

Radius Health, Inc.  
Form 10-Q  
November 03, 2016  
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number 001-35726

Radius Health, Inc.  
(Exact name of registrant as specified in its charter)  
Delaware 80-0145732  
(State or other jurisdiction of (IRS Employer  
Incorporation or organization) 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

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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 October 31, 2016:  
43,111,707 shares

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RADIUS HEALTH, INC.  
FORM 10-Q  
FOR THE QUARTER ENDED SEPTEMBER 30, 2016

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CURRENCY AND CONVERSIONS

In this report, references to “dollar” or “\$” are to the legal currency of the United States, 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 and references to "Swiss Francs" or "CHF" are to the legal currency of Switzerland. 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 and Swiss Francs 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 September 30, 2016, which was €1.00 = 1.1238 and CHF1.00 = \$1.0316, respectively. Such translations should not be construed as a representation that the euro or Swiss Franc, as the case may be, has been, could have been or could be converted into U.S. dollars at the rate indicated, any particular rate or at all.

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## Item 1. Condensed Consolidated Financial Statements

Radius Health, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	September 30, 2016 (unaudited)	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 198,565	\$ 159,678
Marketable securities	171,267	313,661
Prepaid expenses and other current assets	3,661	6,969
Total current assets	373,493	480,308
Property and equipment, net	4,057	1,897
Other assets	551	260
Total assets	\$ 378,101	\$ 482,465
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,665	\$ 6,228
Accrued expenses and other current liabilities	22,642	14,952
Total current liabilities	25,307	21,180
Other non-current liabilities	402	—
Total liabilities	\$ 25,709	\$ 21,180
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 43,109,927 shares and 42,984,243 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	4	4
Additional paid-in-capital	928,184	907,040
Accumulated other comprehensive income	52	5
Accumulated deficit	(575,848	) (445,764 )
Total stockholders' equity	352,392	461,285
Total liabilities and stockholders' equity	\$ 378,101	\$ 482,465

See accompanying notes to unaudited condensed consolidated financial statements.

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Radius Health, Inc.  
 Condensed Consolidated Statements of Comprehensive Loss  
 (Unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>OPERATING EXPENSES:</b>				
Research and development	\$27,453	\$18,217	\$81,827	\$46,054
General and administrative	19,240	8,456	50,079	19,212
Loss from operations	(46,693 )	(26,673 )	(131,906 )	(65,266 )
<b>OTHER (EXPENSE) INCOME:</b>				
Other (expense) income, net	(78 )	1	(174 )	(127 )
Loss on retirement of note payable	—	(1,572 )	—	(1,572 )
Interest income	585	274	1,996	564
Interest expense	—	(294 )	—	(1,885 )
<b>NET LOSS</b>	<b>\$(46,186)</b>	<b>\$(28,264)</b>	<b>\$(130,084)</b>	<b>\$(68,286)</b>
<b>OTHER COMPREHENSIVE LOSS, NET OF TAX:</b>				
Unrealized (loss) gain from available-for-sale securities	(136 )	89	47	120
<b>COMPREHENSIVE LOSS</b>	<b>\$(46,322)</b>	<b>\$(28,175)</b>	<b>\$(130,037)</b>	<b>\$(68,166)</b>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED (Note 10)</b>	<b>\$(46,186)</b>	<b>\$(28,264)</b>	<b>\$(130,084)</b>	<b>\$(68,286)</b>
<b>LOSS PER SHARE:</b>				
Basic and diluted	\$(1.07 )	\$(0.68 )	\$(3.02 )	\$(1.77 )
<b>WEIGHTED AVERAGE SHARES:</b>				
Basic and diluted	43,092,921	41,331,612	43,049,734	38,525,827

See accompanying notes to unaudited condensed consolidated financial statements.

