AGILE THERAPEUTICS INC
Form 10-Q
November 06, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2017

OR

o 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	**23-2936302**
(State or other jurisdiction of incorporation or organization)	(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 x No o

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 x No o

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if smaller reporting company)	Smaller reporting company o
	Emerging growth company x

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

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

There were 34,186,342 shares of the registrant s common stock, $0.0001 par value, outstanding as of November 3, 2017.

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Agile Therapeutics, Inc.

Quarterly Report on Form 10-Q

For The Quarter Ended September 30, 2017

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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 thereon 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 and assessments 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:

- our ability to obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- 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;
- the success and timing of our clinical trials;
- 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;
- 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.

Twirla® is one of our trademarks used in this Form 10-Q. This Form 10-Q also includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this Form 10-Q may appear without the ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

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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, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 43,806	$ 48,750
Prepaid expenses	1,161	2,768
Total current assets	44,967	51,518
Property and equipment, net	13,426	12,330
Other assets	18	18
Total assets	$ 58,411	$ 63,866
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,823	$ 2,050
Accrued expenses	1,857	3,644
Loan payable, current portion	6,190	5,104
Warrant liability	90	172
Total current liabilities	10,960	10,970
Loan payable, long-term	5,887	10,607
Commitments and contingencies		
Stockholders equity:		
Common stock, $.0001 par value, authorized 150,000,000 shares; 34,158,004 shares issued and outstanding as of September 30, 2017 and 28,759,731 shares issued and outstanding as of December 31, 2016;	3	3
Additional paid-in capital	257,093	235,754
Accumulated deficit	(215,532)	(193,468)
Total stockholders equity	41,564	42,289
Total liabilities and stockholders equity	$ 58,411	$ 63,866

See accompanying notes to unaudited financial statements.

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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,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	$ 3,175	$ 4,911	$ 11,694	$ 15,415
General and administrative	3,526	2,180	9,130	6,497
Total operating expenses	6,701	7,091	20,824	21,912
Loss from operations	(6,701)	(7,091)	(20,824)	(21,912)
Other income (expense)				
Interest expense	(459)	(784)	(1,509)	(1,879)
Interest income	78	33	187	83
Change in fair value of warrants	(20)	38	82	168
Loss before benefit from income taxes	(7,102)	(7,804)	(22,064)	(23,540)
Benefit from income taxes				
Net loss	$ (7,102)	$ (7,804)	$ (22,064)	$ (23,540)
Net loss per share - basic and diluted	$ (0.22)	$ (0.27)	$ (0.74)	$ (0.84)
Weighted-average shares outstanding basic and diluted	31,937,628	28,754,458	29,847,972	28,110,587

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,	
	2017	2016
Cash flows from operating activities		
Net loss	$ (22,064)	$ (23,540)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	16	14
Noncash stock based compensation	2,727	2,607
Noncash interest	520	759
Change in fair value of warrants	(82)	(168)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,606	595
Other assets		
Accounts payable and accrued expenses	(1,473)	(648)
Net cash used in operating activities	(18,750)	(20,381)
Cash flows from investing activities		
Acquisition of property and equipment	(771)	(25)
Net cash used in investing activities	(771)	(25)
Cash flows from financing activities		
Cash paid for debt financing costs		(175)
Principal payments on long-term debt	(4,035)	(985)
Return of principal payments on long-term debt		985
Proceeds from the issuance of common stock, net	18,536	37,527
Proceeds from exercise of stock options	76	329
Net cash provided by financing activities	14,577	37,681
Ne (decrease) increase in cash and cash equivalents	(4,944)	17,275
Cash and cash equivalents, beginning of period	48,750	34,395
Cash and cash equivalents, end of period	$ 43,806	$ 51,670
Supplemental disclosure of noncash financing activities		
Supplemental cash flow information		
Interest paid	$ 1,023	$ 1,125
Income taxes paid	$	$

See accompanying notes to unaudited financial statements.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(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 forward-thinking women s healthcare company dedicated to fulfilling the unmet health needs of today s women. 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 s lead product candidate, Twirla®, also known as AG200-15, is a once-weekly prescription contraceptive patch that is at the end of Phase 3 clinical development. Substantially all of the Company s resources are currently dedicated to developing and seeking regulatory approval for Twirla. 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, 2017, the Company had an accumulated deficit of approximately $215.5 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, 2017, the Company had cash and cash equivalents of $43.8 million. The Company believes that its existing cash and cash equivalents will not be sufficient to fund its current and planned operations through the next 12 months, which raises substantial doubt about the Company s ability to continue as a going concern. The Company has based this belief on assumptions and estimates that may prove to be wrong, and the Company could spend its available cash and cash equivalents less or more rapidly than expected. The Company will continue to require additional funding to support its continued development and commercialization efforts for Twirla as well as advancing the development of its other product candidates. Management intends to seek additional capital through equity and/or debt financings or through other sources of financing in the future. Adequate additional funding may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise additional capital when required or on acceptable terms, the Company may be required to delay or scale back the planned development and planned commercialization of Twirla and its business, operating results and financial condition would be adversely affected.

The unaudited condensed financial statements as of September 30, 2017 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company s ability to continue as a going concern is dependent upon its uncertain ability to obtain additional equity and/or debt financing and reduce expenditures. The unaudited condensed financial statements as of September 30, 2017 do not include any adjustments that might result from the outcome of this uncertainty.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

1. Organization and Description of Business (Continued)

Basis of Presentation

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, 2016 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. Certain prior period amounts have been reclassified to conform to the current period presentation. The results of operations for the three and nine months ended September 30, 2017 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 is described in Note 2 to the Company s audited financial statements as of December 31, 2016 included in its annual report on Form 10-K filed with the SEC.

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 Accounting Standards Codification (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.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

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 an outstanding share, that, at inception, is indexed to an obligation to repurchase 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 the Black-Scholes 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, 2017, 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.

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 Company elects to account for forfeitures when they occur. 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 and its board of directors. 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. In April 2017, the Company granted up to 260,000 shares pf performance-based restricted stock units (Performance Units) under the Company s 2014 Incentive Compensation Plan, to executive officers which are primarily contingent upon achievement of performance goals during the performance period beginning on the date of grant and ending on December 31, 2018 as set forth in each officer s performance unit agreement. For awards with a performance condition which affects the vesting of the Performance Units, cost is recognized only if the performance condition is probable of being satisfied. Given the uncertainty of the achievement of the performance goals during the performance period, the Company has not recorded compensation expense related to these awards for the three and nine months ended September 30, 2017.

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.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

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 were the same for all periods presented.

The following table sets forth the outstanding 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, 2017 and 2016, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	September 30,	
	2017	**2016**
Common stock warrants	242,779	242,779
Common stock options	3,798,951	2,829,939
Unvested restricted stock units	264,361	33,334
Total	4,306,091	3,106,052

Going Concern

Accounting Standards Update (ASU) No. 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,* 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 Company will perform quarterly evaluations to identify current conditions which may raise substantial doubt about the entity s ability to continue as a going concern within one year after the date that the financial statements are issued.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU 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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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements (Continued)

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* This ASU eliminates the requirement to consider down round features when determining whether certain equity-linked financial instruments or embedded features are indexed to an entity s own stock. ASU 2017-11 is effective for annual periods beginning after December 31, 2018. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2017-11 on its financial statements.

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.

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.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

3. Fair Value Measurements (Continued)

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, 2017 and December 31, 2016.

	Level 1	Level 2	Level 3
September 30, 2017			
Assets:			
Cash equivalents	$ 43,745	$	$
Total assets at fair value	$ 43,745	$	$
Liabilities:			
Common stock warrants	$	$	$ 90
Total liabilities at fair value	$	$	$ 90

The significant assumptions used in preparing the option pricing model for valuing the Company s warrants as of September 30, 2017 include (i) volatility (70.0%), (ii) risk free interest rate of 1.62% (estimated using treasury bonds with a 2.25 year life), (iii) strike price ($6.00) for the common stock warrants, (iv) fair value of common stock ($4.46) and (v) expected life (2.25 years).

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

Beginning balance at December 31, 2016	$ 172
Change in fair value	(82)
Ending balance at September 30, 2017	$ 90

	Level 1	Level 2	Level 3
December 31, 2016			
Assets:			
Cash equivalents	$ 48,659	$	$
Total assets at fair value	$ 48,659	$	$

Liabilities:			
Common stock warrants	$	$	$ 172
Total liabilities at fair value	$	$	$ 172

The significant assumptions used in preparing the option pricing model for valuing the Company s warrants as of December 31, 2016 include (i) volatility (75.0%), (ii) risk free interest rate of 1.47% (estimated using treasury bonds with a 3 year life), (iii) strike price ($6.00) for the common stock warrants, (iv) fair value of common stock ($5.70) and (v) expected life (three years).

There were no transfers between Level 1, 2 or 3 during 2017 or 2016. 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.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

4. Prepaid Expenses

Prepaid expenses consist of the following:

	September 30, 2017	December 31, 2016
Prepaid clinical trial expense	$ 327	$ 2,005
Prepaid insurance	626	665
Other	208	98
Total prepaid expenses	$ 1,161	$ 2,768

5. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2017	December 31, 2016
Employee bonuses	$ 946	$ 1,041
Accrued clinical trial costs	281	1,908
Other	630	695
Total accrued liabilities	$ 1,857	$ 3,644

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).

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

6. Loan and Security Agreements (Continued)

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 amended certain terms of the Hercules Loan. In May 2017, the Company entered into the Second Amendment to Loan and Security Agreement (the Second Amendment) with Hercules which further amended 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 extended 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 Second Amendment further extended the Company s option to draw the Second Term Loan Advance until January 31, 2018, and continues to make the Second Term Loan Advance subject to the consent of Hercules, among other customary conditions. The First Amendment also extended 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 provides the Term Loan will mature on December 1, 2018. 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 $165. The facility fee represents a debt issue cost which is being reflected as a reduction to the carrying amount of loan payable in accordance with ASU 2015-03. Such issue costs are being amortized to interest expense over the life of the loan using the effective interest method.

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 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 amount of the end of term final payment is

being accrued over the loan term as interest expense.

The Company may prepay all, but not less than all, of the Hercules Loan subject to a prepayment premium of 1.0% of the outstanding principal. 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.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

6. Loan and Security Agreements (Continued)

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.

7. Stockholders Equity

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 offerings of common stock in both January 2016 and August 2017 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.

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 was also affiliated with a member of the Company s board of directors at the time of the public offering, purchased 393,700 shares of common stock for approximately $2.5 million in the public offering.

2017 Public Offering of Common Stock

In August 2017, the Company completed an underwritten public offering of 5,333,334 shares of its common stock at a public offering price of $3.75 per share. Proceeds from the this offering, net of underwriting discounts, commissions and other offering costs were approximately $18.5 million.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

7. Stockholders Equity (Continued)

Stock-Based Compensation Expense

Stock-based compensation expense was allocated as follows:

	Three Months Ended September 30,	
	2017	2016
Research and development	$ 309	$ 299
General and administrative	658	641
Total stock-based compensation expense	$ 967	$ 940

	Nine Months Ended September 30,	
	2017	2016
Research and development	$ 889	$ 796
General and administrative	1,838	1,811
Total stock-based compensation expense	$ 2,727	$ 2,607

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. In connection with the resignation of our Chief Commercial Officer, who

was affiliated with SmartPharma, on July 6, 2016, the Company appointed a new Chief Commercial Officer.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2017

(in thousands, except share and per share data)

9. Commitments and Contingencies

Legal Proceedings

On January 6, 2017, and January 20, 2017, two previously disclosed complaints captioned *Peng v. Agile Therapeutics, Inc., Alfred Altomari, and Elizabeth Garner*, No. 17-cv-119 (D.N.J.), and *Lichtenthal v. Agile Therapeutics, Inc., Alfred Altomari, and Elizabeth Garner*, No. 17-cv-405 (D.N.J.), respectively, were filed in the United States District Court for the District of New Jersey on behalf of a putative class of investors who purchased shares of the Company s common stock from March 9, 2016, through January 3, 2017. The complaints alleged violations of the federal securities laws based on public statements made regarding the Company s Phase 3 SECURE clinical trial and sought an unspecified amount of damages to be determined at trial. The Company denied all allegations in the complaints. On May 15, 2017, the complaints were consolidated the lawsuits as *In re Agile Therapeutics, Inc. Securities Litigation*, Master File No. 17-cv-119 (D.N.J.), and Hoyt W. Clark was appointed as a class representative for the putative class. On June 26, 2017, Mr. Clark agreed to dismiss the consolidated case voluntarily, without payment by the Company of any consideration and with each side bearing its own attorneys fees and costs. The presiding judge dismissed the consolidated action with prejudice as to all defendants on July 13, 2017.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could have an adverse effect on the Company s operations or its financial position. As of September 30, 2017, the Company has not recorded a provision for any contingent losses.

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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 15, 2017. 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 forward-thinking women s healthcare company dedicated to fulfilling the unmet health needs of today s women. Our current product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, also known as AG200-15, is a once-weekly prescription contraceptive patch that is at the end of Phase 3 clinical development.

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 $20.9 million, $25.6 million and $13.4 million during the years ended December 31, 2016, 2015 and 2014, respectively. We incurred research and development expenses of $3.2 million and $11.7 million for the three and nine months ended September 30, 2017, 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. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital to fund our operating needs including, among other items, continued commercial activities after the initial commercial launch of Twirla, if approved, and to advance the development of our other 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, 2017 and December 31, 2016 respectively, we had $43.8 million and $48.8 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 approximately $49.7 million.

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

In February 2015, we entered into a loan and security agreement with Hercules Technology Growth 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 to March 31, 2017 and extended the period during which we make interest-only payments until January 31, 2017. The Hercules Loan Agreement was further amended in May 2017 to extend the period during which we can draw the second tranche of $8.5 million to January 31, 2018. On February 1, 2017, we began making principal payments

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with respect to the Hercules Loan. 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.

In August 2017, we completed an underwritten public offering of 5,333,334 shares of common stock at a public offering price of $3.75 per share. Proceeds from our August 2017 public offering, net of underwriting discounts, commissions and other offering costs were approximately $18.5 million.

We have not generated any revenue and have never been profitable for any year. Our net loss was $28.7 million, $30.3 million and $16.1 million for the years ended December 31, 2016, 2015 and 2014, respectively. Our net loss was $7.1 million and $22.1 million for the three and nine months ended September 30, 2017, respectively. We expect to incur increased expenses and increasing operating losses for the foreseeable future as we seek the approval of our New Drug Application, or NDA for Twirla, which was supplemented with the results of our completed Phase 3 clinical trial, which we refer to as the SECURE clinical trial, to respond to the U.S. Food and Drug Administration, or FDA s February 2013 Complete Response Letter, or CRL, and was received by the FDA on June 26, 2017, complete the qualification and validation of our commercial manufacturing process, initiate pre-launch commercial activities, commercially launch Twirla, advance our other product candidates and expand our research and development programs. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital to fund our operating needs including, among other items, continued commercial activities after the initial commercial launch of Twirla, if approved, and to advance the development of our other product candidates.

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. Based on our interactions with the FDA on the chemistry, manufacturing and controls, or CMC issues raised in the CRL and our plan with Corium to validate the commercial scale equipment to manufacture Twirla, we believe we have addressed the CMC CRL issues in the resubmission of our NDA. 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 and expansion of our commercial manufacturing process to be completed after the target Prescription Drug User Fee Act, or PDUFA goal date of December 26, 2017. 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, which will require additional capital.

