

GERON CORP
Form 10-Q
May 05, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from to .

GERON CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

75-2287752

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

149 COMMONWEALTH DRIVE, SUITE 2070, MENLO PARK, CA

(Address of principal executive offices)

94025

(Zip Code)

(650) 473-7700

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class:
Common Stock, \$0.001 par value

Outstanding at April 29, 2016:
158,960,258 shares

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GERON CORPORATION

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2016

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	MARCH 31, 2016 (UNAUDITED)	DECEMBER 31, 2015 (NOTE 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,802	\$ 21,248
Restricted cash	267	267
Marketable securities	96,846	92,524
Interest and other receivables	624	1,206
Prepaid assets	416	647
Total current assets	110,955	115,892
Noncurrent marketable securities	31,976	32,661
Property and equipment, net	212	207
	\$ 143,143	\$ 148,760
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 396	\$ 160
Accrued compensation and benefits	1,619	2,974
Accrued collaboration charges	3,537	2,328
Accrued restructuring charges	35	52
Accrued liabilities	1,071	1,120
Total current liabilities	6,658	6,634
Commitments and contingencies		
Stockholders' equity:		
Common stock	159	159
Additional paid-in capital	1,073,515	1,070,567
Accumulated deficit	(937,229)	(928,387)
Accumulated other comprehensive income (loss)	40	(213)
Total stockholders' equity	136,485	142,126
	\$ 143,143	\$ 148,760

See accompanying notes.

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GERON CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(UNAUDITED)

	THREE MONTHS ENDED	
	2016	2015
	MARCH 31,	
Revenues:		
License fees and royalties	\$ 749	\$ 537
Operating expenses:		
Research and development	5,033	4,987
Restructuring charges		406
General and administrative	4,793	4,600
Total operating expenses	9,826	9,993
Loss from operations	(9,077)	(9,456)
Unrealized gain on derivatives		16
Interest and other income	256	149
Interest and other expense	(21)	(24)
Net loss	\$ (8,842)	\$ (9,315)
Basic and diluted net loss per share	\$ (0.06)	\$ (0.06)
Shares used in computing basic and diluted net loss per share	158,896,038	157,547,568

See accompanying notes.

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GERON CORPORATION
CONDENSED STATEMENTS OF COMPREHENSIVE LOSS
(IN THOUSANDS)
(UNAUDITED)

	THREE MONTHS ENDED			
	MARCH 31,			
	2016		2015	
Net loss	\$	(8,842)	\$	(9,315)
Net unrealized gain on marketable securities		253		67
Comprehensive loss	\$	(8,589)	\$	(9,248)

See accompanying notes.

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GERON CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
CHANGE IN CASH AND CASH EQUIVALENTS
(IN THOUSANDS)
(UNAUDITED)

	THREE MONTHS ENDED	
	2016	2015
	MARCH 31,	
Cash flows from operating activities:		
Net loss	\$ (8,842)	\$ (9,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21	9
Accretion and amortization on investments, net	284	629
Stock-based compensation for services by non-employees	50	67
Stock-based compensation for employees and directors	2,019	2,013
Amortization related to 401(k) contributions	53	154
Unrealized gain on derivatives		(16)
Changes in assets and liabilities:		
Other current assets	813	(95)
Other current liabilities	24	(1,151)
Net cash used in operating activities	(5,578)	(7,705)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	(7)
Purchases of marketable securities	(46,751)	(78,869)
Proceeds from maturities of marketable securities	43,083	52,490
Net cash used in investing activities	(3,694)	(26,386)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	826	1,477
Net cash provided by financing activities	826	1,477
Net decrease in cash and cash equivalents	(8,446)	(32,614)
Cash and cash equivalents at the beginning of the period	21,248	42,796
Cash and cash equivalents at the end of the period	\$ 12,802	\$ 10,182
Supplemental Disclosure of Non-Cash Investing Activities:		
Net unrealized gain on marketable securities	\$ 253	\$ 67

See accompanying notes.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2016

(UNAUDITED)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The terms Geron, the Company, we and us as used in this report refer to Geron Corporation. The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management of Geron, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016 or any other period. These financial statements and notes should be read in conjunction with the financial statements for each of the three years ended December 31, 2015, included in the Company's Annual Report on Form 10-K. The accompanying condensed balance sheet as of December 31, 2015 has been derived from audited financial statements at that date.