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Radius Health, Inc.  
Condensed Consolidated Statements of Cash Flows  
(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2016	2015
<b>CASH FLOWS USED IN OPERATING ACTIVITIES:</b>		
Net loss	\$(130,084)	\$(68,286 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	371	126
Amortization of premium on marketable securities, net	797	1,024
Stock-based compensation	18,702	10,022
Non-cash interest	—	183
Loss on retirement of note payable	—	1,572
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,308	(2,426 )
Other long-term assets	(291 )	(108 )
Accounts payable	(3,563 )	2,218
Accrued expenses and other current liabilities	7,284	(4,391 )
Other non-current liabilities	402	—
Net cash used in operating activities	(103,074 )	(60,066 )
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(2,125 )	(230 )
Purchases of marketable securities	(225,497 )	(420,734 )
Sales and maturities of marketable securities	367,141	164,474
Net cash provided by (used in) investing activities	139,519	(256,490 )
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>		
Payments on note payable	—	(25,000 )
Fee for early prepayment of note payable	—	(1,502 )
Proceeds from exercise of stock options	2,442	958
Proceeds from issuance of common stock, net	—	482,254
Net cash provided by financing activities	2,442	456,710
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>38,887</b>	<b>140,154</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>\$198,565</b>	<b>\$168,672</b>
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	\$—	\$1,490
Property and equipment purchases in accrued expenses at period end	\$406	\$—

See accompanying notes to unaudited condensed consolidated financial statements.

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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 (“MAA”) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe and a New Drug Application (“NDA”) has been accepted for filing by the U.S. Food and Drug Administration (“FDA”) with a Prescription Drug User Fee Act date of March 30, 2017. 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 cancer.

The Company is subject to the risks associated 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 September 30, 2016, the Company had an accumulated deficit of \$575.8 million, and total cash, cash equivalents and marketable securities of \$369.8 million.

Based upon its cash, cash equivalents and marketable securities balance as of September 30, 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 collaboration agreements, future offerings of its equity, or the incurrence of debt. However, there is no guarantee that any of these 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 studies and clinical trials and obtain approval of certain investigational product candidates from the 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 nine months ended September 30, 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 financial statements. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2015 (“2015 Form 10-K”), filed with the Securities and Exchange Commission (“SEC”) on February 25, 2016.

**Significant Accounting Policies**— The significant accounting policies identified in the Company’s 2015 Form 10-K 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 nine months ended September 30, 2016.

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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.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, Measurement of Credit Losses on Financial Statements (“ASU 2016-13”). ASU 2016-13 affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. ASU 2016-13 affects loans, debt securities, trade receivables, net investments in leases, off-balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have contractual right to receive cash. ASU 2016-13 requires that a financial asset (or a group of financial assets) measured at amortized cost basis be presented at the net amount expected to be collected using an allowance for credit losses valuation account. ASU 2016-13 requires that credit losses relating to available-for-sale debt securities should be limited by the amount which the fair value is below amortized cost. ASU 2016-13 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. Early adoption is permitted as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and related disclosures.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (“ASU 2016-15”). ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted. The Company does not expect the adoption of ASU 2016-05 to have a material impact on its results of operations, financial position or cash flows.

### 3. Accrued Expenses and Other Current Liabilities

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

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	September 30, December 31,	
	2016	2015
Research costs - Nordic (1)	\$ 2,224	\$ 2,898
Research costs - other	8,491	5,178
Payroll and employee benefits	5,704	3,330
Professional fees	6,152	3,546
Other current liabilities	\$ 71	\$ —
Total accrued expenses and other current liabilities	\$ 22,642	\$ 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”).

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):

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	\$2,270	\$ —	\$ —	\$ 2,270
Money market funds	196,295	—	—	196,295
Domestic corporate commercial paper	—	—	—	—
Total	\$ 198,565	\$ —	\$ —	\$ 198,565
Marketable securities:				
Domestic corporate debt securities	\$48,402	\$ 1	\$ (9)	\$ 48,394
Domestic corporate commercial paper	51,118	61	—	51,179

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Asset-backed securities	71,694	4	(4	)	71,694
Total	\$171,214	\$ 66	\$ (13	)	\$171,267

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	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	\$2,934	\$ —	\$ —	\$2,934
Money market funds	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
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 September 30, 2016 or December 31, 2015. There were 14 debt securities in an unrealized loss position for less than 12 months at September 30, 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 September 30, 2016 and December 31, 2015 was approximately \$13 thousand and \$150 thousand, respectively, and the fair value was \$78.5 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 September 30, 2016.