In December 2016, we completed the SECURE clinical trial, in which we enrolled over 2,000 women for up to one year of treatment. We announced top-line data in early January 2017. In March 2017, at our request, we met with the FDA to share preliminary data from the SECURE clinical trial, including key safety data and BMI-related efficacy findings, and to seek FDA input as to whether the SECURE clinical trial results constitute a basis for addressing the clinical deficiencies cited in the CRL. We also requested feedback on whether the proposed Twirla NDA content will meet the FDA s requirements for submission. The FDA did not provide us with any feedback on whether the results of the SECURE clinical trial and the contents of the planned, resubmitted NDA will be sufficient to obtain regulatory approval of Twirla. We resubmitted our NDA for Twirla which was received by the FDA on June 26, 2017 and we were given a target

PDUFA goal date of December 26, 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

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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.

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, and 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. In 2017, we expect the expenses associated with the SECURE clinical trial to decrease as compared to 2016 as we complete the close-out activities associated with the trial and because no additional clinical trials are planned at this time. During 2017, we expect to increase activities related to equipment qualification and validation of our commercial manufacturing process as we continue to prepare for the commercialization of Twirla.

To date, our research and development expenses have related primarily to the development of Twirla. As we near completion of the SECURE clinical trial close-out activities and completed the resubmission of our Twirla NDA, we expect research and development expenses to continue to shift away from costs associated with our SECURE clinical trial and NDA resubmission and toward the costs associated with completing the qualification and validation of our commercial manufacturing process. We began incurring expenses for the clinical development of AG200-SP in the second half of 2016. We have decided to postpone the planned Phase 2 clinical trial for AG200-SP and will continue to evaluate the timing for initiating dosing of subjects for the planned Phase 2 clinical trial, which is dependent on financial and other capital resources. For the three months ended September 30, 2017 and

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2016, our research and development expenses were approximately $3.2 million and $4.9 million, respectively. For the nine months ended September 30, 2017 and 2016, our research and development expenses were approximately $11.7 million and $15.4 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three months ended September 30,		Nine months ended September 30,	
	(In thousands)			
	2017	2016	2017	2016
Clinical development	$ 588	$ 3,030	$ 2,609	$ 9,942
Regulatory	95	72	1,191	225
Personnel related	675	665	2,129	1,910
Manufacturing commercialization	1,379	470	4,082	1,431
Manufacturing	129	375	794	1,111
Stock-based compensation	309	299	889	796
Total research and development expenses	$ 3,175	$ 4,911	$ 11,694	$ 15,415

We have nearly completed the close-out activities associated with our SECURE clinical trial for Twirla and expect the process to be complete by the end of 2017. It is difficult to determine with any certainty the exact duration and completion costs of our future clinical trials of Twirla or our other current and future product candidates we may advance. 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 assumes the FDA will complete its review of our NDA resubmission by the target PDUFA goal date, December 26, 2017. We may, however, never succeed in achieving regulatory approval for Twirla or any of our product candidates or such approval may be delayed. 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 rate of subject enrollment, obtaining additional capital, 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. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital to fund our operating needs, including, among other items, continued commercial activities, after our initial commercial launch of Twirla, if approved, as well as advancing the development of our other product candidates.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including payroll taxes and health insurance, stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, insurance 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, 2017 and 2016, our general and administrative expenses totaled approximately $3.5 million and $2.2 million, respectively. For the nine months ended September 30, 2017 and 2016, our general and administrative expenses totaled approximately $9.1 million and $6.5 million, respectively. We anticipate that our general and administrative expenses will increase in the future with the continued research,

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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 continue to increase 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.

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.

Results of Operations

Comparison of the Three Months Ended September 30, 2017 and 2016

	Three months ended September 30,		
	2017	2016	Change
	(In thousands)		
Operating expenses:			
Research and development	$ 3,175	$ 4,911	$ (1,736)
General and administrative	3,526	2,180	1,346
Total operating expenses	6,701	7,091	(390)
Other income (expenses)			
Interest expense	(459)	(784)	325
Interest income	78	33	45
Change in fair value of warrants	(20)	38	(58)
Loss before income taxes	(7,102)	(7,804)	702
Benefit from income taxes			
Net loss	$ (7,102)	$ (7,804)	$ 702

Research and development expenses. Research and development expenses decreased by $1.7 million, or 35%, from $4.9 million for the three months ended September 30, 2016 to $3.2 million for the three months ended September 30,

2017. 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, 2017 as compared to the three months ended September 30, 2016. During the fourth quarter of 2016, we completed subject visits for our SECURE clinical trial. This decrease reflects reduced clinical trial activity in the three months ended September 30, 2017 as compared to the three months ended September 30, 2016 as we complete the close-out activities associated with our SECURE clinical trial; and

- an increase in manufacturing commercialization expenses of $0.9 million for the three months ended September 30, 2017 as compared to the three months ended September 30, 2016. This increase reflects materials, labor and other costs associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment. During the remainder of 2017, we

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expect these expenses to increase significantly as we continue to advance our plan related to equipment qualification and validation of our commercial manufacturing process and as we continue to prepare for the commercialization of Twirla.

General and administrative expenses. General and administrative expenses increased by $1.3 million, or 62%, from $2.2 million for the three months ended September 30, 2016 to $3.5 million for the three months ended September 30, 2017. This increase in general and administrative expense was primarily due to the following:

- an increase in commercial development expense of $1.1 million for the three months ended September 30, 2017 compared to the three months ended September 30, 2016. This increase relates to the initiation of certain pre-commercialization activities such as brand building, advocacy and consulting. During the remainder of 2017, we expect these expenses to increase significantly as we continue to prepare for the commercialization of Twirla.

Interest expense. Interest expense is primarily attributable to our term loan with Hercules for the three months ended September 30, 2017 and 2016, 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 expense decreased by $0.3 million, or 41%, from $0.8 million for the three months ended September 30, 2016 to $0.5 million for the three months ended September 30, 2017. This decrease is primarily the result of a decrease in the principal outstanding under our term loan with Hercules for the three months ended September 30, 2017 as compared to the three months ended September 30, 2016.

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, 2017, we reported expense of $20 thousand related to the increase in the fair value of the warrants as compared to income of $38 thousand for the three months ended September 30, 2016, representing an increase in expense of $58 thousand. The market price of our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of the warrant liability.

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Comparison of the Nine Months Ended September 30, 2017 and 2016

	Nine months ended September 30,		
	2017	2016	Change
	(In thousands)		
Operating expenses:			
Research and development	$ 11,694	$ 15,415	$ (3,721)
General and administrative	9,130	6,497	2,633
Total operating expenses	20,824	21,912	(1,088)
Other income (expenses)			
Interest expense	(1,509)	(1,879)	370
Interest income	187	83	104
Change in fair value of warrants	82	168	(86)
Loss before income taxes	(22,064)	(23,540)	1,476
Benefit from income taxes			
Net loss	$ (22,064)	$ (23,540)	$ 1,476

Research and development expenses. Research and development expenses decreased by $3.7 million, or 24%, from $15.4 million for the nine months ended September 30, 2016 to $11.7 million for the nine months ended September 30, 2017. This decrease in research and development expenses was primarily due to the following:

- a decrease in clinical development expenses of $7.3 million for the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016. During the fourth quarter of 2016, we completed subject visits for our SECURE clinical trial. This decrease reflects reduced clinical trial activity in the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016 as we complete the close-out activities associated with our SECURE clinical trial;

- an increase in manufacturing commercialization expenses of $2.7 million for the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016. This increase reflects materials, labor and other costs associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment. During the remainder of 2017, we expect these expenses to increase significantly as we continue to advance our plan related to equipment qualification and validation of our commercial manufacturing process and as we continue to prepare for the commercialization of Twirla; and

- an increase in regulatory expenses of $0.9 million for the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016. This increase primarily represents external costs associated with the preparation of our NDA resubmission and response to the CRL.

General and administrative expenses. General and administrative expenses increased by $2.6 million, or 41%, from $6.5 million for the nine months ended September 30, 2016 to $9.1 million for the nine months ended September 30, 2017. This increase in general and administrative expense was primarily due to the following:

- an increase in commercial development expense of $2.2 million for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016. This increase relates to the initiation of certain pre-commercialization activities such as brand building, advocacy and consulting. During the remainder of 2017, we expect these expenses to increase significantly as we continue to prepare for the commercialization of Twirla.

Interest expense. Interest expense is primarily attributable to our term loan with Hercules for the nine months ended September 30, 2017 and 2016, 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

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expense decreased by $0.4 million, or 20% from $1.9 million for the nine months ended September 30, 2016 to $1.5 million for the three months ended September 30, 2017. This decrease is primarily the result of a decrease in the principal outstanding under our term loan with Hercules for the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016.

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 nine months ended September 30, 2017, we reported income of $82 thousand related to the decrease in the fair value of the warrants as compared to income of $0.2 million for the nine months ended September 30, 2016. The market price of our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of the warrant liability.

Liquidity and Capital Resources

At September 30, 2017, we had cash and cash equivalents totaling $43.8 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,	
	2017	**2016**
Cash used in operating activities	$ (18,750)	$ (20,381)
Cash used in investing activities	(771)	(25)
Cash provided by financing activities	14,577	37,681
Net increase (decrease) in cash and cash equivalents	$ (4,944)	$ 17,275

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 $18.8 million for the nine months ended September 30, 2017 and consisted primarily of a net loss of $22.1 million which was offset by non-cash stock-based compensation expense of $2.7 million, non-cash interest expense of $0.5 million and a working capital decrease of $0.1 million. 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. We began incurring expenses for the clinical development of AG200-SP in the third quarter of 2016. We have decided to postpone the planned Phase 2 clinical trial for AG200-SP and will continue to evaluate the timing for initiating dosing of subjects for the planned Phase 2 clinical trial, which is dependent on financial and other capital resources. The decreased clinical development expenses are being offset by increased commercial development and commercial manufacturing expenses which will continue to increase as we prepare for the commercialization of Twirla.

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Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2017 and 2016 was $0.8 million and $25 thousand, respectively. Cash used in investing activities for these periods primarily represents the acquisition of equipment to be used in the commercialization of Twirla, if approved.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2017 was $14.6 million which primarily represented net proceeds of $18.5 million received from the sale of 5,333,334 shares of common stock in August 2017, offset, in part, by principal payments pf $4.0 million under the Hercules Loan Agreement, which began on February 1, 2017. 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.

Funding Requirements and Other Liquidity Matters

The resubmission of our NDA for Twirla was received by the FDA on June 26, 2017. We are continuing to plan for the commercialization of Twirla, and advancing our plan for the scale-up of the commercial manufacturing process for Twirla. 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 in preparation for potential commercial operations;
- continue to evaluate additional line extensions for Twirla and initiate development of product candidates in addition to Twirla;

- 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, 2017, will enable us to fund our operating expenses and capital expenditures requirements into the second quarter of 2018. Our current business plan assumes the FDA will complete its review of our NDA resubmission by the target PDUFA goal date, December 26, 2017, initiation of certain pre-commercial activities prior to approval of Twirla and initiation and completion of validation of our commercial manufacturing process after the target PDUFA goal date, if the FDA approves Twirla. We expect that we will require additional capital to fund operating needs thereafter, including among other items, continued commercial activities after the initial commercial launch for Twirla and advancing the development of our other product candidates. 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. In the event of unforeseen changes to our planned timelines and business plan assumptions, as stated above, we still believe that we have the ability to continue funding operations into the second quarter of 2018 by postponing certain planned commercial and validation spending. 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, FDA review of the NDA for Twirla and commercialization of Twirla, if approved, we are unable to estimate the amounts of

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increased capital outlays and operating expenses associated with completing the development of Twirla. Our future capital requirements will depend on many factors, including:

- the costs and timing of final close-out activities for the Phase 3 SECURE clinical trial for Twirla;

- the costs, timing and outcome of regulatory review of Twirla;

- the costs of the equipment qualification and validation related to the expansion of Corium s manufacturing facility in preparation for potential commercial operations;

- the costs of future commercialization activities, including the commercial launch, product sales, marketing, manufacturing and distribution, for Twirla, if approved;

- the revenue, if any, received from commercial sales of Twirla, if approved;

- 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 even terminate our operations, 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, 2017 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(In thousands)		
Term loan	$ 14,066	$ 7,395	$ 6,671		
Operating lease	639	198	441		
Total	$ 14,705	$ 7,593	$ 7,112	$	$

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 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 $19.3 million.

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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 Hercules Loan Agreement was further amended in May 2017 to extend the period during which we can draw the second tranche of $8.5 million to January 31, 2018 and continues to make the Second Term Loan Advance subject to the consent of Hercules, among other customary conditions. The First Amendment also extended the 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 provides that the Term Loan will mature on December 1, 2018. 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 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. On February 1, 2017, we began making principal payments with respect to the Hercules Loan.

We may prepay all, but not less than all, of the Hercules Loan subject to a prepayment premium of 3.0% of the outstanding principal if prepaid during the first year, 2.0% of the outstanding principal if prepaid during the second year and 1.0% of the outstanding principal if prepaid after the second year. 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 year ended December 31, 2015, primarily representing a prepayment premium and the write off of deferred financing costs.

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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 and the third quarter of 2017, we completed offerings 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.

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 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.

2017 Public Offering of Common Stock

In August 2017, we completed an underwritten public offering of 5,333,334 shares of common stock registered under the 2015 Shelf Registration Statement at a public offering price of $3.75 per share. Proceeds from this public offering, net of underwriting discounts, commissions and other offering costs were approximately $18.5 million.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 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. We adopted ASU 2014-15 in the fourth quarter of 2016, which resulted in no change to our financial statements. Additionally, we will perform quarterly evaluations to identify current conditions which may raise substantial doubt about the entity s ability to continue as a going concern within one year after the date that the financial statements are issued. See Note 1 to our financial statements for additional information on our liquidity risks and management s plans.

In February 2016, the FASB issued ASU 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.

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In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* This ASU eliminates the requirement to consider down round features when determining whether certain equity-linked financial instruments or embedded features are indexed to an entity s own stock. ASU 2017-11 is effective for annual periods beginning after December 31, 2018. Early adoption is permitted. We are currently evaluating the impact of the adoption of ASU 2017-11 on our financial statements.

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

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, financing, exchange rates or other factors. These market risks are principally limited to interest rate fluctuations.

We had cash and cash equivalents of $43.8 million and $48.8 million at September 30, 2017 and December 31, 2016, 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.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the three and nine months ended September 30, 2017, respectively.

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.

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Changes to Internal Controls Over Financial Reporting

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.

On January 6, 2017, and January 20, 2017, two previously disclosed complaints captioned *Peng v. Agile Therapeutics, Inc., Alfred Altomari, and Elizabeth Garner*, No. 17-cv-119 (D.N.J.), and *Lichtenthal v. Agile Therapeutics, Inc., Alfred Altomari, and Elizabeth Garner*, No. 17-cv-405 (D.N.J.), respectively, were filed in the United States District Court for the District of New Jersey on behalf of a putative class of investors who purchased shares of the Company s common stock from March 9, 2016, through January 3, 2017. The complaints alleged violations of the federal securities laws based on public statements made regarding our Phase 3 SECURE clinical trial and sought an unspecified amount of damages to be determined at trial. We denied all allegations in the complaints. On May 15, 2017, the complaints were consolidated as *In re Agile Therapeutics, Inc. Securities Litigation*, Master File No. 17-cv-119 (D.N.J.), and Hoyt W. Clark was appointed as class representative for the putative class. On June 26, 2017, Mr. Clark agreed to dismiss the case voluntarily, without payment by us of any consideration and with each side bearing its own attorneys fees and costs. The presiding judge dismissed the consolidated action with prejudice as to all defendants on July 13, 2017.