Net Loss Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the periods presented, without consideration for common stock equivalents. Diluted net income per share is calculated by adjusting the weighted-average number of shares of common stock outstanding for the dilutive effect of common stock equivalents outstanding for the periods presented, as determined using the treasury-stock method. Potential dilutive securities primarily consist of outstanding stock options, restricted stock awards, and warrants to purchase our common stock. Diluted net loss per share excludes common stock equivalents outstanding for the periods presented, as determined using the treasury-stock method, as their effect would be anti-dilutive, resulting in the same number of shares being used for the calculation of basic and diluted net loss per share. For all periods presented in the accompanying condensed statements of operations, the net loss applicable to common stockholders is equal to the reported net loss.

Since we incurred a net loss for the three months ended March 31, 2016 and 2015, 3,593,074 and 4,122,123 common stock equivalents, respectively, related to outstanding stock options and restricted stock awards (as determined using the treasury-stock method at the estimated average market value) were excluded from the diluted net loss per share calculation as their effect would have been anti-dilutive. In addition, for the three months ended March 31, 2016 and 2015, 10,617,930 and 8,783,291 potentially dilutive securities, respectively, were excluded from the treasury-stock method and calculation of diluted net loss per share as their effect would have been anti-dilutive.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On a regular basis, management evaluates these estimates and assumptions. Actual results could differ from those estimates.

Fair Value of Financial Instruments

Cash Equivalents and Marketable Securities

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. We are subject to credit risk related to our cash equivalents and marketable securities. We place our cash and cash equivalents in money market funds, commercial paper, corporate notes and cash operating accounts. Our marketable securities include U.S. government-sponsored enterprise securities, commercial paper and corporate notes with original maturities ranging from four to 24 months.

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MARCH 31, 2016

(UNAUDITED)

We classify our marketable securities as available-for-sale. We record available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses are included in interest and other income and are derived using the specific identification method for determining the cost of securities sold and have been insignificant to date. Dividend and interest income are recognized when earned and included in interest and other income in our condensed statements of operations. We recognize a charge when the declines in the fair values below the amortized cost basis of our available-for-sale securities are judged to be other-than-temporary. We consider various factors in determining whether to recognize an other-than-temporary charge, including whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security before recovery of the amortized cost basis. Declines in market value associated with credit losses judged as other-than-temporary result in a charge to interest and other income. Other-than-temporary charges not related to credit losses are included in accumulated other comprehensive income (loss) in stockholders' equity. We have not recorded any other-than-temporary impairment charges on our available-for-sale securities for the three months ended March 31, 2016 and 2015. See Note 2 on Fair Value Measurements.

Revenue Recognition

We recognize revenue for each unit of accounting when all of the following criteria have been met: (a) persuasive evidence of an arrangement exists, (b) delivery has occurred or services have been rendered, (c) the seller's price to the buyer is fixed or determinable, and (d) collectability is reasonably assured. Amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as noncurrent deferred revenue.

License and/or Collaboration Agreements

In addition to the exclusive collaboration and license agreement, or Collaboration Agreement, that we entered into with Janssen Biotech, Inc., or Janssen, in November 2014 (which is more fully described in Note 3 on Collaboration and License Agreement), we have entered into several license or collaboration agreements with various oncology, diagnostics, research tools and biologics production companies. Economic terms in these agreements may include non-refundable license payments in cash or equity securities, option payments in cash or equity securities, cost reimbursements, cost-sharing arrangements, milestone payments, royalties on future sales of products, or any combination of these items. In applying the appropriate revenue recognition guidance related to these agreements, we first assess whether the arrangement contains multiple elements. In this evaluation, we consider: (i) the deliverables included in the arrangement and (ii) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner or licensee and the

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availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner or licensee can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s) and whether there are other vendors that can provide the undelivered element(s).