As of September 30, 2016, marketable securities consisted of investments that mature within one year.

## 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 September 30, 2016 and December 31, 2015 (in thousands):



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As of September 30, 2016  
Level 1    Level 2    Level 3    Total

Assets				
Cash and cash equivalents:				
Cash	\$2,270	\$—	\$	—\$2,270
Money market funds (1)	196,295	—	—	196,295
Domestic corporate commercial paper (2)	—	—	—	—
Total	\$198,565	\$—	\$	—\$198,565
Marketable Securities				
Domestic corporate debt securities (2)	\$—	\$48,394	\$	—48,394
Domestic corporate commercial paper (2)	—	51,179	—	51,179
Asset-backed securities (2)	—	71,694	—	71,694
Total	\$—	\$171,267	\$	—\$171,267

As of December 31, 2015  
Level 1    Level 2    Level 3    Total

Assets				
Cash and cash equivalents:				
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 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). 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

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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 (\$11.2 million to \$40.4 million). Following acceptance of the Company's NDA submission for review by the FDA in the second quarter of 2016, the Company made a milestone payment of €3.0 million (\$3.3 million) to Ipsen, which was recognized as research and development expense during the three months ended June 30, 2016. 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.

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 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

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The Company entered into agreements with Nordic to conduct its Phase 3 clinical trial of abaloparatide-SC (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 (\$4.6 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 (\$13.3 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. As of September 30, 2016, services related to the Second Extension Period are ongoing. All obligations due to Nordic in relation to the Extension Study were paid as of September 30, 2015.

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 19-month period, respectively. The Company recorded \$0.7 million and \$1.5 million for the three months ended September 30, 2016 and 2015, respectively, and \$2.6 million and \$4.1 million for the nine months ended September 30, 2016 and 2015, respectively, for per patient costs incurred.

As of September 30, 2016, the Company had a liability of \$2.2 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 nine months ended September 30, 2016 is as follows (in thousands, except for per share amounts):

	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	2,095	36.10		
Exercised	(126 )	19.36		
Cancelled	(102 )	42.12		
Expired	(1 )	79.90		
Options outstanding at September 30, 2016	6,274	\$ 31.17	8.16	\$ 156,384

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Options exercisable at September 30, 2016	2,469	\$ 19.77	6.86	\$87,873
Options vested or expected to vest at September 30, 2016	6,153	\$ 30.98	8.14	\$ 154,436

The weighted-average grant-date fair value per share of options granted during the three and nine months ended September 30, 2016 was \$27.19 and \$19.25, respectively. As of September 30, 2016, there was approximately \$70.0 million of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately three years.

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## Restricted Stock Units

In April 2016, the Company awarded 58,500 restricted stock units ("RSUs") to employees at an average grant date fair value of \$33.03 per RSU. Each RSU entitles the holder to receive one share of the Company's common stock if and when the RSU vests. The RSUs vest in four substantially equal installments on each of the first four anniversaries of the vesting commencement date, subject to the employee's continued employment on such vesting date. Compensation expense is recognized over the vesting period.

A summary of RSU activity during the nine months ended September 30, 2016 is as follows (in thousands, except for per share amounts):

	RSUs	Weighted-Average Grant Date Fair Value (in dollars per share)
RSUs Outstanding at December 31, 2015	—	\$ —
Granted	59	33.03
Vested	—	—
Forfeited	(2 )	33.03
RSUs Outstanding at September 30, 2016	57	\$ 33.03

As of September 30, 2016, there was approximately \$1.6 million of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately four years.

## Employee Stock Purchase Plan

In September 2016, the Company initiated the first offering period for an employee stock purchase plan ("ESPP") pursuant to which eligible employees may purchase shares of the Company's common stock on the last day of each bi-annual offering period at 85% of the fair market value per share on the enrollment date or purchase date, whichever is lower. The offering periods run from March 1 through August 31 and from September 1 through February 28 (or 29, in a leap year) of each year.

As of September 30, 2016, the Company had recorded a liability of \$0.2 million related to its ESPP obligation.