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.

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 a new drug application, or 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 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, or resubmission, of an NDA, the FDA must make an initial determination that

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the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions we might make will be accepted for filing and review by the FDA, or ultimately be approved. If the application is not approved, the FDA may require that we conduct additional clinical or preclinical trials, or take other actions before it will reconsider our application, which we experienced in the previous submission of our NDA for Twirla in 2012. 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.

We have previously conducted two Phase 3 clinical trials for Twirla, and we filed an 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. We have continued to interact with the FDA on its CMC and other questions and continued additional supportive testing in order to respond to the FDA s CMC questions. In addition, we have gathered the requested information and have conducted 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 and was completed in December 2016. In January 2017, we announced top-line results. Based on the results of the SECURE clinical trial and additional information relating to the manufacture of Twirla, we resubmitted our NDA which was received by the FDA on June 26, 2017, acknowledged as a complete response ready for FDA review on July 27, 2017, and assigned a target goal date under the Prescription Drug User Fee Act, or PDUFA, for completion of the FDA s review, or Target PDUFA Goal Date, of December 26, 2017. Our NDA resubmission, as discussed more fully below, is intended to be a complete response to the CRL. Although we met with the FDA in October 2013 to discuss an additional Phase 3 clinical trial as requested in the CRL 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 assessment regarding the completed SECURE clinical trial. In March 2017, at our request, we met with the FDA to share preliminary data from the SECURE clinical trial, including key safety data and BMI-related efficacy findings, and to seek FDA input as to whether the SECURE clinical trial results constitute a basis for addressing the clinical deficiencies cited in the CRL. We also requested feedback on whether the proposed Twirla NDA content will meet the FDA s requirements for submission. In April 2017, we received final meeting minutes from our March 2017 meeting with the FDA. The FDA indicated that based on the preliminary information provided by us, the SECURE clinical trial results appear acceptable for resubmission and provided feedback on our proposed approach to the FDA s other questions in the CRL, including those questions relating to our analysis to support manufacturing controls and release specifications and our use of laser etching on the Twirla patches. The FDA further provided responses to us regarding the presentation of efficacy, safety and clinical pharmacology analyses in the NDA and requested that subgroup analysis of efficacy by body weight be provided. The FDA did not provide us with any feedback on whether the results of the SECURE clinical trial and the contents of the planned, resubmitted NDA would be sufficient to obtain regulatory approval of Twirla. Our resubmitted NDA included efficacy and safety data from the SECURE clinical trial, the requested manufacturing information, and a summary response to the CRL and is intended to address the questions raised in the CRL. We cannot predict whether regulators will agree with our conclusions regarding the results of the SECURE clinical trial or any clinical trials we have conducted to date, including whether our data are reliable and generalizable. For example, based on the SECURE top-line data, the Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06, but in the obese subpopulation of subjects 35 years of age and under, the Pearl Index was 6.42 with an upper-bound of the 95% confidence interval of 8.88. If we were to exclude the top-line data on the obese subpopulation, our Pearl Index for non-obese patients was 3.94 with an upper-bound of the 95% confidence interval of 5.35. The highest Pearl Index for a hormonal contraceptive product approved by the FDA to date was 3.19 and the highest upper-bound of the 95% confidence interval was 5.03. In the combined safety database for our three Agile Phase 3 trials (n>3,000), there were 5 subjects with potentially study drug related deep vein thromboses, or DVTs, or pulmonary embolisms, or PEs, 4 of whom were obese (BMI $\geq$ 30 kg/m2). Although ultimate

approvability of a hormonal contraceptive is based on a risk/benefit assessment of the overall safety and efficacy profile of a product, not only a specific Pearl Index, the FDA could conclude that the Pearl Index is too high to demonstrate efficacy and an adequate risk/benefit profile for either the overall study population or a subgroup of the study population. Accordingly, the FDA may not approve our Twirla NDA. Alternatively, the FDA may determine that for a specific subgroup of patients, Twirla has lower efficacy and presents a higher risk, necessitating labeling restrictions. For instance, the FDA may require labeling restrictions on the use of Twirla for patients in certain BMI categories. As such, we may not obtain approval of Twirla based on these data or any other basis, or if approved,

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may only receive approval with significant labeling restrictions. In addition, the FDA may re-inspect our manufacturing partner s facilities as well as SECURE clinical trial sites during its review of our resubmission before approval can be granted. The FDA may also determine that our responses to the manufacturing questions in the CRL are not sufficient or require additional analyses and/or studies and deny approval of the Twirla NDA on this basis as well.

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. For example, we believe that Twirla, if approved, will have labeling 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 boxed warning regarding risks of smoking and CHC use, particularly in women over 35 years old who smoke. However, regulatory authorities may require the inclusion of additional statements about adverse events in the labeling, including additional black box warnings or contraindications. 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 our operations at planned levels and be forced to reduce, or even terminate, our operations.

The publicly reported results of the SECURE clinical trial are based on top-line data and may ultimately differ from actual results submitted to the FDA.

In January 2017, we publicly reported top-line results of the SECURE clinical trial. Generally, top-line results are based on preliminary analyses of efficacy and safety data, and therefore the reported results, findings and conclusions related to the SECURE clinical trial were subject to change following the full analysis. Since the initial reporting of the top-line data, all analyses as planned in the statistical analysis plan have been completed and submitted to the FDA. Additional public disclosures of clinical trial data have also been provided in the form of posters and an oral presentation although such public disclosures did not contain the complete, final clinical trial results. The clinical trial data that were submitted to the FDA in our NDA for Twirla on June 26, 2017, contained the final, complete clinical trial results, and contain minor differences from the results that were reported in January 2017 and subsequent posters and oral presentation. While, as expected, minor updates in the study results have occurred since the original top-line data were reported, we believe the overall conclusions regarding the efficacy and safety results of the SECURE clinical trial have not changed. However, third parties, including regulatory agencies,

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may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the potential for approval of Twirla, or if approved, the labeling and commercial value of Twirla and our business in general.

The FDA may disagree with our interpretation of clinical results obtained from the SECURE clinical trial, our results do not guarantee support for regulatory approval of our NDA, and, even if the SECURE clinical trial data are deemed to be positive by the FDA, the FDA may disagree with other aspects of the SECURE clinical trial and decline to approve Twirla for the proposed indication.

We have reported positive top-line data from the SECURE clinical trial. However, even if we believe that the data from the SECURE clinical trial are positive, the FDA could determine that the data from the SECURE clinical trial were negative or inconclusive or could reach a different conclusion than we did on that same data. Negative or inconclusive results of a clinical trial or difference of opinion could cause the FDA to decline to approve our application or require us to repeat the trial or conduct additional clinical trials prior to obtaining approval for commercialization, and there is no guarantee that additional trials would achieve positive results to the satisfaction of the FDA or that the FDA will agree with our interpretation of the results. Any such determination by the FDA would delay the timing of our commercialization plan for Twirla or prevent its further development, or the further development of our other product candidates, and adversely affect our business operations. Additionally, the FDA may provide review commentary at any time during the resubmission and review process which could delay the review timeline, adversely affect the review process, or even prevent the approval of Twirla, any of which would adversely affect our business. We may not be able to appropriately remedy issues that the FDA may raise in its review of our NDA resubmission, and we may not have sufficient time or financial resources to conduct future activities to remediate issues raised by the FDA.

In March 2017, at our request, we met with the FDA to share preliminary data from the SECURE clinical trial, including key safety data and BMI-related efficacy findings, and to seek FDA input as to whether the SECURE clinical trial results constitute a basis for addressing the clinical deficiencies cited in the CRL. We also requested feedback on whether the proposed Twirla NDA content will meet the FDA s requirements for submission. In April 2017, we received final meeting minutes from our March meeting with the FDA. The FDA indicated that based on the preliminary information provided by us, the SECURE clinical trial results appear acceptable for resubmission and provided feedback on our proposed approach to the FDA s other questions in the CRL, including those questions relating to analysis to support manufacturing controls and release specifications and use of laser etching on the Twirla patches. The FDA further provided responses to us regarding the presentation of efficacy, safety and clinical pharmacology analyses in the NDA and requested that subgroup analysis of efficacy by body weight be provided. The FDA did not provide us with any feedback on whether the results of the SECURE clinical trial and the contents of the planned, resubmitted NDA will be sufficient to obtain regulatory approval of Twirla. There is no guarantee that the data obtained from the SECURE clinical trial will be supportive of, or guarantee, or result in our successfully obtaining FDA approval of Twirla in a timely fashion and for a commercially viable indication, if at all. For example, the FDA could determine that the trial did not meet its objectives, or the FDA could still have concerns regarding the conduct of the SECURE clinical trial, including regarding discontinuance of subjects from the trial. At any future point in time, the FDA could require us to complete further clinical or preclinical trials, or take other actions which could delay or preclude approval of the NDA and would require us to obtain significant additional funding. There is no guarantee such funding would be available to us on favorable terms, if at all, nor is there any guarantee that FDA would consider any additional information complete or sufficient to support approval. During its review of the Twirla resubmission NDA, the FDA may hold an advisory committee meeting to obtain committee input on the safety and efficacy of Twirla. Typically, advisory committees will provide responses to specific questions asked by the FDA, including the committee s view on the approvability of the product candidate under review. Advisory committee decisions are not binding but an adverse decision at the advisory committee may have a negative impact on the regulatory review of Twirla. Additionally, we may choose to engage in the dispute resolution process with the FDA if we do not receive approval, which could extend the timeline for any potential approval.

Further, we have resubmitted our NDA for Twirla with the clinical data from the SECURE clinical trial and there is no guarantee that such data will be deemed sufficient by the FDA. While we designed the protocols for the SECURE clinical trial to address the issues raised in the CRL, there is no guarantee that the FDA will deem such

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protocols or results from the study sufficient to address those issues when they are formally reviewed as a part of an NDA resubmission or to demonstrate safety and efficacy to the satisfaction of the FDA. The FDA has significant discretion in the review process, and we cannot predict whether the FDA will agree with our conclusions regarding the results of the SECURE clinical trial, including whether our data are reliable and generalizable. For example, the FDA may disagree with our calculations relating to the number of pregnancies occurring on study, or may view the SECURE data as insufficient to demonstrate a favorable benefit/risk profile for approval for the proposed indication. In addition, based on top-line data, the Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06, but in the obese subpopulation of subjects 35 years of age and under, the Pearl Index was 6.42 with an upper-bound of the 95% confidence interval of 8.88. If we were to exclude the top-line data on the obese subpopulation, our Pearl Index for non-obese patients was 3.94 with an upper-bound of the 95% confidence interval of 5.35. The highest Pearl Index for a hormonal contraceptive product approved by the FDA to date was 3.19 and the highest upper-bound of the 95% confidence interval was 5.03. In the combined safety database for our three Agile Phase 3 trials (n>3,000), there were 5 subjects with potentially study drug related DVTs or PEs, 4 of whom were obese (BMI $\geq$ 30 kg/m2). Although ultimate approvability of a hormonal contraceptive is based on a risk/benefit assessment of the overall safety and efficacy profile of a product, not only a specific Pearl Index, the FDA could conclude that our Pearl Index for either the overall study population or a subgroup of the study population or only the non-obese study population is too high to demonstrate efficacy and an adequate risk/benefit profile, and as such, the FDA could decline to approve Twirla on this or any other basis. Further, the FDA may not agree with our analysis of the relationship between BMI and efficacy for Twirla and the FDA may interpret our overall data differently than we do and may decline to approve Twirla on this or any other basis.

Moreover, even if we obtain approval of Twirla, any such approval might significantly limit the approved indications for use, including by limiting the approved label for use by more limited patient populations than we propose, 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 Twirla. For example, the FDA may deem the higher Pearl Index in the obese subpopulation when combined with safety findings for this subpopulation to warrant a labeling limitation or warning for such subpopulation, which could limit the commercial potential of the product, if approved. Moreover, because we did not conduct any head-to-head studies of Twirla against Ortho Evra, we will not be able to make direct comparative claims regarding the safety, efficacy or pharmacokinetics of Twirla and Ortho Evra or its generic version, Xulane®.

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 application. The SECURE 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 the FDA could conclude that there was significant variability in the safety and efficacy results of these trials. Additionally, while our SECURE clinical trial was designed and implemented in a manner to address the FDA s comments and guidance, it is possible that the FDA could conclude the data are not supportive of approval, 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.

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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 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. For example, consistent with other recent hormonal contraceptive clinical trials, including Ortho Evra® and Quartette®, and the 2015 meta-analysis conducted by FDA authors on the effect of obesity on the effectiveness of hormonal contraceptives, a relationship between obesity and efficacy was observed among subjects 35 years of age and under in our SECURE clinical trial. 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. The FDA may interpret the data from the SECURE clinical trial differently than we do and may decline to approve Twirla on this or any other basis.

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 original Phase 3 clinical trials for Twirla and we experienced slower than anticipated enrollment in our SECURE clinical 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 Phase 3 clinical trials for Twirla completed prior to SECURE;

- 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;

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- 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.

In December 2016, we completed our SECURE 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 two Phase 3 clinical trials for Twirla completed prior to SECURE, 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 clinical trial of Twirla, which we began enrolling in the fourth quarter of 2014, and, as a result, we completed the clinical trial in December 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;

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- Our inability to enroll or retain a sufficient number of subjects who meet the inclusion and exclusion criteria in our clinical trials;

- 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 adequately address the FDA s request in the CRL for additional information on controls and release specifications related to Twirla, and manufacturing and control information related to the Drug Master File of one of the raw materials in Twirla, and 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.

In December 2016, we completed our Phase 3 SECURE clinical trial and announced top-line data in early January 2017. In March 2017, at our request, we met with the FDA to share preliminary data from the SECURE clinical trial, including key safety data and BMI-related efficacy findings, and to seek FDA input as to whether the SECURE clinical trial results constitute a basis for addressing the clinical deficiencies cited in the CRL. We also requested feedback on whether the proposed Twirla NDA content will meet the FDA s requirements for submission. In April 2017, we received final meeting minutes from our March meeting with the FDA. The FDA indicated that based on the preliminary information provided by us, the SECURE clinical trial results appear acceptable for resubmission and provided feedback on our proposed approach to the FDA s other questions in the CRL, including those questions relating to analysis to support manufacturing controls and release specifications and use of laser etching on the Twirla patches. The FDA further provided responses to us regarding the presentation of efficacy, safety and clinical pharmacology analyses in the NDA and requested that subgroup analysis of efficacy by body weight be provided. The FDA did not provide us with any feedback on whether the results of the SECURE clinical trial and the contents of the planned, resubmitted NDA will be sufficient to obtain regulatory approval of Twirla. Our resubmitted NDA was received by the FDA on June 26, 2017 and acknowledged as a complete response ready

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for FDA review on July 26, 2017, with a Target PDUFA Goal Date of December 26, 2017. The resubmitted NDA included efficacy and safety data from the SECURE clinical trial, the requested manufacturing information, and a summary response to the CRL and is intended to address the questions raised in the CRL. 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 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, and we may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

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 original NDA for Twirla requesting, among other items, an additional Phase 3 clinical study, which has delayed our ability to obtain regulatory approval for that product candidate. We may also experience delays due to 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 Phase 3 trials completed prior to the SECURE clinical trial, 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 DVT. 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. In the SECURE clinical trial, SAEs were observed in approximately 2.0% of the SECURE clinical trial population, and 0.6% of subjects had SAEs that were considered potentially study drug related, including DVT, PE, gallbladder disease, ectopic pregnancy, and depression. In the combined safety database for the three Agile Phase 3 trials (n >3,000), there were 5 subjects with potentially study drug related DVTs or PEs, 4 of whom were obese (BMI >30kg/m2).