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. We then apply the applicable revenue recognition criteria noted above to each of the separate units of accounting in determining the appropriate period and pattern of recognition. We determine how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under relevant accounting guidance. The estimated fair value of deliverables under the arrangement may be derived using a best estimate of selling price if vendor-specific-objective evidence and third-party evidence are not available.

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Upfront non-refundable signing, license or non-exclusive option fees are recognized as revenue: (i) when rights to use the intellectual property have been delivered, if the license has standalone value from the other deliverables to be provided under the agreement, or (ii) over the term of the agreement if we have continuing performance obligations, as the arrangement would be accounted for as a single unit of accounting. When payments are received in equity securities, we do not recognize any revenue unless such securities are determined to be realizable in cash.

At the inception of an arrangement that includes milestone payments, we assess whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We consider various factors, such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone, in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Milestone payments for milestones that are considered substantive would be recognized as revenue in their entirety upon successful accomplishment of the milestone, assuming all other revenue recognition criteria are met. Milestone payments for milestones that are not considered substantive would be recognized as revenue over the remaining period of performance, assuming all other revenue recognition criteria are met.

Royalties are recognized as earned in accordance with contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received. Revenue from commercial milestone payments is accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Cost-sharing expenses are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. For arrangements in which we and our collaboration partner in the agreement are exposed to significant risks and rewards depending on the commercial success of the activity, we recognize payments between the parties on a net basis and record such amounts as a reduction or addition to research and development expense. For arrangements in which we have agreed to perform certain research and development services for our collaboration partner and are not exposed to significant risks and rewards depending on the commercial success of the activity, we recognize the respective cost reimbursements as revenue under the collaborative agreement as the related research and development services are rendered.

Restricted Cash

Restricted cash consists of funds maintained in a separate certificate of deposit account for credit card purchases.

Research and Development Expenses

Research and development expenses consist of expenses incurred in identifying, developing and testing product candidates resulting from our independent efforts as well as efforts associated with collaborations. These expenses include, but are not limited to, in-process research and development acquired in an asset acquisition and deemed to have no alternative future use, payroll and personnel expense, lab supplies, preclinical studies, clinical trials, including support for investigator-sponsored clinical trials, raw materials to manufacture clinical trial drugs, manufacturing costs for research and clinical trial materials, sponsored research at other labs, consulting, costs to maintain technology licenses, our proportionate share of research and development costs under cost-sharing arrangements with collaboration partners and research-related overhead. Research and development costs are expensed as incurred, including payments made under our collaboration and/or license agreements.

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For the clinical development activities being conducted by Janssen, we monitor patient enrollment levels and related activities to the extent possible through discussions with Janssen personnel and base our estimates on the best information available at the time. However, additional information may become available to us which would allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

Depreciation and Amortization

We record property and equipment at cost and calculate depreciation using the straight-line method over the estimated useful lives of the assets, generally four years. Leasehold improvements are amortized over the shorter of the estimated useful life or remaining term of the lease.

Stock-Based Compensation

We recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period. The following table summarizes the stock-based compensation expense included in operating expenses on our condensed statements of operations related to stock options, restricted stock awards and employee stock purchases for the three months ended March 31, 2016 and 2015 which was allocated as follows:

(In thousands)	Three Months Ended March 31,	
	2016	2015
Research and development	\$ 332	\$ 622
Restructuring charges		90
General and administrative	1,687	1,301
Stock-based compensation expense included in operating expenses	\$ 2,019	\$ 2,013

In connection with a restructuring we announced in March 2015, the post-termination exercise period for certain stock options previously granted to employees affected by the restructuring was extended from 90 days to one year from their respective termination dates, subject to each employee's continuous service until his/her specified termination date. The incremental value associated with these stock option modifications was recognized as non-cash stock-based compensation expense over each employee's remaining service period with the Company and recorded as restructuring charges on our condensed statements of operations as reflected in the table above. See Note 4 on Restructuring for a further discussion of the March 2015 restructuring.

