

Radius Health, Inc.  
Form 10-Q  
May 05, 2016  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended 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            .

Commission File Number 001-35726

**Radius Health, Inc.**

(Exact name of registrant as specified in its charter)

Edgar Filing: Radius Health, Inc. - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
Incorporation or organization)

**80-0145732**  
(IRS Employer  
Identification Number)

**950 Winter Street**

**Waltham, Massachusetts 02451**

(Address of Principal Executive Offices and Zip Code)

**(617) 551-4000**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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

Smaller reporting company

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

Number of shares of the registrant's Common Stock, \$.0001 par value per share, outstanding as of May 2, 2016: 43,037,677 shares

Table of Contents

**RADIUS HEALTH, INC.**  
**FORM 10-Q**  
**FOR THE QUARTER ENDED MARCH 31, 2016**

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements (Unaudited)</u>	2
	<u>Condensed Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015</u>	2
	<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2016 and 2015</u>	3
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2015</u>	4
	<u>Notes to Condensed Consolidated Financial Statements</u>	5
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	21
<u>Item 4.</u>	<u>Controls and Procedures</u>	22

**PART II OTHER INFORMATION** 23

<u>Item 1.</u>	<u>Legal Proceedings</u>	23
<u>Item 1A.</u>	<u>Risk Factors</u>	23
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	24
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	24
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	24
<u>Item 5.</u>	<u>Other Information</u>	24
<u>Item 6.</u>	<u>Exhibits</u>	24

**SIGNATURES** 25

Table of Contents

**CURRENCY AND CONVERSIONS**

In this report, references to dollar or \$ are to the legal currency of the United States, and references to euro or are to the single currency introduced on January 1, 1999 at the start of the third stage of European Economic and Monetary Union, pursuant to the Treaty establishing the European Communities, as amended by the Treaty on European Union and the Treaty of Amsterdam. Unless otherwise indicated, the financial information in this report has been expressed in U.S. dollars. Unless otherwise stated, the U.S. dollar equivalent information translating euros into U.S. dollars has been made, for convenience purposes, on the basis of the noon buying rate published by the Board of Governors of the Federal Reserve as of March 31, 2016, which was 1.00 = \$1.1390. Such translations should not be construed as a representation that the euro has been, could have been or could be converted into U.S. dollars at the rate indicated, any particular rate or at all.

Trademarks appearing in this report are the property of their respective holders.

Table of Contents**Item 1. Financial Statements****Radius Health, Inc.****Condensed Consolidated Balance Sheets**

(In thousands, except share and per share amounts)

	<b>March 31, 2016 (unaudited)</b>	<b>December 31, 2015</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 104,414	\$ 159,678
Marketable securities	332,894	313,661
Prepaid expenses and other current assets	2,755	6,969
Total current assets	440,063	480,308
Property and equipment, net	2,180	1,897
Marketable securities, long-term	2,510	
Other assets	338	260
Total assets	\$ 445,091	\$ 482,465
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,808	\$ 6,228
Accrued expenses and other current liabilities	15,107	14,952
Total current liabilities	18,915	21,180
Total liabilities	\$ 18,915	\$ 21,180
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 43,014,243 shares and 42,984,243 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	4	4
Additional paid-in-capital	912,161	907,040
Accumulated other comprehensive income	237	5
Accumulated deficit	(486,226)	(445,764)
Total stockholders' equity	426,176	461,285
Total liabilities and stockholders' equity	\$ 445,091	\$ 482,465

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**Radius Health, Inc.****Condensed Consolidated Statements of Comprehensive Loss**

(Unaudited)

(In thousands, except share and per share amounts)

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>OPERATING EXPENSES:</b>		
Research and development	\$ 27,483	\$ 11,559
General and administrative	13,646	4,756
Loss from operations	(41,129)	(16,315)
<b>OTHER (EXPENSE) INCOME:</b>		
Other (expense) income, net	(1)	(50)
Interest income	667	105
Interest expense		(797)
<b>NET LOSS</b>	<b>\$ (40,463)</b>	<b>\$ (17,057)</b>
<b>OTHER COMPREHENSIVE INCOME, NET OF TAX:</b>		
Unrealized gain from available-for-sale securities	232	62
<b>COMPREHENSIVE LOSS</b>	<b>\$ (40,231)</b>	<b>\$ (16,995)</b>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED</b>		
(Note 10)	\$ (40,463)	\$ (17,057)
<b>LOSS PER SHARE:</b>		
Basic and diluted	\$ (0.94)	\$ (0.47)
<b>WEIGHTED AVERAGE SHARES:</b>		
Basic and diluted	43,012,924	36,268,975

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**Radius Health, Inc.****Condensed Consolidated Statements of Cash Flows**

(Unaudited)

(In thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS USED IN OPERATING ACTIVITIES:</b>		
Net loss	\$ (40,463)	\$ (17,057)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	96	36
Amortization of premium (accretion of discount) marketable securities, net	566	290
Stock-based compensation	4,192	2,061
Non-cash interest		78
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	4,214	(428)
Other long-term assets	(78)	(31)
Accounts payable	(2,420)	881
Accrued expenses and other current liabilities	155	(6,159)
Net cash used in operating activities	(33,738)	(20,329)
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(379)	(56)
Purchases of marketable securities	(157,922)	(170,088)
Sales and maturities of marketable securities	135,846	38,351
Net cash used in investing activities	(22,455)	(131,793)
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	929	
Proceeds from issuance of common stock, net		158,414
Net cash provided by financing activities	929	158,414
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(55,264)</b>	<b>6,292</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR</b>	<b>159,678</b>	<b>28,518</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 104,414</b>	<b>\$ 34,810</b>
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	\$	\$ 626

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

**Radius Health, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Organization**

Radius Health, Inc. ( Radius or the Company ) is a science-driven biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Radius lead product candidate, the investigational drug abaloparatide for subcutaneous injection ( abaloparatide-SC ), has completed Phase 3 development for potential use in the reduction of fracture risk in postmenopausal women with osteoporosis. Radius Marketing Authorisation Application for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe and a New Drug Application ( NDA ) was submitted in the U.S. at the end of the first quarter of 2016. The Radius clinical pipeline also includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug RAD1901 for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius preclinical pipeline includes RAD140, a non-steroidal, selective androgen receptor modulator under investigation for potential use in multiple applications including cancer.

The Company is subject to the risks associated with emerging companies with a limited operating history, including dependence on key individuals, a developing business model, the necessity of securing regulatory approval to market its investigational product candidates, market acceptance of the Company s investigational product candidates following receipt of regulatory approval, competition for its investigational product candidates following receipt of regulatory approval, and the continued ability to obtain adequate financing to fund the Company s future operations. The Company has incurred losses and expects to continue to incur additional losses for the foreseeable future. As of March 31, 2016, the Company had an accumulated deficit of \$486.2 million, and total cash, cash equivalents and marketable securities of \$439.8 million.

Based upon its cash, cash equivalents and marketable securities balance as of March 31, 2016, the Company believes that, prior to the consideration of revenue from the potential future sales of any of its investigational products that may receive regulatory approval or proceeds from collaboration activities, it has sufficient capital to fund its development plans, U.S. commercial scale-up and other operational activities into 2018. The Company expects to finance the future development costs of its clinical product portfolio with its existing cash and cash equivalents and marketable securities, or through strategic financing opportunities that could include, but are not limited to partnering or other collaboration agreements, future offerings of its equity, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company fails to obtain additional future capital, it may be unable to complete its planned preclinical and clinical trials and obtain approval of certain investigational product candidates from the U.S. Food and Drug Administration ( FDA ) or foreign regulatory authorities.