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. For instance, FDA may determine that for specific subgroups of patients, Twirla has lower efficacy and presents a higher risk. Accordingly, FDA may not approve our Twirla NDA or may require labeling restrictions. By example, FDA may require labeling restrictions on the use of Twirla for patients in certain BMI categories. Adverse effects in any clinical trial could also impact subject recruitment or the

NOTE G – SUPPLEMENTAL BALANCE SHEET INFORMATION

Components of selected captions in our accompanying unaudited condensed consolidated balance sheets are as follows:

Cash, cash equivalents, restricted cash and restricted cash equivalents

(in millions)	As of March 31, 2018	December 31, 2017
Cash and cash equivalents	$287	$ 188
Restricted cash included in Other current assets	850	803
Restricted cash included in Other long-term assets	31	26
Total cash, cash equivalents and restricted cash	$1,168	$ 1,017

Trade accounts receivable, net

(in millions)	As of March 31, 2018	December 31, 2017
Accounts receivable	$1,650	$ 1,645
Allowance for doubtful accounts	(67)	(68)
Allowance for sales returns	—	(30)
Other sales reserves	(3)	—
	$1,580	$ 1,548

Note: Due to the adoption of FASB ASC Topic 606 effective January 1, 2018, the allowance for sales returns has been prospectively reclassified from Trade accounts receivable, net to Other current liabilities within the unaudited condensed consolidated balance sheets. Prior period balances remain unchanged.

The following is a rollforward of our allowance for doubtful accounts:

(in millions)	Three Months Ended March 31, 2018	2017
Beginning balance	$68	$73
Net charges to expenses	4	3
Utilization of allowances	(5)	(1)
Ending balance	$67	$75

Inventories

(in millions)	As of March 31, 2018	December 31, 2017
Finished goods	$717	$ 685
Work-in-process	105	110
Raw materials	291	284
	$1,113	$ 1,078

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Property, plant and equipment, net

(in millions)	As of March 31, 2018	December 31, 2017
Land	$103	$ 102
Buildings and improvements	1,132	1,120
Equipment, furniture and fixtures	3,246	3,183
Capital in progress	215	219
	4,696	4,625
Accumulated depreciation	(2,996)	(2,928)
	$1,700	$ 1,697

Depreciation expense was $68 million for the first quarter of 2018 and $63 million for the first quarter of 2017.

Accrued expenses

(in millions)	As of March 31, 2018	December 31, 2017
Legal reserves	$1,255	$ 1,176
Payroll and related liabilities	488	591
Accrued contingent consideration	62	36
Other	643	653
	$2,447	$ 2,456

Other long-term liabilities

(in millions)	As of March 31, 2018	December 31, 2017
Accrued income taxes	$1,119	$ 1,275
Legal reserves	256	436
Accrued contingent consideration	92	133
Other	787	525
	$2,254	$ 2,370

NOTE H – INCOME TAXES

Our effective tax rate from continuing operations is presented below:

	Three Months Ended March 31,	
	2018	2017
Effective tax rate from continuing operations	8.0%	4.9%

The change in our reported tax rates for the first quarter of 2018, as compared to the same period in 2017, relates primarily to the impact of certain receipts and charges that are taxed at different rates than our effective tax rate, including intangible asset impairment charges, acquisition-related items, restructuring items, litigation-related items, as well as certain discrete tax items including impacts of the Tax Cuts and Jobs Act (TCJA), enacted on December 22, 2017.

As of March 31, 2018, we had $1.240 billion of gross unrecognized tax benefits, of which a net $1.157 billion, if recognized, would affect our effective tax rate. As of December 31, 2017, we had $1.238 billion of gross unrecognized tax benefits, of which a net $1.150 billion, if recognized, would affect our effective tax rate.

We have received Notices of Deficiency from the Internal Revenue Service (IRS) reflecting proposed audit adjustments for Guidant Corporation for its 2001 through 2006 tax years and for Boston Scientific Corporation for its 2006 and 2007 tax years. The total

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incremental tax liability asserted by the IRS for the applicable periods is $1.162 billion plus interest. The primary issue in dispute for all years is the transfer pricing associated with the technology license agreements between domestic and foreign subsidiaries of Guidant. In addition, the IRS has proposed adjustments in connection with the financial terms of our Transaction Agreement with Abbott Laboratories pertaining to the sale of Guidant's vascular intervention business to Abbott Laboratories in April 2006. During 2014, we received a Revenue Agent Report from the IRS reflecting significant proposed audit adjustments to our 2008, 2009 and 2010 tax years based upon the same transfer pricing methodologies that the IRS applied to our 2001 through 2007 tax years.

We do not agree with the transfer pricing methodologies applied by the IRS or its resulting assessment. We have filed petitions with the U.S. Tax Court contesting the Notices of Deficiency for the 2001 through 2007 tax years in challenge and submitted a letter to the IRS Office of Appeals protesting the Revenue Agent Report for the 2008 through 2010 tax years and requesting an administrative appeal hearing. The issues in dispute were scheduled to be heard in U.S. Tax Court in July 2016. On July 19, 2016, we entered into a Stipulation of Settled Issues with the IRS intended to resolve all of the aforementioned transfer pricing issues, as well as the issues related to our transaction with Abbott Laboratories, for the 2001 through 2007 tax years. The Stipulation of Settled Issues was contingent upon the IRS Office of Appeals applying the same basis of settlement to all transfer pricing issues for the Company’s 2008, 2009 and 2010 tax years as well as review by the United States Congress Joint Committee on Taxation (JCT). In October 2016, we reached an agreement in principle with the IRS Office of Appeals as to the resolution of transfer pricing issues in 2008, 2009 and 2010 tax years, subject to additional calculations of tax as well as documentation to memorialize our agreement. The IRS has recalculated our final tax liabilities under this agreement for all of our tax years from 2001 through 2010 and the JCT has completed its review of the recalculations for the 2001 through 2010 tax years.

In the event that the conditions in the Stipulation of Settled Items are satisfied, we expect to make net tax payments of approximately $275 million, plus interest through the date of payment with respect to the settled issues. If finalized, payments related to the resolution are expected in the next six months. We believe that our income tax reserves associated with these matters are adequate as of March 31, 2018 and we do not expect to recognize any additional charges related to resolution of this controversy. However, the final resolution of these issues remains contingent and if the Stipulation of Settled Issues is not finalized, it could have a material impact on our financial condition, results of operations, or cash flows.

We recognize interest and penalties related to income taxes as a component of income tax expense. We had $675 million accrued for gross interest and penalties as of March 31, 2018 and $655 million as of December 31, 2017. We recognized net tax expense related to interest and penalties of $17 million during the first quarter of 2018 and $13 million in the first quarter of 2017.

It is reasonably possible that within the next 12 months we will resolve multiple issues including transfer pricing and transactional-related issues with foreign, federal and state taxing authorities, in which case we could record a reduction in our balance of unrecognized tax benefits of up to approximately $897 million.

There are a number of key provisions under the TCJA that impact us and we continue to monitor and analyze the ramification of the new law as the implementation is executed. The final impact of the TCJA may differ from the estimates reported due to, among other things, changes in interpretations and assumptions made by us, additional guidance that may be issued by the U.S. Department of the Treasury and actions that we may take as a result. The TCJA reduces the US Federal corporate income tax rate from 35 percent to 21 percent, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred, and creates new taxes on certain foreign sourced earnings. Due to insufficient guidance, as well as the availability of information to accurately analyze the impact of the TCJA, we have made a reasonable estimate of the effects, as described below and in other cases we have not been able to make a reasonable estimate and continue to account for those items based on

our existing accounting under FASB ASC Topic 740, Income Taxes and the provisions of the tax laws that were in effect immediately prior to enactment. In the first quarter of 2018, we recognized an additional tax benefit of $9 million, resulting in a total provisional estimate of $852 million related to the TCJA.

We are required to record deferred tax assets and liabilities based on the enacted tax rates at which they are expected to reverse in the future. Therefore, any U.S. related deferred taxes were re-measured from 35 percent down to 21 percent based on the recorded balances as of December 31, 2017. The analysis included a preliminary assessment on the deductibility of certain amounts for which deferred tax assets may have been recorded. However, we are still analyzing certain aspects of the TCJA and refining our calculations based on the available information, which could potentially affect the measurement of these balances or give rise to new deferred tax amounts. As of March 31, 2018, we have not adjusted our provisional estimate related to re-measurement of our deferred tax balances. As of December 31, 2017, we recorded an estimated tax benefit of approximately $99 million.

We are required to calculate a one-time transition tax based on our total post-1986 foreign earnings and profits (E&P) that we previously deferred from U.S. income taxes. In the first quarter of 2018, we recognized an additional tax benefit of $9 million, which results in a revised provisional amount of approximately $1.035 billion. We anticipate offsetting this liability against existing

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tax attributes reducing the required payment to approximately $454 million which will be remitted over an eight year period. We have not yet completed our calculation of the total post-1986 E&P for these foreign subsidiaries and we continue to refine the analysis. Additionally, no income taxes have been provided for any remaining undistributed foreign earnings that are not subject to the transition tax or any additional outside basis difference inherent in these entities, as we expect these amounts will remain indefinitely reinvested in foreign operations. Determining the amount of unrecognized deferred tax liability related to any remaining undistributed foreign earnings not subject to the transition tax and additional outside basis difference in these entities is not practicable.

We are subject to a territorial tax system under the TCJA, in which we are required to provide for tax on Global Intangible Low Taxed Income (GILTI) earned by certain foreign subsidiaries. Additionally, we are required to make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or provide for the tax expense related to GILTI in the year the tax is incurred as a period expense. As of March 31, 2018, we are still evaluating the effects of the GILTI provisions as guidance and interpretations continue to emerge. Therefore, we have not determined our accounting policy on the GILTI provisions. However, the standard requires that we reflect the impact of the GILTI provisions as a period expense until the accounting policy is finalized. Therefore, we have included the provisional estimate of GILTI related to current-year operations in our estimated annual effective tax rate only and will be updating the impact and accounting policy as the analysis related to the GILTI provisions is completed.

NOTE I – COMMITMENTS AND CONTINGENCIES

The medical device market in which we primarily participate is largely technology driven. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. Over the years, there has been litigation initiated against us by others, including our competitors, claiming that our current or former product offerings infringe patents owned or licensed by them. Intellectual property litigation is inherently complex and unpredictable. In addition, competing parties frequently file multiple suits to leverage patent portfolios across product lines, technologies and geographies and to balance risk and exposure between the parties. In some cases, several competitors are parties in the same proceeding or in a series of related proceedings or litigate multiple features of a single class of devices. These forces frequently drive settlement not only for individual cases, but also for a series of pending and potentially related and unrelated cases. Although monetary and injunctive relief is typically sought, remedies and restitution are generally not determined until the conclusion of the trial court proceedings and can be modified on appeal. Accordingly, the outcomes of individual cases are difficult to time, predict or quantify and are often dependent upon the outcomes of other cases in other geographies.

During recent years, we successfully negotiated closure of several long-standing legal matters and have received favorable rulings in several other matters, however, there continues to be outstanding intellectual property litigation. Adverse outcomes in one or more of these matters could have a material adverse effect on our ability to sell certain products and on our operating margins, financial position, results of operations and/or liquidity.

In the normal course of business, product liability, securities and commercial claims are asserted against us. Similar claims may be asserted against us in the future related to events not known to management at the present time. We maintain an insurance policy providing limited coverage against securities claims and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims or adverse decisions. Product liability claims, securities and commercial litigation and other legal proceedings in the future, regardless of their outcome, could have a material adverse effect on our financial position, results of operations and/or liquidity.

In addition, like other companies in the medical device industry, we are subject to extensive regulation by national, state and local government agencies in the U.S. and other countries in which we operate. From time to time we are the subject of qui tam actions and governmental investigations often involving regulatory, marketing and other business practices. These qui tam actions and governmental investigations could result in the commencement of civil and criminal proceedings, substantial fines, penalties and administrative remedies and have a material adverse effect on our financial position, results of operations and/or liquidity.

In accordance with FASB ASC Topic 450, Contingencies, we accrue anticipated costs of settlement, damages, losses for product liability claims and, under certain conditions, costs of defense, based on historical experience or to the extent specific losses are probable and estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range.

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Our accrual for legal matters that are probable and estimable was $1.511 billion as of March 31, 2018 and $1.612 billion as of December 31, 2017 and includes certain estimated costs of settlement, damages and defense. As of March 31, 2018 and December 31, 2017, a portion of our legal accrual is funded and included in our restricted cash balance as disclosed in Note G – Supplemental Balance Sheet Information. We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

In management's opinion, we are not currently involved in any legal proceedings other than those disclosed in our most recent Annual Report on Form 10-K and those specifically identified below, which, individually or in the aggregate, could have a material adverse effect on our financial condition, operations and/or cash flows. Unless included in our legal accrual or otherwise indicated below, a range of loss associated with any individual material legal proceeding cannot be estimated.

Patent Litigation

On November 9, 2015, Edwards Lifesciences, LLC filed an invalidity claim against one of our subsidiaries, Sadra Medical, Inc. (Sadra), in the High Court of Justice, Chancery Division Patents Court in the United Kingdom, alleging that a European patent owned by Sadra relating to a repositionable heart valve is invalid. On January 15, 2016, we filed our defense and counterclaim for a declaration that our European patent is valid and infringed by Edwards. On February 25, 2016, we amended our counterclaim to allege infringement of a second patent related to adaptive sealing technology. A trial was held from January 18 to January 27, 2017. On March 3, 2017, the court found one of our patents valid and infringed and some claims of the second patent invalid and the remaining claims not infringed. Both parties have filed an appeal. On March 28, 2018, the Court of Appeals affirmed the decision of the High Court.

On April 19, 2016, a subsidiary of Boston Scientific filed suit against Edwards Lifesciences Corporation in the U.S. District Court for the District of Delaware for patent infringement. We allege that Edwards' SAPIEN™ 3 Valve infringes a patent related to adaptive sealing technology. On June 9, 2016, Edwards filed a counterclaim alleging that our Lotus™ Valve System infringes three patents owned by Edwards. On October 12, 2016, Edwards filed a petition for inter partes review of our patent with the U.S. Patent and Trademark Office (USPTO), Patent Trial and Appeal Board. On March 29, 2017, the USPTO granted the inter partes review request. On April 18, 2017, Edwards filed a second petition for inter partes review of our patent with the USPTO. On March 23, 2018, the USPTO found the patent invalid. The Company plans to appeal that decision.

On April 26, 2016, Edwards Lifesciences PVT, Inc. filed a patent infringement action against us and one of our subsidiaries, Boston Scientific Medizintechnik GmbH, in the District Court of Düsseldorf, Germany alleging a European patent (Spenser '550) owned by Edwards is infringed by our Lotus Transcatheter Heart Valve System. The trial began on February 7, 2017. On March 9, 2017, the court found that we infringed the Spenser '550 patent. The Company filed an appeal. The appeal hearing is scheduled for May 17, 2018. On April 13, 2018, the '550 patent was revoked by the European Patent Office.

On December 22, 2016, Edwards Lifesciences PVT, Inc. and Edwards Lifesciences SA (AG) filed a plenary summons against Boston Scientific Limited and Boston Scientific Group Public Company in the High Court of Ireland alleging that a European patent (Spenser) owned by Edwards is infringed by our Lotus Valve System. On April 13, 2018, the '550 patent was revoked by the European Patent Office.

