9,452	7,291	46,381
Bonds	370,502	141,996	254,426	791,009	1,008,830	2,703,451	5,270,214

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Subordinate bonds	2,564	1,756	181,592	52,627	46,038	501,036	785,613
Other financial obligations	132,762	2,108	9,982	19,237	7,928	1,064	173,081
Total liabilities	14,248,919	2,073,690	4,528,276	1,788,208	1,208,565	3,540,727	27,388,385

(**) Excluding term saving accounts, which amount to Ch\$215,042 million (Ch\$205,171 million as of December 31, 2015).

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS, continued

41. Subsequent Events:

In Management's opinion, there are no other significant subsequent events that affect or could affect the Interim Condensed Consolidated Financial Statements of the Bank and its subsidiaries between September 30, 2016 and the date of issuance of these Interim Condensed Consolidated Financial Statements.

Héctor Hernández G,
General Accounting Manager

Eduardo Ebensperger O,
Chief Executive Officer

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SIGNATURE

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.

Date: October 27, 2016

Banco de Chile

/S/ Eduardo Ebensperger O.

By: Eduardo Ebensperger O.
CEO