**2. Basis of Presentation and Significant Accounting Policies**

*Basis of Presentation* The accompanying unaudited condensed consolidated financial statements and the related disclosures of the Company have been prepared in accordance with accounting principles generally accepted in the United States ( GAAP ) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly,



they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included.

When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three months ended March 31, 2016 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2016. Subsequent events have been evaluated up to the date of issuance of these financials. For further information, refer to the financial statements and footnotes included in the Company's audited financial statements for the year ended December 31, 2015 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on February 25, 2016.

*Significant Accounting Policies* The significant accounting policies identified in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 that require the Company to make estimates and assumptions include: research and development costs, stock-based compensation and fair value measures. There were no changes to significant accounting policies during the three months ended March 31, 2016.

Table of Contents

*Accounting Standards Updates* In August 2014, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2014-15, *Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern* ( ASU 2014-15 ). ASU 2014-15 provides guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The amendments under ASU 2014-15 are effective for interim and annual fiscal periods beginning after December 15, 2016, with early adoption permitted. The Company does not expect the adoption of ASU 2014-15 to have a material impact on its results of operations, financial position or cash flows.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, *Financial Statements - Overall (Subtopics 825-10)*( ASU 2016-01 ). ASU 2016-01 provides updated guidance on the recognition and measurement of financial assets and financial liabilities that will supersede most current guidance. ASU 2016-01 primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. The amendments in ASU 2016-01 supersede the guidance to classify equity securities with readily determinable fair values into different categories and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The amendments under ASU 2016-01 are effective, for public business entities, for periods beginning after December 15, 2017, including interim periods within those fiscal years, and with early adoption permitted. The Company does not expect the adoption of ASU 2016-01 to have a material impact on its results of operations, financial position or cash flows.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases* ( ASU 2016-02 ). ASU 2016-02 supersedes the lease guidance under FASB Accounting Standards Codification ( ASC ) Topic 840, *Leases*, resulting in the creation of FASB ASC Topic 842, *Leases*. ASU 2016-02 requires a lessee to recognize in the statement of financial position a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating leases. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-02 on its financial statements and related disclosures.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ( ASU 2016-09 ). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-09 on its financial statements and related disclosures.

### 3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	March 31, 2016	December 31, 2015
Research costs - Nordic(1)	\$ 2,663	\$ 2,898
Research costs - other	5,753	5,178
Payroll and employee benefits	1,815	3,330
Professional fees	4,876	3,546

Total accrued expenses and other current liabilities	\$	15,107	\$	14,952
--	----	--------	----	--------

---

(1) Includes amounts accrued ratably over the estimated per patient treatment period under the Work Statement NB-3 with Nordic Bioscience Clinical Development VII A/S ( Nordic ). Amounts do not include pass-through costs which are expensed as incurred or upon delivery. See note 8 for additional information.

#### 4. Loan and Security Agreement

On May 30, 2014, the Company entered into a Loan and Security Agreement (the Credit Facility ), with Solar Capital Ltd. ( Solar ), as collateral agent and a lender, and Oxford Finance LLC ( Oxford ), as a lender (the Lenders ), pursuant to which Solar and Oxford agreed to make available to the Company \$30.0 million in the aggregate subject to certain conditions to funding. An initial term loan was made on May 30, 2014 in an aggregate principal amount equal to \$21.0 million (the Initial Term Loan ).

Table of Contents

On July 10, 2014, the Company entered into a first amendment to the Credit Facility (the First Amendment). The terms of the First Amendment, among other things, provided the Company with, subject to certain customary funding conditions, additional term loans in an aggregate principal amount of \$4.0 million upon the closing of the First Amendment. The Company borrowed the additional \$4.0 million on July 10, 2014.

The Initial Term Loan bore interest per annum at 9.85% plus one-month LIBOR (customarily defined).

On August 4, 2015, the Company prepaid all amounts owed under the Credit Facility and the First Amendment. After consideration of relevant fees required under the Credit Facility and the First Amendment, the total payment amounted to \$26.5 million, which resulted in a loss on retirement of \$1.6 million during the third quarter of 2015.

**5. Marketable Securities**

Available-for-sale marketable securities and cash and cash equivalents consist of the following (in thousands):

	Amortized Cost Value	March 31, 2016		Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
<b>Cash and cash equivalents:</b>				
Cash	\$ 2,935	\$	\$	\$ 2,935
Money market	71,948			71,948
Domestic corporate commercial paper	12,246			12,246
Domestic corporate debt securities	17,285			17,285
<b>Total</b>	<b>\$ 104,414</b>	<b>\$</b>	<b>\$</b>	<b>\$ 104,414</b>
<b>Marketable securities:</b>				
Domestic corporate debt securities	\$ 127,902	\$ 21	\$ (6)	\$ 127,917
Domestic corporate commercial paper	136,568	239		136,807
Asset-backed securities	70,697	4	(21)	70,680
<b>Total</b>	<b>\$ 335,167</b>	<b>\$ 264</b>	<b>\$ (27)</b>	<b>\$ 335,404</b>
	Amortized Cost Value	December 31, 2015		Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
<b>Cash and cash equivalents:</b>				
Cash	\$ 2,934	\$	\$	\$ 2,934
Money market	83,257			83,257
Domestic corporate commercial paper	39,984			39,984
Government-sponsored enterprise debt securities	15,996			15,996
Domestic corporate debt securities	10,007			10,007

Edgar Filing: Radius Health, Inc. - Form 10-Q

Asset-backed securities		7,500				7,500
Total	\$	159,678	\$	\$	\$	159,678
Marketable securities:						
Domestic corporate debt securities	\$	173,142	\$	\$	(107)	\$ 173,035
Domestic corporate commercial paper		84,004		154		84,158
Asset-backed securities		56,510		1	(43)	56,468
Total	\$	313,656	\$	155	\$ (150)	\$ 313,661

There were no debt securities that had been in an unrealized loss position for more than 12 months as of March 31, 2016 or December 31, 2015. There were 22 debt securities in an unrealized loss position for less than 12 months at March 31, 2016 and there were 57 debt securities that had been in an unrealized loss position for less than 12 months at December 31, 2015. The aggregate unrealized loss on these securities as of March 31, 2016 and December 31, 2015 was less than \$28 thousand and \$150 thousand, respectively, and the fair value was \$96.1 million and \$225.7 million, respectively. The Company considered the decline in market value for these securities to be primarily attributable to current economic conditions. As it was not more likely than not that the Company would be required to sell these securities before the recovery of their amortized cost basis, which may be maturity, the Company did not consider these investments to be other-than-temporarily impaired as of March 31, 2016.

Table of Contents

As of March 31, 2016, marketable securities consisted of investments that mature within one year, with the exception of certain asset-backed securities, which have maturities within two years and an aggregate fair value of \$2.5 million.

**6. Fair Value Measurements**

The Company determines the fair values of its financial instruments based upon the fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Below are the three levels of inputs that may be used to measure fair value:

- **Level 1** Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- **Level 2** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- **Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table summarizes the financial instruments measured at fair value on a recurring basis in the accompanying condensed consolidated balance sheets as of March 31, 2016 and December 31, 2015 (in thousands):

	As of March 31, 2016			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Cash and cash equivalents:				
Cash	\$ 2,935	\$	\$	\$ 2,935
Money market funds (1)	71,948			71,948
Domestic corporate commercial paper (2)		12,246		12,246
Domestic corporate debt securities (2)		17,285		17,285
Total	\$ 74,883	\$ 29,531	\$	\$ 104,414
Marketable Securities				
Domestic corporate debt securities (2)	\$	\$ 127,917	\$	\$ 127,917
Domestic corporate commercial paper (2)		136,807		136,807
Asset-backed securities (2)		70,680		70,680
Total	\$	\$ 335,404	\$	\$ 335,404

	As of December 31, 2015			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Cash and cash equivalents:				

Edgar Filing: Radius Health, Inc. - Form 10-Q

Cash	\$	2,934	\$		\$		\$	2,934
Money market funds (1)		83,257						83,257
Domestic corporate commercial paper (2)				39,984				39,984
Government-sponsored enterprise debt securities (2)				15,996				15,996
Domestic corporate debt securities (2)				10,007				10,007
Asset-backed securities (2)				7,500				7,500
Total	\$	86,191	\$	73,487	\$		\$	159,678
Marketable Securities								
Domestic corporate debt securities (2)	\$		\$	173,035	\$		\$	173,035
Domestic corporate commercial paper (2)				84,158				84,158
Asset-backed securities (2)				56,468				56,468
Total	\$		\$	313,661	\$		\$	313,661

---

(1) Fair value is based upon quoted market prices.