On November 20, 2017, The Board of Regents, University of Texas System (UT) and TissueGen. Inc. (TissueGen), served a lawsuit against us in the Western District of Texas. The complaint against us alleges patent infringement of two U.S. patents owned by UT, relating to "Drug Releasing Biodegradable Fiber Implant" and "Drug Releasing

Biodegradable Fiber for Delivery of Therapeutics," and affects the manufacture, use and sale of our Synergy™ Stent System. On March 12, 2018, the court dismissed the action and transferred it to the United States District Court for the District of Delaware.

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Product Liability Litigation

As of April 24, 2018, approximately 49,500 product liability cases or claims related to transvaginal surgical mesh products designed to treat stress urinary incontinence and pelvic organ prolapse have been asserted against us. The pending cases are in various federal and state courts in the United States and include eight putative class actions. There were also approximately 20 cases in Canada, inclusive of one certified and three putative class actions and fewer than 25 claims in the United Kingdom. Generally, the plaintiffs allege personal injury associated with use of our transvaginal surgical mesh products. The plaintiffs assert design and manufacturing claims, failure to warn, breach of warranty, fraud, violations of state consumer protection laws and loss of consortium claims. Over 3,100 of the cases have been specially assigned to one judge in state court in Massachusetts. On February 7, 2012, the Judicial Panel on Multi-District Litigation (MDL) established MDL-2326 in the United States District Court for the Southern District of West Virginia and transferred the federal court transvaginal surgical mesh cases to MDL-2326 for coordinated pretrial proceedings. During the fourth quarter of 2013, we received written discovery requests from certain state attorneys general offices regarding our transvaginal surgical mesh products. We have responded to those requests. As of April 24, 2018, we have entered into master settlement agreements in principle or are in final stages of entering one with certain plaintiffs' counsel to resolve an aggregate of approximately 47,500 cases and claims. These master settlement agreements provide that the settlement and distribution of settlement funds to participating claimants are conditional upon, among other things, achieving minimum required claimant participation thresholds. Of the approximately 47,500 cases and claims, approximately 21,000 have met the conditions of the settlement and are final. All settlement agreements were entered into solely by way of compromise and without any admission or concession by us of any liability or wrongdoing.

We have established a product liability accrual for known and estimated future cases and claims asserted against us as well as with respect to the actions that have resulted in verdicts against us and the costs of defense thereof associated with our transvaginal surgical mesh products. While we believe that our accrual associated with this matter is adequate, changes to this accrual may be required in the future as additional information becomes available. While we continue to engage in discussions with plaintiffs’ counsel regarding potential resolution of pending cases and claims and intend to vigorously contest the cases and claims asserted against us, that do not settle, the final resolution of the cases and claims is uncertain and could have a material impact on our results of operations, financial condition and/or liquidity. Initial trials involving our transvaginal surgical mesh products have resulted in both favorable and unfavorable judgments for us. We do not believe that the judgment in any one trial is representative of potential outcomes of all cases or claims related to our transvaginal surgical mesh products.

Other Proceedings

Refer to Note H – Income Taxes for information regarding our tax litigation.

NOTE J – WEIGHTED AVERAGE SHARES OUTSTANDING

	Three Months Ended March 31,	
(in millions)	2018	2017
Weighted average shares outstanding - basic	1,376.5	1,365.4
Net effect of common stock equivalents	20.2	24.8
Weighted average shares outstanding - assuming dilution	1,396.8	1,390.2

The impact of stock options outstanding with exercise prices greater than the average fair market value of our common stock was immaterial for all periods presented.

We issued approximately six million shares of our common stock in the first quarter of 2018 and seven million shares of our common stock in the first quarter of 2017, following the exercise of underlying stock options, vesting of deferred stock units or purchases under our employee stock purchase plan. We did not repurchase any shares of our common stock during the first three months of 2018 or 2017.

NOTE K – SEGMENT REPORTING

We have three reportable segments comprised of MedSurg, Rhythm and Neuro, and Cardiovascular, which represent an aggregation of our operating segments.
Each of our reportable segments generates revenues from the sale of medical devices. We measure and evaluate our reportable segments based on segment net sales and operating income, excluding intersegment profits. In 2017, we updated our presentation

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of segment net sales and operating income to the impact of foreign currency fluctuations, since our chief operating decision maker (CODM) reviews operating results both including and excluding the impact of foreign currency fluctuations and the following presentation more closely aligns to our consolidated financial statements. We exclude from segment operating income certain corporate-related expenses and certain transactions or adjustments that our CODM considers to be non-operational, such as amounts related to amortization expense, intangible asset impairment charges, acquisition-related items, restructuring and restructuring-related items and litigation-related items. Although we exclude these amounts from segment operating income, they are included in reported consolidated operating income (loss) and are included in the reconciliation below.

Effective January 1, 2018, following organizational changes to align the company's business and organization structure focused on active implantable devices, we revised our reportable segments, in accordance with FASB ASC Topic 280, Segment Reporting. The revision reflects a reclassification of our Neuromodulation business from our Medical Surgical (MedSurg) segment to our newly created Rhythm and Neuro segment. We have revised prior year amounts to conform to the current year’s presentation (as denoted with an asterisk throughout *). There was no revision to operating segments or reporting units as a result of the organizational change.

A reconciliation of the totals reported for the reportable segments to the applicable line items in our accompanying unaudited condensed consolidated statements of operations is as follows:

(in millions)	Three Months Ended March 31, 2018	2017
Net sales		
MedSurg*	$711	$641
Rhythm and Neuro*	736	668
Cardiovascular	933	851
	$2,379	$2,160
Income (loss) before income taxes		
MedSurg*	$259	$215
Rhythm and Neuro*	153	109
Cardiovascular	290	233
Operating income allocated to reportable segments	703	557
Corporate expenses, including hedging activities	(100)	(61)
Intangible asset impairment charges, acquisition-related, restructuring- and restructuring-related and litigation-related net credits (charges)	(54)	11
Amortization expense	(141)	(143)
Operating income (loss)	407	364
Other expense, net	(84)	(59)
Income (loss) before income taxes	$323	$305

Operating income as a percentage of segment net sales	Three Months Ended March 31, 2018	2017
MedSurg*	36.4%	33.5%
Rhythm and Neuro*	20.8%	16.3%
Cardiovascular	31.1%	27.3%

NOTE L – REVENUE

We generate revenue primarily from the sale of single-use medical devices and present revenue net of sales taxes in our unaudited condensed consolidated statements of operations. The following tables disaggregate our revenue from contracts with customers by business and geographic region:

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Businesses (in millions)	Three Months Ended March 31, 2018	2017
Endoscopy		
U.S.	$231	$215
International	187	164
Worldwide	418	379
Urology and Pelvic Health		
U.S.	197	183
International	96	79
Worldwide	293	262
Cardiac Rhythm Management		
U.S.	290	283
International	203	180
Worldwide	493	463
Electrophysiology		
U.S.	35	32
International	39	32
Worldwide	75	64
Neuromodulation		
U.S.	131	116
International	38	25
Worldwide	169	141
Interventional Cardiology		
U.S.	281	278
International	364	312
Worldwide	645	590
Peripheral Interventions		
U.S.	145	142
International	142	119
Worldwide	288	261
Total Company		
U.S.	1,310	1,249
International	1,069	911
Net Sales	$2,379	$2,160

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Geographic Regions (in millions)	Three Months Ended March 31, 2018	2017
U.S.	$1,310	$1,249
EMEA (Europe, Middle East and Africa)	563	454
APAC (Asia-Pacific)	415	371
LACA (Latin America and Canada)	91	84
	$2,379	$2,160
Emerging Markets (1)	$255	$208

(1) Emerging Markets is defined as certain countries that we believe have strong growth potential based on their economic conditions, healthcare sectors and our global capabilities. Currently, we include 20 countries in our definition of Emerging Markets.

We sell our products primarily through a direct sales force. In certain international markets, we sell our products through independent distributors. We consider revenue to be earned when all of the following criteria are met: we have a contract with a customer that creates enforceable rights and obligations; promised products or services are identified; the transaction price, or the amount we expect to receive, is determinable and we have transferred control of the promised items to the customer. Transfer of control is evidenced upon passage of title and risk of loss to the customer unless we are required to provide additional services. We treat shipping and handling costs performed after a customer obtains control of the good as a fulfillment cost and record these costs as a selling expense when incurred. We recognize revenue from consignment arrangements based on product usage, or implant, which indicates that the sale is complete. We recognize a receivable at the point in time we have an unconditional right to payment. Payment terms are typically 30 days in the U.S., but may be longer in international markets.

Deferred Revenue

We record a contract liability, or deferred revenue, when we have an obligation to provide a product or service to the customer and payment is received or due in advance of our performance. When we sell a device with a future service obligation, we defer revenue on the unfulfilled performance obligation and recognize this revenue over the related service period. Many of our Cardiac Rhythm Management (CRM) product offerings combine the sale of a device with our LATITUDE™ Patient Management System, which represents a future service obligation. Generally, we do not have observable evidence of the standalone selling price related to our future service obligations; therefore we estimate the selling price using an expected cost plus a margin approach. We allocate the transaction price using the relative standalone selling price method. The use of alternative estimates could result in a different amount of revenue deferral.

Contract liabilities are classified as other current liabilities and other long-term liabilities on the balance sheet. Our deferred revenue balance as of March 31, 2018 was $393 million and $411 million as of January 1, 2018. Our contractual liabilities are primarily composed of deferred revenue related to the LATITUDE™ Patient Management System. Revenue is recognized over the average service period which is based on device and patient longevity. During the first quarter of 2018, we recognized $26 million of revenue that was included in the above January 1, 2018 contract liability balance. We have elected not to disclose the transaction price allocated to unsatisfied performance obligations when the original expected contract duration is one year or less. In addition, we have not identified material unfulfilled performance obligations for which revenue is not currently deferred.

Variable Consideration

We generally allow our customers to return defective, damaged and, in certain cases, expired products for credit. We base our estimate for sales returns upon historical trends and record the amount as a reduction to revenue when we sell the initial product. In addition, we may allow customers to return previously purchased products for next− generation product offerings. For these transactions, we defer recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next−-generation products are shipped to the customer. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls and variation in product utilization all affect our estimates related to sales returns and could cause actual returns to differ from these estimates.

We also offer sales rebates and discounts to certain customers. We treat sales rebates and discounts as a reduction of revenue and classify the corresponding liability as current. We estimate rebates for products where there is sufficient historical information available to predict the volume of expected future rebates. If we are unable to estimate the expected rebates reasonably, we record a liability for the maximum rebate percentage offered. We have entered certain agreements with group purchasing organizations

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to sell our products to participating hospitals at negotiated prices. We recognize revenue from these agreements following the same revenue recognition criteria discussed above.

Capitalized Contract Costs

We capitalize commission fees related to contracts with customers when the associated revenue is expected to be earned over a period that exceeds one year. Deferred commissions are primarily related to the sale of devices enabled with our LATITUDE Patient Management System. We have elected to expense commission costs when incurred for contracts with an expected duration of one year or less. Capitalized commission fees are amortized over the period the associated products or services are transferred. Similarly, we capitalize certain recoverable costs related to the delivery of the LATITUDE Remote Monitoring Service. These fulfillment costs are amortized over the average service period. Our total capitalized contract costs are immaterial to our consolidated financial statements.

NOTE M – CHANGES IN OTHER COMPREHENSIVE INCOME

The following table provides the reclassifications out of other comprehensive income, net of tax.

Three Months Ended March 31, 2018

(in millions)	Foreign Currency Translation Adjustments	Unrealized Gains/Losses on Derivative Financial Instruments	Unrealized Gains/Losses on Available-for-Sale Securities	Defined Benefit Pension Items/Other	Total
Balance as of December 31, 2017	$ (32)	$ 1	$ (1)	$ (27)	$(59)
Other comprehensive income (loss) before reclassifications	10	(91)	—	—	(81)
(Income) loss amounts reclassified from accumulated other comprehensive income	—	12	1	—	13
Net current-period other comprehensive income (loss)	10	(80)	—	—	(69)
Balance as of March 31, 2018	$ (22)	$ (79)	$ —	$ (27)	$(128)

Three Months Ended March 31, 2017

(in millions)	Foreign Currency Translation Adjustments	Unrealized Gains/Losses on Derivative Financial Instruments	Unrealized Gains/Losses on Available-for-Sale Securities	Defined Benefit Pension Items/Other	Total
Balance as of December 31, 2016	$ (79)	$ 107	$ (6)	$ (21)	$1
Other comprehensive income (loss) before reclassifications	8	(37)	—	(3)	(32)
(Income) loss amounts reclassified from accumulated other comprehensive income	—	(18)	—	3	(15)
Net current-period other comprehensive income (loss)	8	(55)	—	—	(47)
Balance as of March 31, 2017	$ (71)	$ 52	$ (6)	$ (21)	$(46)

Refer to Note D – Hedging Activities and Fair Value Measurements for further detail on the reclassifications related to derivatives.

We adopted Update No. 2016-01 in the first quarter of 2018, as a result of adopting the standard, we recorded a cumulative effect adjustment to retained earnings for unrealized gains and losses for available-for-sale securities

previously recorded to accumulated other comprehensive income.

The gains and losses on defined benefit and pension related items before reclassifications and gains and losses on defined benefit and pension items reclassified from accumulated other comprehensive income were reduced by immaterial income tax impacts in the first three months of 2018 and 2017.

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NOTE N – NEW ACCOUNTING PRONOUNCEMENTS

Periodically, new accounting pronouncements are issued by the FASB or other standard setting bodies. Recently issued standards typically do not require adoption until a future effective date. Prior to their effective date, we evaluate the pronouncements to determine the potential effects of adoption on our unaudited condensed consolidated financial statements.

Standards to be Implemented

ASC Update No. 2016-02

In February 2016, the FASB issued ASC Update No. 2016-02, Leases (Topic 842). The purpose of Update No. 2016-02 is to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet, including those previously classified as operating leases under current U.S. GAAP and disclosing key information about leasing arrangements. Update No. 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods. Early adoption is permitted and a modified retrospective approach is required for adoption. While we are still in the process of determining the effect that the new standard will have on our financial position and results of operations, we expect to recognize additional assets and corresponding liabilities on our consolidated balance sheets, as a result of our operating lease portfolio as it exists at the date we adopt the new standard. Please refer to Note F - Lease and Other Purchase Obligations in our most recent Annual Report on Form 10-K for information regarding our most current lease activity. Additionally, we are in the process of implementing a new lease administration and lease accounting system, and updating our controls and procedures for maintaining and accounting for our lease portfolio under the new standard. As a result, we anticipate adopting the new standard on January 1, 2019.

ASC Update No. 2016-13

In June 2016, the FASB issued ASC Update No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The purpose of Update No. 2016-13 is to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. Update No. 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods. Early adoption is permitted for annual periods beginning after December 15, 2018. We are in the process of determining the effect that the adoption will have on our financial position and results of operations.

No other new accounting pronouncements, issued or effective, during the period had, or are expected to have, a material impact on our condensed consolidated financial statements.

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

Introduction

Boston Scientific Corporation is a global developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. Our mission is to transform lives through innovative medical solutions that improve the health of patients around the world. Our products and technologies are used to diagnose or treat a wide range of medical conditions, including cardiovascular, digestive, respiratory, urological, pelvic health and neurological conditions. We continue to innovate in these areas and are intent on extending our innovations into new geographies and high-growth adjacency markets. When used in this report, the terms, "we," "us," "our," and "the Company" mean Boston Scientific Corporation and its divisions and subsidiaries.