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As stock-based compensation expense recognized in our condensed statements of operations for the three months ended March 31, 2016 and 2015 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures, but at a minimum, reflects the grant-date fair value of those awards that actually vested in the period. Forfeitures have been estimated at the time of grant based on historical data and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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GERON CORPORATION
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MARCH 31, 2016
(UNAUDITED)

Stock Options

We grant options with service-based vesting under our equity plans to employees, non-employee directors and consultants. The vesting period for employee options is generally four years. The fair value of options granted during the three months ended March 31, 2016 and 2015 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2016	2015
Dividend yield	0%	0%
Expected volatility	0.890	0.884
Risk-free interest rate	1.21%	1.70%
Expected term	5.5 yrs	5.5 yrs

Employee Stock Purchase Plan

The fair value of employees' purchase rights during the three months ended March 31, 2016 and 2015 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2016	2015
Dividend yield	0%	0%
Expected volatility range	0.684	0.721 to 1.392
Risk-free interest rate range	0.28%	0.11% to 0.25%
Expected term range	12 mos	6 to 12 mos

Dividend yield is based on historical cash dividend payments. The expected volatility is based on historical volatilities of our stock since traded options on Geron stock do not correspond to option terms and the trading volume of options is limited. The risk-free interest rate is based on the U.S. Zero Coupon Treasury Strip Yields for the expected term in effect on the date of grant for an award. The expected term of options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that options granted are expected to be outstanding. The expected term of employees' purchase rights is equal to the purchase period.

Restricted Stock Awards

We have granted restricted stock awards to employees and non-employee directors with service-based vesting schedules that generally vest annually over four years. The fair value for service-based restricted stock awards is determined using the fair value of our common stock on the date of grant. The fair value is amortized as stock-based compensation expense over the requisite service period of the award, which is generally the vesting period, on a straight-line basis and is reduced for estimated forfeitures, as applicable.

Non-Employee Stock-Based Awards

For our non-employee stock-based awards, the measurement date on which the fair value of the stock-based award is calculated is equal to the earlier of: (i) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or (ii) the date at which the counterparty's performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of non-employee awards in our condensed statements of operations.

Segment Information

Our executive management team represents our chief decision maker. We view our operations as a single segment, the development of therapeutic products for oncology. As a result, the financial information disclosed herein materially represents all of the financial information related to our principal operating segment.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2016

(UNAUDITED)

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, or ASU 2014-09, which creates Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or Topic 606, and supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In summary, the core principle of Topic 606 is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Companies are allowed to select between two transition methods: (1) a full retrospective transition method with the application of the new guidance to each prior reporting period presented, or (2) a retrospective transition method that recognizes the cumulative effect on prior periods at the date of adoption together with additional footnote disclosures. The amendments in ASU 2014-09 are effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, and early application is not permitted. We are currently evaluating the impact that the adoption of ASU 2014-09 will have on our financial statements and related disclosures and have not made any decision on the method of adoption.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*, or ASU 2015-17. Current generally accepted accounting principles requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. We are currently evaluating the impact that the adoption of ASU 2015-17 will have on our financial statements and related disclosures and have not made any decision regarding the timing of adoption.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02. ASU 2016-02 requires an entity to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Recognition, measurement and presentation of expenses will depend on classification as a finance or operating lease. Certain quantitative and qualitative disclosures about leasing arrangements also are required. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The updated guidance requires a modified retrospective adoption. We are currently evaluating the impact that the adoption of ASU 2016-02 will have on our financial statements and related disclosures and have not made any decision regarding the timing of adoption.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09, which amends Accounting Standards Codification Topic 718, *Compensation - Stock Compensation*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either

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equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods and early adoption is permitted. We are currently evaluating the impact of the adoption of ASU 2016-09 on our financial statements and related disclosures and have not made any decision regarding the timing of adoption.

With the exception of the standards discussed above, there have been no new accounting pronouncements not yet effective that have significance, or potential significance, to our financial statements.

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NOTES TO CONDENSED FINANCIAL STATEMENTS
MARCH 31, 2016