(2) Fair value is based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are

Table of Contents

observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Inputs are obtained from various sources, including market participants, dealers and brokers.

**7. License Agreements**

*Ipsen*

On September 27, 2005, the Company entered into a license agreement (the *Ipsen Agreement*), as amended, with SCRAS S.A.S, a French corporation on behalf of itself and its affiliates (collectively, *Ipsen*). Under the *Ipsen Agreement*, Ipsen granted to the Company an exclusive right and license under certain Ipsen compound technology and related patents to research, develop, manufacture and commercialize certain compounds and related products, including abaloparatide, in all countries, except Japan (where the Company does not hold development and commercialization rights) and France (where the Company's commercialization rights are subject to certain co-marketing and co-promotion rights exercisable by Ipsen, provided that certain conditions included in the *Ipsen Agreement* have been met). With respect to France, if Ipsen exercises its co-marketing and co-promotion rights, then Ipsen may elect to receive a percentage of the net sales of the products by both parties in France (subject to a mid-double digit percentage cap), and Ipsen shall bear a corresponding percentage of the costs and expenses incurred by both parties with respect to such marketing and promotion efforts in France. Ipsen shall also pay the Company a mid-single digit royalty on Ipsen's allocable portion of net sales of the product by both parties in France. Ipsen also granted the Company an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen also granted the Company an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling the Company to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan (where the Company does not hold commercialization rights) and France (where the Company's commercialization rights are subject to certain co-marketing and co-promotion rights exercisable by Ipsen, provided that certain conditions included in the *Ipsen Agreement* have been met).

In consideration for these licenses, the Company made a nonrefundable, non-creditable payment of \$0.25 million to Ipsen, which was expensed during 2005. The *Ipsen Agreement* provides for further payments upon the achievement of certain future regulatory and commercial milestones, including upon acceptance of an NDA submission for review by the FDA. The range of milestone payments that could be paid under the agreement is 10.0 million to 36.0 million (\$11.4 million to \$41.0 million). Should abaloparatide be approved and subsequently commercialized, the Company will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product by the Company or its sublicensees on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country.

If the Company sublicenses the rights licensed from Ipsen, then the Company will also be required to pay Ipsen a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double digit range. In addition, if the Company or its sublicensees commercialize a product that includes a compound discovered by it based on or derived from confidential Ipsen know-how, it will be obligated to pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of licensed patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country.

*Eisai Co. Ltd.*



## Edgar Filing: Radius Health, Inc. - Form 10-Q

In June 2006, the Company entered into a license agreement (the Eisai Agreement), with Eisai Co. Ltd., (Eisai). Under the Eisai Agreement, Eisai granted to the Company an exclusive right and license to research, develop, manufacture and commercialize RAD1901 and related products from Eisai in all countries, except Japan. In consideration for the rights to RAD1901, the Company paid Eisai an initial license fee of \$0.5 million, which was expensed during 2006. The Eisai Agreement provides for further payments in the range of \$1.0 million to \$20.0 million (inclusive of the \$0.5 million initial license fee), payable upon the achievement of certain clinical and regulatory milestones.

On March 9, 2015, the Company entered into an amendment to the Eisai Agreement (the Eisai Amendment) in which Eisai granted to the Company the exclusive right and license to research, develop, manufacture and commercialize RAD1901 in Japan. In consideration for the rights to RAD1901 in Japan, the Company paid Eisai an initial license fee of \$0.4 million upon execution of the Eisai Amendment, which was recognized as research and development expense in 2015. The Eisai Amendment also provides for additional payments, payable upon the achievement of certain clinical and regulatory milestones in Japan.

Under the Eisai Agreement, as amended, should a product covered by the licensed technology be commercialized, the Company will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the product on a country-by-country basis. The royalty rate will be reduced, on a country-by-country basis, at such time as the last remaining valid claim in the licensed

Table of Contents

patents expires, lapses or is invalidated and the product is not covered by data protection clauses. In addition, the royalty rate will be reduced further, on a country-by-country basis, at such time as sales of lawful generic versions of the product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. The latest valid claim to expire, barring any extension thereof, is expected on August 18, 2026.

The Eisai Agreement, as amended, also grants the Company the right to grant sublicenses with prior written approval from Eisai. If the Company sublicenses the licensed technology to a third party, the Company will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees received from such sublicensee and royalties in the low single digit range based on net sales of the sublicensee. The license agreement expires on a country-by-country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the product is not covered by data protection clauses, and the sales of a lawful generic version of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated.

## **8. Research Agreements**

### *Abaloparatide-SC Phase 3 Clinical Extension Study*

The Company has entered into agreements with Nordic to conduct its Phase 3 clinical trial of abaloparatide-SC, or the Phase 3 Clinical Trial. On February 21, 2013, the Company entered into a Work Statement NB-3 with Nordic, as amended on February 28, 2014, March 23, 2015, July 8, 2015, October 21, 2015 and January 15, 2016 (the Work Statement NB-3 ). Pursuant to the Work Statement NB-3, Nordic performed an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial (the Extension Study ), and, upon completion of the Extension Study, an additional period of 18 months of standard-of-care osteoporosis management (the Second Extension Period ).

In April 2015, the Company entered into an amendment to the Work Statement NB-3 (the NB-3 Amendment ). The NB-3 Amendment was effective as of March 23, 2015 and provides that Nordic will perform additional services, including additional monitoring of patients enrolled in the Second Extension Period. Payments in cash to be made to Nordic under the NB-3 Amendment are denominated in euros and total up to approximately 4.1 million (\$4.7 million).

Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to 11.9 million (\$13.5 million) and \$1.1 million, respectively. In addition, payments were due to Nordic in connection with the Work Statement NB-3 pursuant to the Stock Issuance Agreement entered into between the Company and Nordic, as amended and restated on May 16, 2011, and as further amended on February 21, 2013, March 28, 2014, and May 19, 2014 (the Stock Issuance Agreement ). As of March 31, 2016, services related to the Second Extension are ongoing and all obligations due to Nordic in relation to the Extension Study had been paid as of September 30, 2015.

## Edgar Filing: Radius Health, Inc. - Form 10-Q

The Company recognizes research and development expense for the amounts due to Nordic under the Extension Study and the Second Extension Period ratably over the estimated per patient treatment periods beginning upon enrollment, or over a nine-month and nineteen-month period, respectively. The Company recorded \$1.0 million and \$1.4 million for the three months ended March 31, 2016 and 2015, respectively, for per patient costs incurred.

As of March 31, 2016, the Company had a liability of \$2.7 million reflected in accrued expenses and other current liabilities on the condensed consolidated balance sheet resulting from services provided by Nordic under the Second Extension Period, which are payable in cash.