Financial Summary

Three Months Ended March 31, 2018

Our net sales for the first quarter of 2018 were $2.379 billion, as compared to net sales of $2.160 billion for the first quarter of 2017, an increase of $219 million, or 10.1 percent. Our operational net sales, which exclude a 390 basis point impact of foreign currency fluctuations, increased $136 million, or 6.2 percent as compared to the same period in the prior year.[1] This increase in the first quarter of 2018 included operational net sales of $21 million, with no prior year period related net sales, due to the acquisition of Symetis SA (Symetis) during the second quarter of 2017. Refer to Quarterly Results and Business Overview for a discussion of our net sales by global business.

Our reported net income for the first quarter of 2018 was $298 million, or $0.21 per share. Our reported results for the first quarter of 2018 included certain charges and/or credits totaling $157 million (after-tax), or $0.11 per share. Adjusted net income, which excludes these items, for the first quarter of 2018, was $455 million, or $0.33 per share.[1]

Our reported net income for the first quarter of 2017 was $290 million, or $0.21 per share. Our reported results for the first quarter of 2017 included certain charges and/or credits totaling $107 million (after-tax), or $0.08 per share. Excluding these items, net income for the first quarter of 2017, was $397 million, or $0.29 per share.[1]

[1]Operational net sales, which exclude the impact of foreign currency fluctuations, and adjusted net income and adjusted net income per share, which exclude certain items required by generally accepted accounting principles in the United States (U.S. GAAP), are not prepared in accordance with U.S. GAAP and should not be considered in isolation from, or as a replacement for, the most directly comparable GAAP measure. Refer to Additional Information for a discussion of management's use of these non-GAAP financial measures.

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The following is a reconciliation of our results of operations prepared in accordance with U.S. GAAP to those adjusted results considered by management. Refer to Quarterly Results and Business Overview for a discussion of each reconciling item:

in millions, except per share data	Three Months Ended March 31, 2018 Net income (loss)	Impact per share
GAAP net income (loss)	$298	$0.21
Non-GAAP adjustments:		
Amortization expense	119	0.08
Intangible asset impairment charges	1	0.00
Acquisition-related net charges (credits)	20	0.01
Restructuring and restructuring-related net charges (credits)	22	0.02
Investment impairment charges	5	0.00
Tax Cuts and Jobs Act net charges	(9)	(0.01)
Adjusted net income	$455	$0.33

in millions, except per share data	Three Months Ended March 31, 2017 Net income (loss)	Impact per share
GAAP net income (loss)	$290	$0.21
Non-GAAP adjustments:		
Amortization expense	122	0.09
Acquisition-related net charges (credits)	(32)	(0.02)
Restructuring and restructuring-related net charges (credits)	15	0.01
Litigation-related net charges (credits)	2	0.00
Adjusted net income	$397	$0.29

Cash provided by operating activities was $193 million for the first three months of 2018. As of March 31, 2018, we had total debt of $5.765 billion, cash and cash equivalents of $287 million and a working capital deficit of $908 million. Refer to Liquidity and Capital Resources for further discussion.

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Quarterly Results and Business Overview

The following section describes an overview of our product offerings and results of operations by business unit. For additional information on our businesses and their product offerings, see Item 1. Business of our most recent Annual Report on Form 10-K.

Net Sales

The following table provides our net sales by business and the relative change in growth on a reported basis and operational basis.

	Three Months Ended March 31, 2018		Change				
(in millions)	2018	2017	Reported Basis		Less: Impact of Foreign Currency		Operational Basis	
Endoscopy	$418	$379	10.2	%	4.0	%	6.2	%
Urology and Pelvic Health	293	262	11.8	%	2.6	%	9.2	%
MedSurg*	711	641	10.9	%	3.5	%	7.4	%
Cardiac Rhythm Management	493	463	6.5	%	4.1	%	2.4	%
Electrophysiology	75	64	17.2	%	5.7	%	11.5	%
Neuromodulation	169	141	19.3	%	2.1	%	17.2	%
Rhythm and Neuro*	736	668	10.2	%	3.8	%	6.4	%
Interventional Cardiology	645	590	9.3	%	4.5	%	4.8	%
Peripheral Interventions	288	261	10.1	%	4.1	%	6.0	%
Cardiovascular	933	851	9.5	%	4.3	%	5.2	%
Net Sales	$2,379	$2,160	10.1	%	3.9	%	6.2	%

Effective January 1, 2018, following organizational changes to align the company's business and organization structure focused on active implantable devices, we revised our reportable segments, in accordance with FASB ASC Topic 280, Segment Reporting. The revision reflects a reclassification of our Neuromodulation business from our Medical Surgical (MedSurg) segment to our newly created Rhythm and Neuro segment. We have revised prior year amounts to conform to the current year’s presentation (as denoted with an asterisk throughout *). There was no revision to operating segments or reporting units as a result of the organizational change.

MedSurg

Endoscopy

Our Endoscopy business develops and manufactures devices to diagnose and treat a broad range of gastrointestinal (GI) and pulmonary conditions with innovative, less invasive technologies.

Our net sales of Endoscopy products of $418 million represented approximately 18 percent of our consolidated net sales for the first quarter of 2018. Our Endoscopy net sales increased $39 million, or 10.2 percent, in the first quarter of 2018, as compared to the same period in the prior year. Our operational net sales, which exclude a 400 basis point impact of foreign currency fluctuations, increased 6.2 percent as compared to the same period in the prior year. This year-over-year increase was primarily driven by growth across several of our key product franchises, including our hemostasis franchise featuring our Resolution 360™ Clips, our biliary franchise with our SpyGlass™ DS Direct Visualization System and AXIOS™ Stent and Delivery System for endoscopic ultrasound-guided transluminal drainage

of symptomatic pancreatic pseudocysts, as well as our infection prevention products and pathology services.

Urology and Pelvic Health

Our Urology and Pelvic Health business develops and manufactures devices to treat various urological and pelvic conditions for both male and female anatomies, including kidney stones, benign prostatic hyperplasia, erectile dysfunction, male incontinence, pelvic floor disorders, abnormal uterine bleeding and uterine fibroids and polyps.

Our net sales of Urology and Pelvic Health products of $293 million represented approximately 12 percent of our consolidated net sales for the first quarter of 2018. Urology and Pelvic Health net sales increased $31 million, or 11.8 percent in the first quarter

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of 2018, as compared to the same period in the prior year. Our operational net sales, which exclude a 260 basis point impact of foreign currency fluctuations, increased 9.2 percent as compared to the same period in the prior year. This year-over-year increase was primarily attributable to growth in sales of our kidney stone products, including our LithoVue™ Digital Flexible Ureteroscope, our benign prostatic hyperplasia (BPH) business, and our men's health products, as well as growth across all of our franchises internationally.

Rhythm and Neuro

Cardiac Rhythm Management

Our Cardiac Rhythm Management (CRM) business develops and manufactures a variety of implantable devices that monitor the heart and deliver electricity to treat cardiac abnormalities.

Our net sales of CRM products of $493 million represented approximately 21 percent of our consolidated net sales for the first quarter of 2018. Our net sales of CRM products increased $30 million, or 6.5 percent, in the first quarter of 2018, as compared to the same period in the prior year. Our operational net sales, which exclude a 410 basis point impact of foreign currency fluctuations, increased 2.4 percent as compared to the same period in the prior year. This year-over-year increase was driven by continued EMBLEM™ Subcutaneous Implantable Cardiac Defibrillator (S-ICD) market penetration, the ongoing launch of our RESONATE™ family of implantable cardioverter defibrillators (ICD) and implantable cardiac resynchronization therapy defibrillators (CRT-D) in the U.S. and Europe, as well as the favorable impact from U.S. magnetic resonance imaging (MRI) safe conditional labeling, which was approved by the FDA in September 2017. Our defibrillator growth was partially offset by softness in pacemaker sales.

Electrophysiology

Our Electrophysiology business develops and manufactures less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart, including a broad portfolio of therapeutic and diagnostic catheters and variety of capital equipment used in the electrophysiology lab.

Our net sales of Electrophysiology products of $75 million represented approximately three percent of our consolidated net sales for the first quarter of 2018. Our Electrophysiology net sales increased $11 million, or 17.2 percent, in the first quarter of 2018, as compared to the same period in the prior year. Our operational net sales, which exclude a 570 basis point impact of foreign currency fluctuations, increased 11.5 percent as compared to the same period in the prior year. This year-over-year increase was primarily driven by increased sales of our next generation Rhythmia™ Mapping System, Rhythmia HDx™ Mapping System, related therapeutic and diagnostic catheters, and accessories.

Neuromodulation

Our Neuromodulation business develops and manufactures devices to treat various neurological movement disorders and manage chronic pain.

Our net sales of Neuromodulation products of $169 million represented approximately seven percent of our consolidated net sales for the first quarter of 2018. Neuromodulation net sales increased $27 million, or 19.3 percent, in the first quarter of 2018, as compared to the same period in the prior year. Our operational net sales, which exclude a 210 basis point impact of foreign currency fluctuations, increased 17.2 percent as compared to the same period in the prior year. This year-over-year increase was primarily driven by continued adoption of our Precision Montage™ Spinal Cord Stimulator and the launch of Spectra Wavewriter ™ Technology SCS System and our Vercise™ Deep Brain Stimulation System in the U.S. combined with an increase in international sales.

Cardiovascular

Interventional Cardiology

Our Interventional Cardiology business develops and manufactures technologies for diagnosing and treating coronary artery disease and other cardiovascular disorders including structural heart conditions. Our broad, innovative product offerings have enabled us to become a leader in the global interventional cardiology market.

Our net sales of Interventional Cardiology products of $645 million represented approximately 27 percent of our consolidated net sales for the first quarter of 2018. Our Interventional Cardiology net sales increased $55 million, or 9.3 percent, in the first quarter

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of 2018, as compared to the same period in the prior year. Our operational net sales, which exclude a 450 basis point impact of foreign currency fluctuations, increased 4.8 percent as compared to the same period in the prior year. This year-over-year increase was primarily related to sales of our complex percutaneous coronary interventions (PCI) product offerings driven by new launches, our structural heart product offerings including the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device and the ACURATE™ Transcatheter Aortic Valve, which was part of our Symetis acquisition in May 2017. Growth was partially offset by price challenges within the global drug-eluting coronary stent (DES) market, coupled with a strong prior period comparison for global DES.

Peripheral Interventions

Our Peripheral Interventions business develops and manufactures products used to diagnose and treat peripheral arterial diseases, including a broad line of medical devices used in percutaneous transluminal angioplasty (PTA) and peripheral vascular diseases, as well as products to diagnose, treat and ease various forms of cancer.

Our net sales of Peripheral Interventions products of $288 million represented approximately 12 percent of our consolidated net sales for the first quarter of 2018. Our Peripheral Interventions net sales increased $26 million, or 10.1 percent, in the first quarter of 2018, as compared to the same period in the prior year. Our operational net sales, which exclude a 410 basis point impact of foreign currency fluctuations, increased 6.0 percent as compared to the same period in the prior year. This year-over-year increase was primarily driven by growth in our core franchises, particularly our stent portfolio, our drug-eluting product franchise and our atherectomy systems.

Emerging Markets

As part of our strategic imperatives to drive global expansion, we are seeking to grow net sales and market share by expanding our global presence, including in Emerging Markets. We define Emerging Markets as including 20 countries that we believe have strong growth potential based on their economic conditions, healthcare sectors and our global capabilities. We have increased our investment in infrastructure in these countries in order to maximize opportunities. Our Emerging Markets net sales represented 10.7 percent of our consolidated net sales in the first quarter of 2018 and 9.6 percent in the first quarter of 2017. In the first quarter of 2018, our Emerging Market net sales grew 22.6 percent on a reported basis and excluding a 540 basis point impact of foreign currency fluctuations, grew 17.2 percent on an operational basis, both as compared to the same period in the prior year.

Gross Profit

Our gross profit was $1.707 billion for the first quarter of 2018 and $1.510 billion for the first quarter of 2017. The following is a reconciliation of our gross profit margins and a description of the drivers of the change from period to period:

	Three Months
Gross profit margin - period ended March 31, 2017	69.9 %
Manufacturing cost reductions	1.7
Sales pricing and mix	0.5
Net impact of foreign currency	(1.9)
All other, including inventory changes and other period expense	1.5
Gross profit margin - period ended March 31, 2018	71.7 %

The primary factors contributing to the increase in our gross profit margins during the first quarter, as compared to the same period in 2017, were the positive impacts of cost reductions resulting from our process improvement programs and restructuring programs, along with the 180 basis point impact in the first quarter of 2017 primarily associated with

the voluntary removal of Lotus™ Valve Devices from global, commercial and clinical sites. Partially offsetting these factors was the net negative impact of foreign currency fluctuations.

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Operating Expenses

The following table provides a summary of certain of our operating expenses:

	Three Months Ended March 31,			
	2018		2017	
(in millions)	$	% of Net Sales	$	% of Net Sales
Selling, general and administrative expenses	860	36.1%	794	36.8%
Research and development expenses	261	11.0%	235	10.9%
Royalty expense	18	0.7 %	17	0.8 %

Selling, General and Administrative (SG&A) Expenses

In the first quarter of 2018, our SG&A expenses increased $66 million, or eight percent, as compared to the first quarter of 2017 and were 70 basis points lower as a percentage of net sales. The decrease in SG&A as a percentage of sales was primarily driven by the benefit of our targeted initiatives focused on reducing SG&A, including end-to-end business process streamlining and automation, expansion of global shared services, and leveraging global sourcing.

Research and Development (R&D) Expenses

We remain committed to advancing medical technologies and investing in meaningful R&D projects across our businesses. In the first quarter of 2018, our R&D expenses increased $26 million, as compared to the first quarter of 2017 and were relatively flat at approximately 11 percent of net sales for both periods as a result of investments across our businesses in order to maintain a healthy pipeline of new products that we believe will contribute to profitable sales growth.

Royalty Expense

Our royalty expense was $18 million in the first quarter of 2018, as compared to $17 million in the first quarter of 2017, remaining relatively flat at approximately one percent of net sales for both periods.

Amortization Expense

Our amortization expense was $141 million in the first quarter of 2018, as compared to $143 million in the first quarter of 2017. Amortization expense is excluded by management for purposes of evaluating operating performance.

Contingent Consideration Expense

We recorded a net expense of $5 million during the first quarter of 2018 and a net benefit of $50 million during the first quarter of 2017 related to the change in fair value of our contingent consideration liabilities. Refer to Note B – Acquisitions and Strategic Investments to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q for additional details related to our contingent consideration expenses. Contingent consideration expense is excluded by management for purposes of evaluating operating performance.

Restructuring Charges and Restructuring-related Activities

The following table provides a summary of our restructuring and restructuring-related charges and cash payments:

(in millions)	Three Months Ended March 31, 2018	2017
Total restructuring charges	$13	$ 4
Total restructuring-related charges	$15	$ 15
Total cash payments	$25	$ 16

Restructuring and restructuring-related costs are excluded by management for purposes of evaluating operating performance.

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The 2016 Restructuring Plan is expected to result in total pre-tax charges of approximately $275 million to $325 million and reduce gross annual expenses by approximately $165 million to $175 million by the end of 2020 as plan benefits are realized. A substantial portion of these savings will be reinvested in strategic growth initiatives.

Refer to Note F – Restructuring-related Activities to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q for additional details related to our restructuring plans.

Litigation-related charges and credits

Litigation-related net charges were immaterial in the first quarter of 2018 and 2017. Litigation-related charges (credits) are excluded by management for purposes of evaluating operating performance. Refer to Note I – Commitments and Contingencies to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q for discussion of our material legal proceedings.