### **9. Stock-Based Compensation**

#### *Stock Options*

A summary of stock option activity during the three months ended March 31, 2016 is as follows (in thousands, except for per share amounts):

Table of Contents

	Shares	Weighted-Average Exercise Price (in dollars per share)	Weighted-Average Contractual Life (In Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2015	4,408	\$ 28.75		
Granted	1,280	32.89		
Exercised	30	30.97		
Cancelled	14	26.38		
Expired				
Options outstanding at March 31, 2016	5,644	\$ 29.68	8.40	\$ 52,173
Options exercisable at March 31, 2016	1,912	\$ 13.53	6.84	\$ 35,580
Options vested or expected to vest at March 31, 2016	5,507	\$ 29.44	8.38	\$ 51,730

The weighted-average grant-date fair value per share of options granted during the three months ended March 31, 2016 was \$17.67. As of March 31, 2016, there was approximately \$67.1 million of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 3 years.

**10. Net Loss Per Share**

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share numbers):

	Three Months Ended March 31,	
	2016	2015
<b>Numerator:</b>		
Net loss	\$ (40,463)	\$ (17,057)
Loss attributable to common stockholders - basic and diluted	\$ (40,463)	\$ (17,057)
<b>Denominator:</b>		
Weighted-average number of common shares used in loss per share - basic and diluted	43,012,924	36,268,975
Loss per share - basic and diluted	\$ (0.94)	\$ (0.47)

The following potentially dilutive securities, prior to the use of the treasury stock method, have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive. For the three months ended March 31, 2016 and 2015, all of the Company's options to purchase common stock, warrants and performance units outstanding were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Three Months Ended March 31,	
	2016	2015
Options to purchase common stock	4,973,694	3,376,071
Warrants	631,588	1,113,622

**11. Commitments and Contingencies**

The Company may be exposed, individually or in the aggregate, to certain claims or assessments in the ordinary course of business. In the opinion of management, the outcome of these matters is not likely to have any material effect on the financial statements of the Company.

Table of Contents

**12. Stockholders Equity**

On January 28, 2015, the Company completed an additional public offering of 4,000,000 shares of its common stock at a price of \$36.75 per share, for aggregate estimated proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$137.8 million. Also, on January 28, 2015, the underwriters purchased an additional 600,000 shares in the aggregate by exercising an option to purchase additional shares that was granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the underwriters option, the Company received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately \$158.4 million.

On July 28, 2015, the Company completed an additional public offering of 4,054,054 shares of its common stock at a price of \$74.00 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$281.5 million. Also, on July 28, 2015, the underwriters purchased an additional 608,108 shares by exercising an option to purchase additional shares that was granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the underwriters option, the Company received aggregate proceeds, net of underwriting discounts, commissions and estimated offering costs of approximately \$323.8 million.

Table of Contents

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

***Cautionary Statement***

*This Quarterly Report on Form 10-Q, including the information incorporated by reference herein, contains, in addition to historical information, forward-looking statements. We may, in some cases, use words such as project, believe, anticipate, plan, expect, estimate, intend, continue, should, would, could, potentially, will, may or similar words and expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q may include, among other things, statements about:*

- *the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;*
- *the success of our clinical studies for our investigational product candidates;*
- *our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards;*
- *our expectations regarding federal, state and foreign regulatory requirements;*
- *the therapeutic benefits and effectiveness of our product candidates;*
- *the safety profile and related adverse events of our product candidates;*
- *our ability to manufacture sufficient amounts of abaloparatide, RAD1901, and RAD140 for commercialization activities with target characteristics following regulatory approvals;*
- *our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates;*

- *our expectations as to future financial performance, expense levels and liquidity sources;*
- *our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;*
- *anticipated trends and challenges in our potential markets; and*
- *our ability to attract and motivate key personnel.*

*The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements. These important factors include our financial performance, our ability to attract and retain customers, our development activities and those factors we discuss in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on February 25, 2016 under the caption Risk Factors. You should read these factors and the other cautionary statements made in this Quarterly Report on Form 10-Q as being applicable to all related forward-looking statements wherever they appear in this Quarterly Report on Form 10-Q. These important factors are not exhaustive and other sections of this Quarterly Report on Form 10-Q may include additional factors which could adversely impact our business and financial performance.*

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and related notes set forth in this report. Unless the context otherwise requires, we, our, us and similar expressions used in this Management Discussion and Analysis of Financial Condition and Results of Operations section refer to Radius Health, Inc., a Delaware corporation.

## **Executive Overview**

We are a science-driven biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Our lead product candidate, the investigational drug abaloparatide for subcutaneous injection, or abaloparatide-SC, has completed Phase 3 development for potential use in the reduction of fracture risk in



Table of Contents

postmenopausal women with osteoporosis. Our Marketing Authorisation Application, or MAA, for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe and a New Drug Application, or NDA, was submitted to the U.S. Food and Drug Administration, or FDA, at the end of the first quarter of 2016. Our clinical pipeline also includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug RAD1901 for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Our preclinical pipeline includes RAD140, a non-steroidal, selective androgen receptor modulator under investigation for potential use in multiple applications including cancer.

*Abaloparatide*

Abaloparatide is an investigational therapy for the potential treatment of women with postmenopausal osteoporosis who are at an increased risk for a fracture. Abaloparatide is a novel synthetic peptide analog that engages the parathyroid hormone receptor, or PTH1 receptor, and was selected for clinical development based on its favorable bone building activity. Abaloparatide was created to have a unique mechanism of action with the goal of stimulating enhanced bone building activity including bone formation, increasing bone mineral density, restoring bone microarchitecture and augmenting bone strength. We are developing two formulations of abaloparatide:

- *Abaloparatide-SC* Abaloparatide has completed Phase 3 development for potential use as a daily self-administered injection. We hold worldwide commercialization rights to abaloparatide-SC, except for Japan. In December 2014, we announced positive 18-month top-line data from our Phase 3 ACTIVE clinical trial, in which abaloparatide-SC met the primary endpoint with a statistically significant reduction of 86% in new vertebral fractures versus placebo, and a statistically significant 43% reduction in the secondary endpoint of nonvertebral fractures versus placebo. In June 2015, we announced the positive top-line data from the first six months of the ACTIVEExtend clinical trial and the 25-month combined fracture data from the ACTIVE and ACTIVEExtend clinical trials, which showed a statistically significant 87% reduction in the primary endpoint of new vertebral fractures for abaloparatide-treated patients for 18 months who were then treated with alendronate for 6 months compared to patients treated with placebo for 18 months and then treated with alendronate for 6 months and a statistically significant reduction of 52% in the secondary endpoint of nonvertebral fractures. Also, in ACTIVEExtend, there was a statistically significant reduction in clinical fractures, and major osteoporotic fractures for the patients initially treated with abaloparatide followed by 6 months of alendronate versus patients treated initially with placebo followed by 6 months of alendronate. The combined 25-month fracture data from our Phase 3 clinical trial program for abaloparatide-SC formed the basis of our regulatory submissions. In November 2015, we submitted an MAA to the European Medicines Agency, or EMA, which was validated and is currently undergoing regulatory review. In March 2016, we submitted an NDA to the FDA. We intend to enter into one or more collaborations for the potential commercialization of abaloparatide-SC prior to a commercial launch. Subject to regulatory review and a favorable regulatory outcome, we anticipate the first commercial sales of abaloparatide-SC will take place in 2016.

- *Abaloparatide-TD* We are also developing abaloparatide-transdermal, which we refer to as abaloparatide-TD, based on 3M's patented Microstructured Transdermal System technology for potential use as a short wear-time transdermal patch. We hold worldwide commercialization rights to the abaloparatide-TD technology. During 2014, we reported progress towards the development of an optimized transdermal patch that may be capable of demonstrating comparability to abaloparatide-SC. In preliminary, nonhuman primate pharmacokinetic studies, we achieved a desirable pharmacokinetic profile, with comparable AUC, Cmax, Tmax and T1/2 relative to

abaloparatide-SC. We believe that these results support continued clinical development of abaloparatide-TD toward future global regulatory submissions as a potential post-approval line extension of the investigational drug abaloparatide-SC. We commenced a human replicative clinical evaluation of the optimized abaloparatide-TD patch in December 2015, with the goal of achieving comparability to abaloparatide-SC. We expect to complete this clinical evaluation of the optimized abaloparatide-TD patch during 2016.

***RAD1901***

RAD1901 is a selective estrogen receptor down-regulator/degrader, or SERD, that at high doses has a potential for use as an oral non-steroidal treatment for hormone-driven, or hormone-resistant, breast cancer. RAD1901 is currently being investigated in postmenopausal women with advanced estrogen receptor positive, or ER-positive, HER2-negative breast cancer, the most common form of the disease. The compound has the potential for use as a single agent or in combination with other therapies to overcome endocrine resistance in breast cancer.

In September 2015, we announced results from a Phase 1 maximum tolerated dose, or MTD, study of RAD1901 in 52 healthy volunteers. In the study, RAD1901 was administered to healthy postmenopausal women in doses ranging from 200mg to 1000mg, and the data showed that RAD1901 was well-tolerated and the overall safety was supportive of continued development. In addition, a subset of subjects that received 18F estradiol positron emission tomography, or FES-PET, imaging demonstrated suppression of the FES-PET signal to background levels after six days of dosing.

In December 2014, we commenced a Phase 1, multicenter, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced ER-positive and HER2-negative breast cancer in the United States to determine the recommended dose for a Phase 2 clinical trial and to make a preliminary evaluation of the potential anti-tumor effect of RAD1901. The Phase 1 study is designed to evaluate escalating doses of RAD1901 in Part A. The Part B expansion cohorts allow for an

Table of Contents

evaluation of additional safety, tolerability and preliminary efficacy. When the study is completed, the results will be submitted to an appropriate scientific meeting for presentation.

In December 2015, we commenced a Phase 1 FES-PET study in patients with metastatic breast cancer in the European Union which includes the use of FES-PET imaging to assess estrogen receptor occupancy in tumor lesions following RAD1901 treatment. When the study is completed, the results will be submitted to an appropriate scientific meeting for presentation.

In July 2015, we announced that early but promising preclinical data showed that our investigational drug RAD1901, in combination with Pfizer's palbociclib, a cyclin-dependent kinase, or CDK 4/6 inhibitor, or Novartis' everolimus, an mTOR inhibitor, was effective in shrinking tumors. In patient-derived xenograft breast cancer models with either wild type or mutant ESR1, treatment with RAD1901 resulted in marked tumor growth inhibition, and the combination of RAD1901 with either agent, palbociclib or everolimus, showed anti-tumor activity that was significantly greater than either agent alone. We believe that this preclinical data suggest that RAD1901 has the potential to overcome endocrine resistance, is well-tolerated, and has a profile that is well suited for use in combination therapy.

In January 2016 we entered into a worldwide clinical collaboration with Novartis Pharmaceuticals to evaluate the safety and efficacy of combining RAD1901, with Novartis' investigational agent LEE011 (ribociclib), a CDK 4/6 inhibitor, and BYL719 (alpelisib), an investigational phosphoinositide 3-kinase inhibitor.

RAD1901 is also being evaluated at low doses as an estrogen receptor ligand for the potential relief of the frequency and severity of moderate to severe hot flashes in postmenopausal women with vasomotor symptoms. We commenced a Phase 2b clinical study of RAD1901 for the potential treatment of postmenopausal vasomotor symptoms in December 2015. When the study is completed, the results will be submitted to an appropriate scientific meeting for presentation.

**Financial Overview**

*Research and Development Expenses*

Research and development expenses consist primarily of clinical testing costs made to contract research organizations, salaries and related personnel costs, fees paid to consultants and outside service providers for regulatory and quality assurance support, licensing of drug compounds and other expenses relating to the manufacture, development, testing and enhancement of our product candidates. We expense our research and development costs as they are incurred.

None of the research and development expenses in relation to our product candidates are currently borne by third parties. Our lead product candidate is the investigational drug abaloparatide, and it represents the largest portion of our research and development expenses for our product candidates. We began tracking program expenses for abaloparatide-SC in 2005, and program expenses from inception to March 31, 2016 were approximately \$201.7 million. We began tracking program expenses for abaloparatide-TD in 2007, and program expenses from

## Edgar Filing: Radius Health, Inc. - Form 10-Q

inception to March 31, 2016 were approximately \$35.8 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to March 31, 2016 were approximately \$35.8 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to March 31, 2016 were approximately \$6.1 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs.

Costs related to facilities, depreciation, stock-based compensation and research and development support services are not directly charged to programs as they benefit multiple research programs that share resources.

The following table sets forth our research and development expenses that are directly attributable to the programs listed below for the three months ended March 31, 2016 and 2015 (in thousands):

	Three Months Ended			
	March 31,			
	2016		2015	
Abaloparatide-SC	\$	5,778	\$	5,134
Abaloparatide-TD		2,145		480
RAD1901		8,117		800
RAD140		357		

Table of Contents

*General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, professional fees, business insurance, rent, general legal activities, including the cost of maintaining our intellectual property portfolio, and other corporate expenses.

Our results also include stock-based compensation expense as a result of the issuance of stock option grants to employees, directors and consultants. The stock-based compensation expense is included in the respective categories of expense in the statement of operations (research and development and general and administrative expenses). We expect to record additional non-cash stock-based compensation expense in the future, which may be significant.

*Interest Income and Interest Expense*

Interest income reflects interest earned on our cash, cash equivalents and marketable securities.

Interest expense for the three months ended March 31, 2015 reflects interest due under our loan and security agreement, entered into on May 30, 2014 and amended on July 10, 2014, February 13, 2015 and April 8, 2015, or the Credit Facility, with Solar Capital Ltd., or Solar, as agent and lender, and Oxford Finance LLC, or Oxford, as lender. Under the Credit Facility, we drew \$21.0 million under an initial term loan on May 30, 2014 and \$4.0 million under a second term loan on July 10, 2014. On August 4, 2015, we paid all amounts owed under the Credit Facility. After consideration of relevant fees required under the Credit Facility, the total payment amounted to \$26.5 million.

**Critical Accounting Policies and Estimates**

Management's discussion and analysis of financial condition and results of operations is based upon our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, as well as related disclosures. We evaluate our policies and estimates on an ongoing basis, including those related to accrued clinical expenses, research and development expenses, stock-based compensation and fair value measures, which we discussed in our Annual Report on Form 10-K for the year ended December 31, 2015. Management bases its estimates on historical experience and other various assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We have reviewed our policies and estimates to determine our critical accounting policies for the three months ended March 31, 2016. We have made no material changes to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2015.

**Results of Operations***Three Months Ended March 31, 2016 and March 31, 2015 (in thousands, except percentages)*

	Three Months Ended March 31,		Change	
	2016	2015	\$	%
<b>Operating expenses:</b>				
Research and development	\$ 27,483	\$ 11,559	\$ 15,924	138%
General and administrative	13,646	4,756	8,890	187%
Loss from operations	(41,129)	(16,315)	24,814	152%
<b>Other (expense) income:</b>				
Other (expense) income, net	(1)	(50)	(49)	-98%
Interest income (expense), net	667	(692)	1,359	196%
Net loss	\$ (40,463)	\$ (17,057)	23,406	137%

*Research and development expenses* For the three months ended March 31, 2016, research and development expense was \$27.5 million compared to \$11.6 million for the three months ended March 31, 2015, an increase of \$15.9 million, or 138%. This increase was primarily driven by higher professional contract services costs associated with the development of RAD1901 to support a Phase 1 study in metastatic breast cancer that commenced in late 2014 and a Phase 2b study in postmenopausal vasomotor symptoms that commenced in December 2015. This increase was also a result of an increase in compensation expense, including stock-based compensation, due to an increase in headcount from 18 research and development employees as of March 31, 2015 to 78 research and development employees as of March 31, 2016.