Interest Expense

The following table provides a summary of our interest expense and average borrowing rate:

(in millions)	Three Months Ended March 31,	
	2018	2017
Interest expense	$(61)	$(57)
Average borrowing rate	4.1 %	4.0 %

Refer to Liquidity and Capital Resources and Note D – Hedging Activities and Fair Value Measurements and Note E – Borrowings and Credit Arrangements to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q for information regarding our debt obligations and related derivative instruments and hedging activities.

Other, net

The following are the components of Other, net:

(in millions)	Three Months Ended March 31,	
	2018	2017
Interest income	$1	$1
Net foreign currency gain (loss)	(8)	—
Net gains (losses) on investments	(13)	—
Other income (expense), net	(3)	(3)
	$(23)	$(2)

Tax Rates

Our effective tax rate from continuing operations is presented below:

	Three Months

	Ended March 31,	
	2018	2017
Effective tax rate from continuing operations	8.0%	4.9%

The change in our reported tax rates for the first quarter of 2018, as compared to the same period in 2017, relates primarily to the impact of certain receipts and charges that are taxed at different rates than our effective tax rate, including intangible asset impairment charges, acquisition-related items, restructuring items, litigation-related items, as well as certain discrete tax items including impacts of the Tax Cuts and Jobs Act (TCJA), enacted on December 22, 2017.

We are contesting in U.S. Tax Court significant proposed adjustments from the Internal Revenue Service (IRS) related to its audit of our transfer pricing methodologies for the 2001 through 2007 tax years. The IRS also proposed similar transfer pricing

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adjustments for the 2008 through 2010 tax years. We disagree with the transfer pricing methodologies being applied by the IRS and we were scheduled to go to trial in the U.S. Tax Court in late July 2016. On July 19, 2016, we entered a Stipulation of Settled Issues with the IRS intended to resolve all of the aforementioned transfer pricing issues, as well as issues related to our transaction with Abbott Laboratories, for the 2001 through 2007 tax years. The Stipulation of Settled Issues is contingent upon the IRS Office of Appeals applying the same basis of settlement to all transfer pricing issues for the Company's 2008, 2009 and 2010 tax years as well as review by the United States Congress Joint Committee on Taxation (JCT). In October 2016, we reached an agreement in principle with the IRS Office of Appeals as to the resolution of the transfer pricing issues in 2008, 2009 and 2010 tax years, subject to additional calculations of tax as well as documentation to memorialize our agreement. The IRS has recalculated our final tax liabilities under this agreement for all of our tax years from 2001 through 2010 and the JCT has completed its review of the recalculations for the 2001 through 2010 tax years.

In the event that the conditions in the Stipulation of Settled Items are satisfied, we expect to make net tax payments of approximately $275 million, plus interest through the date of payment with respect to the settled issues. If finalized, payments related to the resolution are expected in the next six months. We believe that our income tax reserves associated with these matters are adequate as of March 31, 2018 and we do not expect to recognize any additional charges related to resolution of this controversy. However, the final resolution of these issues remains contingent and if the Stipulation of Settled Issues is not finalized, it could have a material impact on our financial condition, results of operations, or cash flows.

Refer to Note H – Income Taxes to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q for information regarding our tax litigation.

Critical Accounting Policies and Estimates

Our financial results are affected by the selection and application of accounting policies and methods. In the three months ended March 31, 2018, there were changes to the application of critical accounting policies previously disclosed in our most recent Annual Report on Form 10-K related to the adoption of FASB ASC Topic 606, Revenue from Contracts with Customers on January 1, 2018, as described below.

Revenue Recognition

Post Implant Services

We provide non-contractual services to customers to ensure the safe and effective use of certain implanted devices. These promises are immaterial in the context of the contract. In accordance with FASB ASC Topic 606, because the revenue related to the immaterial services is recognized before they are delivered, we forward accrue the costs to provide these services at the time the devices are sold. We record these costs to selling, general and administrative expenses. We estimate the amount of time spent by our representatives performing these services and their compensation throughout the device life to determine the service cost. Changes to our business practice or the use of alternative estimates could result in a different amount of accrued cost. Refer to Note L – Revenue for further information on our adoption of FASB ASC Topic 606.

Liquidity and Capital Resources

Based on our current business plan, we believe our existing balance of cash and cash equivalents, future cash generated from operations, access to capital markets and existing credit facilities will be sufficient to fund our operations, invest in our infrastructure, pay our legal-related liabilities, pay taxes due, fund possible mergers and/or acquisitions and service and repay our existing debt for the next twelve months.

As of March 31, 2018, we had $287 million of cash and cash equivalents on hand, comprised of $42 million invested in money market and government funds and $245 million in interest bearing and non-interest bearing bank accounts. We invest excess cash on hand in short-term financial instruments that earn market interest rates while mitigating

principal risk through instrument and counterparty diversification, as well as what we believe to be prudent instrument selection. We limit our direct exposure to securities in any one industry or issuer. We also have full access to our $2.250 billion commercial paper program, which is backed by our 2017 revolving credit facility described below. As of March 31, 2018, we had $886 million in commercial paper debt outstanding resulting in an additional $1.364 billion of available liquidity and $70 million outstanding resulting in an additional $330 million of available liquidity under our credit facility secured by our U.S. trade receivables both described below.

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The following provides a summary and description of our net cash inflows (outflows):

(in millions)	Three Months Ended March 31, 2018	2017 (restated)†
Cash provided by (used for) operating activities	$193	$ (7)
Cash provided by (used for) investing activities	(173)	(140)
Cash provided by (used for) financing activities	130	(15)

† Certain prior year balances related to restricted cash have been reclassified to reflect our adoption of FASB ASC Update No. 2016-18, Statement of Cash Flows (Topic 230) - Restricted Cash in the fourth quarter of 2017. Please refer to our most recent annual report on Form 10-K for additional details.

Operating Activities

During the first three months of 2018, cash provided by operating activities was $193 million, as compared to cash used for operating activities of $7 million during the first three months of 2017, an increase of $200 million. The increase was primarily due to a reduction in litigation-related payments primarily associated with the transvaginal surgical mesh product liability cases and changes in working capital.

Investing Activities

During the first three months of 2018, cash used for investing activities primarily relates to purchases of property, plant and equipment of $60 million and payments related to strategic investments and acquisitions of certain technologies of $103 million, primarily related to our $90 million investment in Millipede, Inc. During the first three months of 2017, cash used for investing activities primarily included purchases of property, plant and equipment of $112 million and payments related to strategic investments and issuances of notes receivable of $28 million.

Financing Activities

Our cash flows for financing activities reflect issuances and repayments of debt, along with cash used to net share settle employee equity awards and stock issuances related to our equity incentive programs. Additionally, our financing activities included $18 million of contingent payments in the first three months of 2017.

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Debt

We had total debt of $5.765 billion as of March 31, 2018 and $5.616 billion as of December 31, 2017. The debt maturity schedule for the significant components of our long-term debt obligations is presented below:

(in millions, except interest rates)	Issuance Date	Maturity Date	As of March 31, 2018	December 31, 2017	Semi-annual Coupon Rate
October 2018 Notes	August 2013	October 2018	—	†	2.650 %
January 2020 Notes	December 2009	January 2020	850	850	6.000 %
May 2020 Notes	May 2015	May 2020	600	600	2.850 %
May 2022 Notes	May 2015	May 2022	500	500	3.375 %
October 2023 Notes	August 2013	October 2023	450	450	4.125 %
May 2025 Notes	May 2015	May 2025	750	750	3.850 %
March 2028 Notes	February 2018	March 2028	1,000	—	4.000 %
November 2035 Notes	November 2005	November 2035	350	350	7.000 %
January 2040 Notes	December 2009	January 2040	300	300	7.375 %
Unamortized Debt Issuance Discount		2020 - 2040	(14)	(6)	
Unamortized Deferred Financing Costs		2020 - 2040	(19)	(18)	
Unamortized Gain on Fair Value Hedges		2020 - 2023	35	38	
Capital Lease Obligation		Various	1	1	
Long-term debt			$4,803	$ 3,815	

†As of December 31, 2017, $600 million under the October 2018 Notes was outstanding and classified as short-term debt.

Note: The table above does not include unamortized amounts related to interest rate contracts designated as cash flow hedges.

Revolving Credit Facility

As of March 31, 2018 and December 31, 2017, we maintained a $2.250 billion revolving credit facility (the 2017 Facility) with a global syndicate of commercial banks that matures on August 4, 2022. This facility provides backing for the commercial paper program described below. There were no amounts borrowed under our revolving credit facility as of March 31, 2018 and December 31, 2017.

The 2017 Facility requires that we maintain certain financial covenants, as follows:

	Covenant Requirement as of March 31, 2018	Actual as of March 31, 2018
Maximum leverage ratio (1)	3.5 times	2.2 times

(1) Ratio of total debt to consolidated EBITDA, as defined by the credit agreement, for the preceding four consecutive fiscal quarters.

The 2017 Facility provides for an exclusion from the calculation of consolidated EBITDA, as defined by the agreement, through maturity, of any non-cash charges and up to $500 million in restructuring charges and restructuring-related expenses related to our current or future restructuring plans. As of March 31, 2018, we had $415 million of the restructuring charge exclusion remaining. In addition, any cash litigation payments (net of any cash litigation receipts), as defined by the 2017 Facility, are excluded from the calculation of consolidated EBITDA, as defined in the 2017 Facility, provided that the sum of any excluded net cash litigation payments does not exceed $2.624 billion in the aggregate. As of March 31, 2018, we had $1.690 billion of the legal exclusion remaining.

Any inability to maintain compliance with these covenants could require us to seek to renegotiate the terms of our credit facility or seek waivers from compliance with these covenants, both of which could result in additional borrowing costs. Further, there can be no assurance that our lenders would agree to such new terms or grant such waivers on terms acceptable to us. In this case, all credit facility commitments would terminate and any amounts borrowed under the facility would become immediately due and payable. Furthermore, any termination of our credit facility may negatively impact the credit ratings assigned to our commercial paper program which may impact our ability to refinance any then outstanding commercial paper as it becomes due and payable.

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Commercial Paper

As of March 31, 2018, we had $886 million of commercial paper outstanding and $1.197 billion outstanding as of December 31, 2017. Our commercial paper program is backed by the 2017 Facility, which allows us to have a maximum of $2.250 billion in commercial paper outstanding. Outstanding commercial paper directly reduces borrowing capacity available under the 2017 Facility. As of March 31, 2018, the commercial paper issued and outstanding had a weighted average maturity of 22 days and a weighted average yield of 2.46 percent. As of December 31, 2017, the commercial paper issued and outstanding had a weighted average maturity of 38 days and a weighted average yield of 1.85 percent.

Senior Notes

We had senior notes outstanding of $4.800 billion as of March 31, 2018 and $4.400 billion as of December 31, 2017.

In February 2018, we completed an offering of $1.000 billion in aggregate principal amount of 4.000% senior notes, due March 2028. We used a portion of the net proceeds from the offering to repay the $600 million plus accrued interest of our 2.650% senior notes due in October 2018. The remaining proceeds were used to repay a portion of our outstanding commercial paper.

Our senior notes were issued in public offerings, are redeemable prior to maturity and are not subject to sinking fund requirements. Our senior notes are unsecured, unsubordinated obligations and rank on parity with each other. These notes are effectively junior to borrowings under our credit and security facility, and to the extent borrowed by our subsidiaries, to liabilities of our subsidiaries (see Other Arrangements below).

Other Arrangements

As of March 31, 2018 and December 31, 2017, we maintained a $400 million credit and security facility secured by our U.S. trade receivables maturing in February 2019. We had outstanding borrowings of $70 million as of March 31, 2018 and no outstanding borrowings as of December 31, 2017 under our credit and security facility.

We have accounts receivable factoring programs in certain European countries that we account for as sales under FASB ASC Topic 860, Transfers and Servicing. These agreements provide for the sale of accounts receivable to third parties, of up to approximately $463 million as of March 31, 2018. We have no retained interests in the transferred receivables, other than collection and administrative responsibilities and, once sold, the accounts receivable are no longer available to satisfy creditors in the event of bankruptcy. We de-recognized $178 million of receivables as of March 31, 2018 at an average interest rate of 2.1 percent and $171 million as of December 31, 2017 at an average interest rate of 1.8 percent.

In March 2018, we entered into a factoring agreement with a commercial Japanese bank. The agreement provides for the sale of accounts receivable and promissory notes of up to 30.000 billion Japanese yen (approximately $282 million as of March 31, 2018). We have no retained interests in the transferred receivables, other than collection and administrative responsibilities and, once sold, the accounts receivable are no longer available to satisfy creditors in the event of bankruptcy. We de-recognized $95 million of receivables as of March 31, 2018 at an average interest rate of 0.5 percent.

In addition, we have uncommitted credit facilities with a commercial Japanese bank that provide for accounts receivable factoring and promissory notes discounting of up to 22.000 billion Japanese yen (approximately $207 million as of March 31, 2018). We have no retained interests in the transferred receivables, other than collection and administrative responsibilities and, once sold, the accounts receivable are no longer available to satisfy creditors in the event of bankruptcy. We de-recognized $124 million of notes receivable as of March 31, 2018 at an average interest

rate of 1.5 percent and $157 million of notes receivable as of December 31, 2017 at an average interest rate of 1.3 percent. De-recognized accounts and notes receivable are excluded from trade accounts receivable, net in the accompanying unaudited condensed consolidated balance sheets.

As of and through March 31, 2018, we were in compliance with all the required covenants related to our debt obligations.

Equity

We received $38 million during the first three months of 2018 and $33 million during the first three months of 2017 in proceeds from stock issuances related to our stock option and employee stock purchase plans. Proceeds from the exercise of employee stock options and employee stock purchases vary from period to period based upon, among other factors, fluctuations in the trading price of our common stock and in the exercise and stock purchase patterns of our employees.

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We did not repurchase any shares of our common stock during the first three months of 2018 and 2017. As of March 31, 2018, the remaining authorization to repurchase shares under our 2013 share repurchase program was $535 million.

Stock-based compensation expense related to our stock ownership plans was approximately $36 million for the first quarter of 2018 and $30 million for the first quarter of 2017.

Contractual Obligations and Commitments

Certain of our acquisitions involve the payment of contingent consideration. See Note B – Acquisitions and Strategic Investments to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q for further details regarding the estimated potential amount of future contingent consideration we could be required to pay associated with our acquisitions. There have been no other material changes to our contractual obligations and commitments as reported in our most recent Annual Report filed on Form 10-K.

Legal Matters

For a discussion of our material legal proceedings see Note I – Commitments and Contingencies to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q and Note J – Commitments and Contingencies to our audited financial statements contained in Item 8 of our most recent Annual Report on Form 10-K.

Recent Accounting Pronouncements

Information regarding new accounting pronouncements implemented since December 31, 2017 is included in Note A – Basis of Presentation and information regarding new accounting pronouncements to be implemented is included in Note N – New Accounting Pronouncements to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q.

Additional Information

Use of Non-GAAP Financial Measures

To supplement our unaudited condensed consolidated financial statements presented on a GAAP basis, we disclose certain non-GAAP financial measures, including adjusted net income (earnings) and adjusted net income (earnings) per share that exclude certain amounts and operational net sales growth that exclude the impact of foreign currency fluctuations. These non-GAAP financial measures are not in accordance with generally accepted accounting principles in the United States and should not be considered in isolation from or as a replacement for the most directly comparable GAAP financial measures. Further, other companies may calculate these non-GAAP financial measures differently than we do, which may limit the usefulness of those measures for comparative purposes.