Table of Contents

We expect that the costs associated with the development of abaloparatide-TD will increase as we begin to advance an optimized abaloparatide-TD product in additional clinical studies.

*General and administrative expenses* For the three months ended March 31, 2016, general and administrative expense was \$13.6 million compared to \$4.8 million for the three months ended March 31, 2015, an increase of \$8.9 million, or 187%. This increase was primarily the result of an increase of approximately \$5.8 million in professional support costs and legal fees during the three months ended March 31, 2016, including the costs associated with increasing headcount and preparing for the potential commercialization of abaloparatide-SC, subject to a favorable regulatory review. This increase was also driven by an increase in compensation expense due to an increase in headcount from 11 general and administrative employees as of March 31, 2015 to 44 general and administrative employees as of March 31, 2016.

*Interest income (expense), net* For the three months ended March 31, 2016, interest income was \$0.7 million compared to interest expense, net of interest income, of \$0.7 million for the three months ended March 31, 2015, a change of \$1.4 million, or 196%. This change was primarily a result of no interest expense recorded for the three months ended March 31, 2016 due to repayment of our Credit Facility on August 4, 2015.

*Liquidity and Capital Resources*

From inception to March 31, 2016, we have incurred an accumulated deficit of \$486.2 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and expenses supporting those activities. Our total cash, cash equivalents and short and long-term marketable securities balance as of March 31, 2016 was \$439.8 million. We have financed our operations since inception primarily through the public offerings of our common stock, private sales of preferred stock, and borrowings under credit facilities.

Based upon our cash, cash equivalents and marketable securities balance, we believe that, prior to the consideration of revenue from the potential future sales of any of our investigational products or proceeds from collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial scale-up and other operational activities into 2018. We expect to finance the future development costs of our clinical product portfolio with our existing cash, cash equivalents and marketable securities, or through strategic financing opportunities, that could include, but are not limited to collaboration agreements, future offerings of equity, or the incurrence of debt. However, there is no guarantee that any of these strategic financing opportunities will be available to us on favorable terms, and some could be dilutive to existing stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development and commercialization activities, the results of our clinical trials, and the review and potential approval of our products by the FDA, and the EMA. The successful development of our investigational product candidates is subject to numerous risks and uncertainties associated with developing drugs, which could have a significant impact on the cost and timing associated with the development of our product candidates. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any investigational product candidates from the FDA and foreign regulatory authorities.

Edgar Filing: Radius Health, Inc. - Form 10-Q

Abaloparatide-SC is our only product candidate in late stage development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. Obtaining approval of a product candidate is an extensive, lengthy, expensive and uncertain process, and any approval of abaloparatide-SC may be delayed, limited or denied for many reasons. See Risk Factors Risks Related to the Discovery, Development and Commercialization of Our Product Candidates set forth under Item 1A. in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities & Exchange Commission on February 25, 2016.

The following table sets forth the major sources and uses of cash for each of the periods set forth below (in thousands):

	Three Months Ended		Change	
	2016	March 31, 2015		
Net cash (used in) provided by:				
Operating activities	\$ (33,738)	\$ (20,329)	\$ 13,409	66%
Investing activities	(22,455)	(131,793)	(109,338)	-83%
Financing activities	929	158,414	(157,485)	-99%
Net increase (decrease) in cash and cash equivalents	\$ (55,264)	\$ 6,292		



Table of Contents

*Cash Flows from Operating Activities*

Net cash used in operating activities during the three months ended March 31, 2016 was \$33.7 million, which was primarily the result of a net loss of \$40.5 million, partially offset by \$4.9 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of \$1.9 million. The \$40.5 million net loss was primarily due to abaloparatide-SC and RAD1901 program development expenses along with employee compensation and consulting costs incurred to support regulatory submissions and preparation for the potential commercial launch of abaloparatide-SC. The \$4.9 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$4.2 million and amortization of premiums (discounts) on marketable securities of \$0.6 million.

Net cash used in operating activities during the three months ended March 31, 2015 was \$20.3 million, which was primarily the result of a net loss of \$17.1 million and net changes in working capital of \$5.7 million, partially offset by \$2.5 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The \$17.1 million net loss was primarily due to abaloparatide-SC program development expenses, including clinical and manufacturing costs, along with employee compensation and consulting costs incurred to support future regulatory submissions and preparation for the potential commercial launch of abaloparatide-SC. The \$2.5 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$2.1 million and amortization of premiums (discounts) on marketable securities of \$0.3 million.

*Cash Flows from Investing Activities*

Net cash used in investing activities during the three months ended March 31, 2016 was \$22.5 million, which was primarily the result of \$157.9 million of purchases of marketable securities, partially offset by \$135.8 million of net proceeds received from the sale or maturity of marketable securities.

Net cash used in investing activities during the three months ended March 31, 2015 was \$131.8 million, which was primarily the result of \$170.1 million of purchases of marketable securities, partially offset by \$38.4 million of net proceeds received from the sale or maturity of marketable securities.

Our investing cash flows will be impacted by the timing of purchases and sales of marketable securities. Because our marketable securities are primarily short-term in duration, we would not expect our operational results or cash flows to be significantly affected by a change in market interest rates.

*Cash Flows from Financing Activities*

Net cash provided by financing activities during the three months ended March 31, 2016 was \$0.9 million, as compared to \$158.4 million net cash provided by financing activities during the three months ended March 31, 2015. Net cash provided by financing activities during

the three months ended March 31, 2016 consisted of \$0.9 million of proceeds received from exercises of stock options.

Net cash provided by financing activities during the three months ended March 31, 2015 consisted of \$158.4 million of net proceeds received from an additional public offering in January of 2015.

***Contractual Obligations***

During the three months ended March 31, 2016, there have been no material changes to our contractual obligations as reported in our Annual Report on Form 10-K for the year ended December 31, 2015.

***Research and Development Agreements***

***Abaloparatide-SC Phase 3 Clinical Extension Study***

We have entered into agreements with Nordic Bioscience Clinical Development VII A/S, or Nordic, to conduct our Phase 3 clinical trial of abaloparatide-SC, or the Phase 3 Clinical Trial. On February 21, 2013, we entered into the Work Statement NB-3, as amended on February 28, 2014, March 23, 2015, July 8, 2015, October 21, 2015 and January 15, 2016, or the Work Statement NB-3. Pursuant to the Work Statement NB-3, Nordic performed an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial, or the Extension Study, and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management, or the Second Extension Period.

Table of Contents

In April 2015, we entered into an amendment to the Work Statement NB-3, or the NB-3 Amendment. The NB-3 Amendment was effective as of March 23, 2015 and provides that Nordic will perform additional services, including monitoring of patients enrolled in the Second Extension Period. Payments in cash to be made to Nordic under the NB-3 Amendment are denominated in euros and total up to approximately 4.1 million (\$4.7 million).

Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to 11.9 million (\$13.5 million) and \$1.1 million, respectively. In addition, payments were due to Nordic in connection with the Work Statement NB-3 pursuant to the Stock Issuance Agreement we entered into with Nordic, as amended and restated on May 16, 2011, and as further amended on February 21, 2013, March 28, 2014, and May 19, 2014, or the Stock Issuance Agreement. As of March 31, 2016, services related to the Second Extension Period are ongoing and all obligations due to Nordic in relation to the Extension Study had been paid as of September 30, 2015.

We recognize research and development expense for the amounts due to Nordic under the Extension Study and the Second Extension Period ratably over the estimated per patient treatment periods beginning upon enrollment or over a nine-month and 19-month period, respectively. We recorded \$1.0 million and \$1.4 million of research and development expense during the three months ended March 31, 2016, and 2015, respectively, for per patient costs incurred.

As of March 31, 2016, we had a liability of \$2.7 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic under the Second Extension Period, which are payable in cash.

***License Agreement Obligations***

*Abaloparatide*

In September 2005, we exclusively licensed the worldwide rights (except for development and commercial rights in Japan) to abaloparatide and analogs from an affiliate of Ipsen Pharma SAS, or Ipsen.

In consideration for the rights to abaloparatide and in recognition of certain milestones having been met to date, we have paid to Ipsen an aggregate amount of \$1.0 million. The license agreement further requires us to make payments upon the achievement of certain future regulatory and commercial milestones, including upon acceptance of an NDA submission for review by the FDA. The range of milestone payments that could be paid under the agreement is 10.0 million to 36.0 million (\$11.4 million to \$41.0 million). Should abaloparatide be approved and subsequently commercialized, we will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product by us or our sublicensees on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense abaloparatide to a third party, we are obligated to pay a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, we will be obligated to pay to Ipsen a fixed low single digit royalty on

## Edgar Filing: Radius Health, Inc. - Form 10-Q

net sales of such product on a country-by-country basis until the later of the last to expire of licensed patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country. The license agreement with Ipsen contains other customary clauses and terms as are common in similar agreements in the industry.

Prior to executing the license agreement for abaloparatide with us, Ipsen licensed the Japanese rights for abaloparatide to Teijin Limited, or Teijin, a Japanese pharmaceutical company. Teijin has completed a Phase 2 clinical study of abaloparatide in Japan for the treatment of postmenopausal osteoporosis.

### *RAD1901*

We exclusively licensed the worldwide rights to RAD1901 from Eisai Co. Ltd., or Eisai. Our license with Eisai did not originally include rights for Japan, however, on March 9, 2015, we entered into an amendment to the Eisai Agreement in which Eisai granted us an exclusive right and license to research, develop, manufacture and commercialize RAD1901 in Japan. In consideration for the rights to RAD1901 in Japan, we paid Eisai an initial license fee of \$0.4 million upon execution of the amendment, which was expensed during the three months ended March 31, 2015.

In consideration for the rights to RAD1901 and in recognition of certain milestones having been met to date, we have paid to Eisai an aggregate amount of \$1.9 million. The range of milestone payments that could be paid under the agreement is \$1.0 million to \$20.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. Should RAD1901 be approved and subsequently become commercialized, we will be obligated to pay to Eisai a royalty in a variable mid-single digit range based on net sales of the product on a country-by-country basis for a period that expires on the later of (1) the date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the

Table of Contents

product is not covered by data protection clauses, and the sales of lawful generic version of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated. The latest valid claim is expected to expire, barring any extension thereof, on August 18, 2026. The royalty rate shall then be subject to reduction and the royalty obligation will expire at such time as sales of lawful generic versions of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. We were also granted the right to grant sublicenses with prior written approval from Eisai. If we sublicense RAD1901 to a third party, we will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees we receive from such sublicensee and royalties in a variable mid-single digit range based on net sales of the sublicensee. The license agreement with Eisai contains other customary clauses and terms as are common in similar agreements in the industry.

***Net Operating Loss Carryforwards***

As of December 31, 2015, we had federal and state net operating loss carryforwards of approximately \$419.5 million and \$323.0 million, respectively, the use of which may be limited, as described below. If not utilized, the net operating loss carryforwards will expire at various dates through 2035.

Under Section 382 of the Internal Revenue Code of 1986, as amended, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be used annually in the future to offset taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards before they expire. The private placements and other transactions that have occurred since our inception, may have triggered an ownership change pursuant to Section 382, which could limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset taxable income, if any. Any such limitation, whether as the result of prior private placements, sales of common stock by our existing stockholders or additional sales of common stock by us, could have a material adverse effect on our results of operations in future years. We are in the process of completing a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal or state income tax benefit in our statement of operations.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements or any relationships with unconsolidated entities of financial partnerships, such as entities often referred to as structured finance or special purpose entities.

**New Accounting Standards**

See note 2, *Basis of Presentation and Significant Accounting Policies – Accounting Standards Updates and Basis of Presentation and Significant Accounting Policies*, in Notes to Condensed Consolidated Financial Statements, for a discussion of new accounting standards.



Table of Contents

**Item 3. Quantitative and Qualitative Disclosure about Market Risk.**

We are exposed to market risk related to changes in the dollar/euro exchange rate because a portion of our development costs are denominated in foreign currencies. We do not hedge our foreign currency exchange rate risk. However, an immediate 10 percent adverse change in the dollar/euro exchange rate would not have a material effect on financial results.

We are exposed to market risk related to changes in interest rates. As of March 31, 2016, we had cash, cash equivalents and short and long-term marketable securities of \$439.8 million, consisting of cash, money market funds, domestic corporate debt securities, domestic corporate commercial paper, and asset-backed securities. This exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable securities. Because our marketable securities are primarily short-term in duration, and have a low risk profile, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We generally have the ability to hold our investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We carry our investments based on publicly available information. As of March 31, 2016, we do not have any hard-to-value investment securities or securities for which a market is not readily available or active.

We are not subject to significant credit risk as this risk does not have the potential to materially impact the value of assets and liabilities.

Table of Contents

**Item 4. Controls and Procedures.**

**Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2016.

**Changes in Internal Control over Financial Reporting**

There have not been any changes in our internal control over financial reporting during the three months ended March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



Table of Contents

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings.**

None.

**Item 1A. Risk Factors.**

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2015, which could materially affect our business, financial condition or future results.

There were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 25, 2016.

Table of Contents

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

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q, and is incorporated herein by reference.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**RADIUS HEALTH, INC.**

By:

*/s/ Robert E. Ward*  
**Robert E. Ward**  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: May 5, 2016