To calculate adjusted net income (earnings) and adjusted net income (earnings) per share we exclude certain charges (credits) from GAAP net income, including amortization expense, intangible asset impairment charges, acquisition-related net charges (credits), restructuring and restructuring-related net charges (credits), litigation-related net charges (credits), certain investment impairment charges and certain discrete tax items, including net income tax charges resulting from the enactment of the TCJA. Amounts are tax effected at the company's effective tax rate, unless the amount is a significant unusual or infrequently occurring item in accordance with FASB ASC section 740-270-30, "General Methodology and Use of Estimated Annual Effective Tax Rate." Please refer to Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our most recent Annual Report filed on Form 10-K filed with the Securities and Exchange Commission for an explanation of each of these adjustments and the reasons for excluding each item.

The GAAP financial measures most directly comparable to adjusted net income and adjusted net income per share is GAAP net income and GAAP net income per share.

To calculate operational net sales, which exclude the impact of foreign currency fluctuations, we convert actual net sales from local currency to U.S. dollars using constant foreign currency exchange rates in the current and prior period. The GAAP financial measure most directly comparable to operational net sales is net sales on a GAAP basis.

Reconciliations of each of these non-GAAP financial measures to the corresponding GAAP financial measure are included elsewhere in this Quarterly Report on Form 10-Q.

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Management uses these supplemental non-GAAP financial measures to evaluate performance period over period, to analyze the underlying trends in our business, to assess our performance relative to our competitors, and to establish operational goals and forecasts that are used in allocating resources. In addition, management uses these non-GAAP financial measures to further its understanding of the performance of our operating segments. The adjustments excluded from our non-GAAP financial measures are consistent with those excluded from our operating segments' measures of net sales and profit or loss. These adjustments are excluded from the segment measures reported to our chief operating decision maker that are used to make operating decisions and assess performance.

We believe that presenting adjusted net income, adjusted net income per share that exclude certain amounts and operational net sales growth that exclude the impact of changes in foreign currency exchange rates, in addition to the corresponding GAAP financial measures, provides investors greater transparency to the information used by management for its operational decision-making and allows investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

Safe Harbor for Forward-Looking Statements

Certain statements that we may make from time to time, including statements contained in this Quarterly Report on Form 10-Q and information incorporated by reference herein, constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "may," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements. Except as required by law, we do not intend to update any forward-looking statements even if new information becomes available or other events occur in the future.

The forward-looking statements in this Quarterly Report on Form 10-Q are based on certain risks and uncertainties, including the risk factors described in "Part I, Item 1A. Risk Factors" in our most recent Annual Report on Form 10-K and the specific risk factors discussed below and in connection with forward-looking statements throughout this Quarterly Report on Form 10-Q, which could cause actual results to vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the forward-looking statements. These additional factors include, among other things, future political, economic, competitive, reimbursement and regulatory conditions, new product introductions, demographic trends, intellectual property, litigation and governmental investigations, financial market conditions and future business decisions made by us and our competitors, all of which are difficult or impossible to predict accurately and many of which are beyond our control. We caution each reader of this Quarterly Report on Form 10-Q to consider carefully these factors.

The following are some of the important risk factors that could cause our actual results to differ materially from our expectations in any forward-looking statements. For further discussion of these and other risk factors, see "Part I, Item 1A. Risk Factors" in our most recent Annual Report on Form 10-K.

Our Businesses

- Our ability to increase net sales, expand the market, capture market share and adapt to market volatility,

- The ongoing impact on our business of physician alignment to hospitals, governmental investigations and audits of hospitals and other market and economic conditions on the overall number of procedures performed,

- Competitive offerings and related declines in average selling prices for our products,

- The performance of and physician and patient confidence in, our products and technologies or those of our competitors,

- The impact and outcome of ongoing and future clinical trials and market studies undertaken by us, our competitors or other third parties or perceived product performance of our or our competitors' products,

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- Variations in clinical results, reliability or product performance of our and our competitor's products,

- Our ability to acquire or develop, launch and supply new or next-generation products and technologies worldwide and in line with our commercialization strategies in a timely and successful manner and with respect to our recent acquisitions,

- The effect of consolidation and competition in the markets in which we do business or plan to do business,

- Disruption in the manufacture or supply of certain components, materials or products or the failure to secure in a timely manner alternative manufacturing or additional or replacement components, materials or products,

- Our ability to retain and attract key personnel,

- The impact of enhanced requirements to obtain regulatory approval in the U.S. and around the world, including the associated timing and cost of product approval, and

- The impact of increased pressure on the availability and rate of third-party reimbursement for our products and procedures in the U.S. and around the world, including with respect to the timing and costs of creating and expanding markets for new products and technologies.

Regulatory Compliance, Litigation and Data Protection

- The impact of healthcare policy changes and legislative or regulatory efforts in the U.S. and around the world to modify product approval or reimbursement processes, including a trend toward demonstrating clinical outcomes, comparative effectiveness and cost efficiency, as well as the impact of other healthcare reform legislation,

- Risks associated with our regulatory compliance and quality systems and activities in the U.S. and around the world, including meeting regulatory standards applicable to manufacturing and quality processes,

- Our ability to minimize or avoid future field actions or FDA warning letters relating to our products and processes and the ongoing inherent risk of potential physician advisories related to medical devices,

- The impact of increased scrutiny of and heightened global regulatory enforcement facing the medical device industry arising from political and regulatory changes, economic pressures or otherwise, including under U.S. Anti-Kickback Statute, U.S. False Claims Act and similar laws in other jurisdictions, U.S. Foreign Corrupt Practices Act (FCPA) and similar laws in other jurisdictions, and U.S. and foreign export control, trade embargo and customs laws,

- Costs and risks associated with litigation,

- The effect of our litigation and risk management practices, including self-insurance and compliance activities on our loss contingencies, legal provision and cash flows,

- The impact of, diversion of management attention as a result of and costs to cooperate with, litigate and/or resolve governmental investigations and our class action, product liability, contract and other legal proceedings,

- The possibility of failure to protect our intellectual property rights and the outcome of patent litigation, and

- Our ability to properly operate our information systems that support our business operations and protect our data integrity and products from a cyber-attack or other breach that has a material adverse effect on our business,

reputation or results of operations.

Innovation and Certain Growth Initiatives

- The timing, size and nature of our strategic growth initiatives and market opportunities, including with respect to our internal research and development platforms and externally available research and development platforms and technologies and the ultimate cost and success of those initiatives and opportunities,

- Our ability to complete planned clinical trials successfully, obtain regulatory approvals and launch new and next generation products in a timely manner consistent with cost estimates, including the successful completion of projects from in-process research and development,

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- Our ability to identify and prioritize our internal research and development project portfolio and our external investment portfolio on profitable revenue growth opportunities as well as to keep them in line with the estimated timing and costs of such projects and expected revenue levels for the resulting products and technologies,

- Our ability to successfully develop, manufacture and market new products and technologies in a timely manner and the ability of our competitors and other third parties to develop products or technologies that render our products or technologies noncompetitive or obsolete,

- The impact of our failure to succeed at our decision to discontinue, write-down or reduce the funding of any of our research and development projects, including in-process projects from in-process research and development, in our growth adjacencies or otherwise,

- Dependence on acquisitions, alliances or investments to introduce new products or technologies and to enter new or adjacent growth markets and our ability to fund them or to fund contingent payments with respect to those acquisitions, alliances and investments, and

- The failure to successfully integrate and realize the expected benefits from the strategic acquisitions, alliances and investments we have consummated or may consummate in the future.

International Markets

- Our dependency on international net sales to achieve growth, including in emerging markets,

- The impact of changes in our international structure and leadership,

- The timing and collectability of customer payments, political and economic conditions (including the impact of the United Kingdom's exit from the EU, often referred to as "Brexit"), protection of our intellectual property, compliance with established and developing U.S. and foreign legal and regulatory requirements, including FCPA and similar laws in other jurisdictions and U.S. and foreign export control, trade embargo and customs laws, as well as changes in reimbursement practices and policies,

- Our ability to maintain or expand our worldwide market positions in the various markets in which we compete or seek to compete, including through investments in product diversification and emerging markets such as Brazil, Russia, India and China,

- Our ability to execute and realize anticipated benefits from our investments in emerging markets, and

- The potential effect of foreign currency fluctuations and interest rate fluctuations on our net sales, expenses and resulting margins.

Liquidity

- Our ability to generate sufficient cash flow to fund operations, capital expenditures, global expansion initiatives, any litigation settlements and judgments, share repurchases and strategic investments and acquisitions as well as maintaining our investment grade ratings and managing our debt levels and covenant compliance,

- Our ability to access the public and private capital markets when desired and to issue debt or equity securities on terms reasonably acceptable to us,

- The unfavorable resolution of open tax matters, exposure to additional tax liabilities and the impact of changes in U.S. and international tax laws,

- The impact of examinations and assessments by domestic and international taxing authorities on our tax provision, financial condition or results of operations,

- The possibility of counterparty default on our derivative financial instruments,

- The impact of goodwill and other intangible asset impairment charges, including on our results of operations, and

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- Our ability to collect outstanding and future receivables and/or sell receivables under our factoring programs.

Cost Reduction and Optimization Initiatives

- Risks associated with significant changes made or expected to be made to our organizational and operational structure, pursuant to our 2016 Restructuring Plan as well as any further restructuring or optimization plans we may undertake in the future and our ability to recognize benefits and cost reductions from such programs and

- Business disruption and employee distraction as we execute our global compliance program, restructuring and optimization plans and divestitures of assets or businesses and implement our other strategic and cost reduction initiatives.

Rule 10b5-1 Trading Plans by Executive Officers

Periodically, certain of our executive officers adopt written stock trading plans in accordance with Rule 10b5-1 under the Exchange Act and our own Stock Trading Policy. A Rule 10b5-1 Trading Plan is a written document that pre-establishes the amount, prices and dates (or formulas for determining the amounts, prices and dates) of future purchases or sales of our stock, including shares issued upon exercise of stock options or vesting of deferred stock units. These plans are entered into at a time when the person is not in possession of material non-public information about our company. We disclose details regarding individual Rule 10b5-1 Trading Plans on the Investor Relations section of our website.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We develop, manufacture and sell medical devices globally and our earnings and cash flows are exposed to market risk from changes in currency exchange rates and interest rates. We address these risks through a risk management program that includes the use of derivative financial instruments. We operate the program pursuant to documented corporate risk management policies. We do not enter derivative transactions for speculative purposes. Gains and losses on derivative financial instruments substantially offset losses and gains on underlying hedged exposures. Furthermore, we manage our exposure to counterparty risk on derivative instruments by entering into contracts with a diversified group of major financial institutions and by actively monitoring outstanding positions.

Our currency risk consists primarily of foreign currency denominated firm commitments, forecasted foreign currency denominated intercompany and third-party transactions and net investments in certain subsidiaries. We use both nonderivative (primarily European manufacturing operations) and derivative instruments to manage our earnings and cash flow exposure to changes in currency exchange rates. We had currency derivative instruments outstanding in the contract amount of $6.161 billion as of March 31, 2018 and $5.923 billion as of December 31, 2017. A ten percent appreciation in the U.S. dollar’s value relative to the hedged currencies would increase the derivative instruments’ fair value by $350 million as of March 31, 2018 as compared to $321 million as of December 31, 2017. A ten percent depreciation in the U.S. dollar’s value relative to the hedged currencies would decrease the derivative instruments’ fair value by $428 million as of March 31, 2018 as compared to $421 million as of December 31, 2017. Any increase or decrease in the fair value of our currency exchange rate sensitive derivative instruments would be substantially offset by a corresponding decrease or increase in the fair value of the hedged underlying asset, liability or forecasted transaction, resulting in minimal impact on our consolidated statements of operations.

Our interest rate risk relates primarily to U.S. dollar borrowings partially offset by U.S. dollar cash investments. We have historically used interest rate derivative instruments to manage our earnings and cash flow exposure to changes in interest rates. We had no interest rate derivative instruments outstanding as of March 31, 2018 and December 31, 2017. As of March 31, 2018, $4.800 billion of our outstanding debt obligations were at fixed interest rates, representing approximately 84 percent of our total debt.

Refer to Note D – Hedging Activities and Fair Value Measurements to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q for further information regarding our derivative financial instruments.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (CEO) and our Chief Financial Officer (CFO), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018 pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures are designed to ensure that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such material information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Based on their evaluation, our CEO and CFO concluded that, as of March 31, 2018, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

During the three month period ended March 31, 2018, we implemented certain controls related to the adoption of FASB ASC Topic 606, effective January 1, 2018. These controls were designed and implemented to ensure the completeness and accuracy over financial reporting. With the exception of the controls implemented for FASB ASC Topic 606, there were no changes in our internal control over financial reporting during the three month period ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note H – Income Taxes and Note I – Commitments and Contingencies to our unaudited condensed consolidated financial statements contained in Item 1 of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS

In addition to the information set forth below and other information contained elsewhere in this report, you should carefully consider the factors discussed in "Part I, Item 1A. Risk Factors" in our most recent Annual Report filed on Form 10-K, which could materially affect our business, financial condition or future results.

ITEM 6. EXHIBITS (* documents filed or furnished with this report, # compensatory plans or arrangements)

4.1	Indenture dated as of May 29, 2013, between Boston Scientific Corporation and U.S. Bank National Association, as trustee (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-3 (Commission File No. 333-188918) filed on May 29, 2013 and incorporated herein by reference).
4.2	4.000% Senior Note due 2028 (incorporated herein by reference to exhibit 4.2, Current Report on Form 8-K dated February 26, 2018, File No. 1-11083).
10.1*	Form of Non-Qualified Stock Option Agreement under the 2011 Long Term Incentive Plan#
10.2*	Form of Global Deferred Stock Unit Award Agreement under the 2011 Long-Term Incentive Plan#
10.3*	Form of 2018 Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Total Shareholder Return)#
10.4*	Form of 2018 Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Free Cash Flow)#
10.5*	Form of Acquisition-Related Non-Qualified Stock Option Award Agreement under the 2011 Long-Term Incentive Plan#
10.6*	Form of Acquisition-Related Deferred Stock Unit Award Agreement under the 2011 Long-Term Incentive Plan#
10.7*	Form of Restricted Stock Award Agreement for Non-Employee Directors under the 2011 Long-Term Incentive Plan#
10.8*	Form of Deferred Stock Unit Award Agreement for Non-Employee Directors under the 2011 Long-Term Incentive Plan#
10.9*	Form of Non-Qualified Stock Option Award Agreement for Non-Employee Directors under the 2011 Long-Term Incentive Plan#
10.10	

Underwriting Agreement, dated February 22, 2018, as supplemented by the Terms Agreement, dated February 22, 2018, among Boston Scientific Corporation and Barclays Capital Inc., Citigroup Global Markets Inc. and Merrill Lynch, Pierce, Fenner & Smith Inc., as representatives of the underwriters (incorporated herein by reference to Exhibit 1.1, Current Report on Form 8-K dated February 26, 2018, File No. 1-11083.

31.1* Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2* Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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32.1*	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Statements of Operations for the three months ended March 31, 2018 and 2017, (ii) the Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2018 and 2017, (iii) the Condensed Consolidated Balance Sheets as of March 31, 2018 and December 31, 2017, (iv) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2018 and 2017 and (v) the notes to the Condensed Consolidated Financial Statements.

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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 on May 1, 2018.

BOSTON SCIENTIFIC CORPORATION

By: /s/ Daniel J. Brennan

Name: Daniel J. Brennan

Title: Executive Vice President and Chief Financial Officer