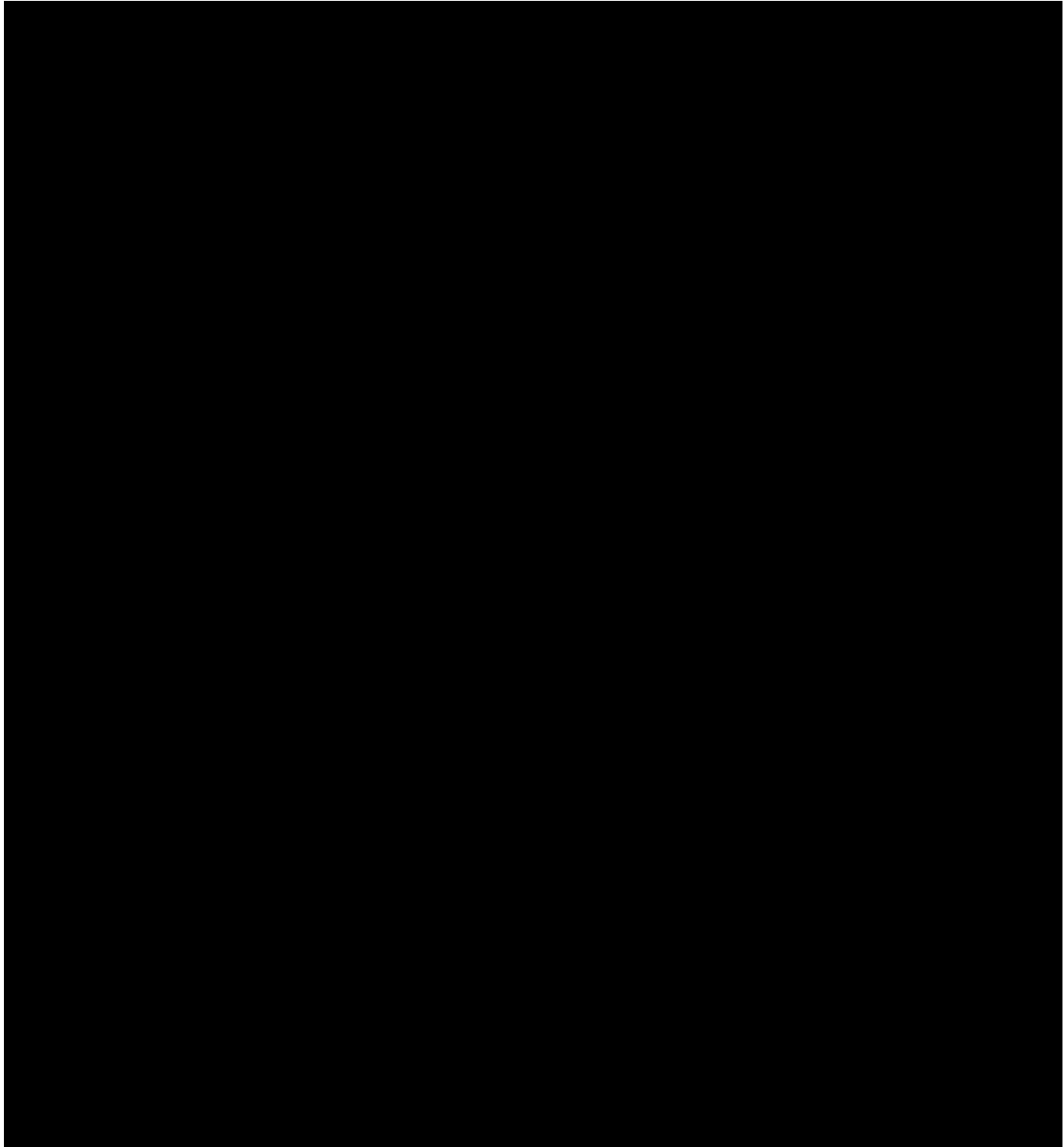
By:

*/s/ B. Nicholas Harvey*  
**B. Nicholas Harvey**  
**Chief Financial Officer**  
**(Principal Accounting and Financial Officer)**

Date: May 5, 2016

Table of Contents

**EXHIBIT INDEX**



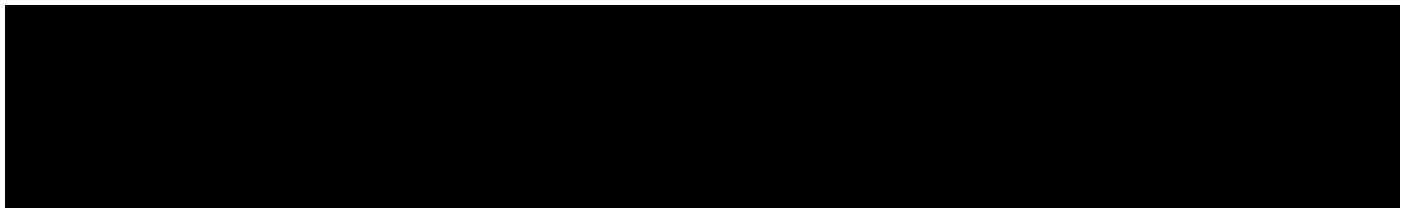
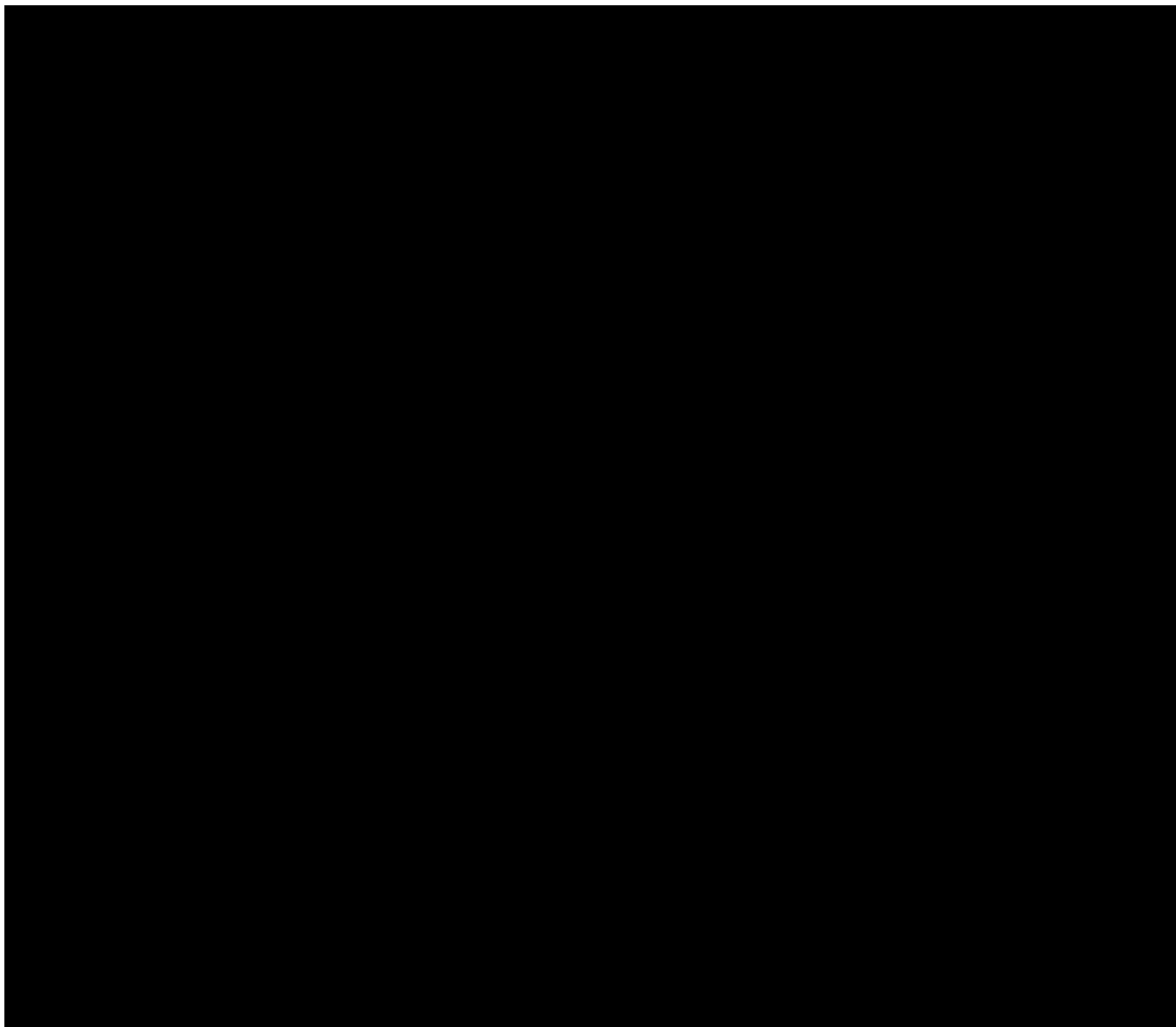


Table of Contents



---

\* Filed herewith.

\*\* Furnished herewith.

Confidential treatment has been requested with respect to certain portions of this exhibit, which portions have been filed separately with the Securities and Exchange Commission.