## 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Numerator:				
Net loss	\$(46,186)	\$(28,264 )	\$(130,084)	\$(68,286 )
Loss attributable to common stockholders - basic and diluted	\$(46,186)	\$(28,264 )	\$(130,084)	\$(68,286 )

Denominator:

Weighted-average number of common shares used in loss per share - basic and diluted	43,092,921	41,331,612	43,049,734	38,525,827
Loss per share - basic and diluted	\$(1.07 )	\$(0.68 )	\$(3.02 )	\$(1.77 )

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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 and nine months ended September 30, 2016 and 2015, all of the Company's options to purchase common stock, warrants, restricted stock units and performance units outstanding were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Options to purchase common stock	6,148,974	4,115,204	5,633,972	3,748,900
Warrants	631,588	703,127	631,588	886,320
Restricted stock units	—	—	37,700	—
Performance units	—	—	—	—

## 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.

**Manufacturing Agreements**

On June 23, 2016, the Company entered into a Supply Agreement (the "Ypsomed Supply Agreement") with Ypsomed AG ("Ypsomed"), effective as of September 30, 2015, pursuant to which Ypsomed agreed to supply to the Company a disposable pen injection device customized for injection of abaloparatide, the Company's drug product candidate (the "Device") for commercial purposes. The Company has agreed to purchase a minimum number of Devices at prices per Device that decrease with an increase in quantity supplied, subject to adjustment based on actual supply amounts. In addition, the Company has agreed to make milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the Device and to pay a one-time capacity fee. All costs and payments under the Ypsomed Supply Agreement are delineated in Swiss Francs. The Ypsomed Supply Agreement has an initial term of three years from the earlier of the date of delivery of the first commercial Devices for regulatory approval and June 1, 2017, after which, it automatically renews for two-year terms until terminated. The Company will purchase the Device subject to minimum annual quantity requirements over a three-year period, as defined in the Ypsomed Supply Agreement. In addition, the Company has agreed to make milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the Device and to pay a one-time capacity fee. The Company estimates that it will be obligated to make total minimum payments to Ypsomed of approximately CHF 3.9 million (\$4.0 million) in the aggregate, including the milestone payments and one-time capacity fee.

On June 28, 2016, the Company entered into a Commercial Supply Agreement (the "Vetter Supply Agreement") with Vetter Pharma International, GmbH ("Vetter"), effective as of January 1, 2016, pursuant to which Vetter has agreed to formulate the drug product containing the active pharmaceutical ingredient ("API") of abaloparatide, to fill cartridges with the drug product, to assemble the pen delivery device, and to package the pen for commercial distribution. Based on forecasts of demand to be provided by the Company, the Company has agreed to purchase the cartridges and pens in specified batch sizes at a price per unit. For labeling and packaging services, the Company has agreed to pay a per unit price dependent upon the number of pens loaded with cartridges that are labeled and packaged. These prices are subject to an annual price adjustment. The Vetter Supply Agreement has an initial term of five years, which began on January 1, 2016, after which, it automatically renews for two-year terms until terminated. The Company will purchase these services subject to minimum annual quantity requirements over a five-year period, as defined in the Vetter Supply Agreement.

On July 13, 2016, the Company entered into a Manufacturing Services Agreement (the "Manufacturing Agreement") with Lonza Sales Ltd ("Lonza"), effective as of June 28, 2016, pursuant to which Lonza has agreed to manufacture the commercial supply of the API for abaloparatide. In accordance with forecasts provided by the Company, the



Company has agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by Lonza. The Company is also required to purchase a minimum number of batches annually. The Manufacturing Agreement has an initial term of a six years, after which, it automatically renews for three-year terms until terminated

## 12. Stockholders' Equity

On January 28, 2015, the Company completed a 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

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\$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 a 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.

## 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 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, commercialization or sale of our product candidates;
- our expectations as to future financial performance, anticipated expenses 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 retain 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’s Discussion and Analysis of Financial Condition and Results of Operations section refer to Radius Health, Inc., a Delaware corporation.

Executive Overview

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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 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 by the European Medicines Agency, or EMA, in Europe and a New Drug Application, or NDA, has been accepted for filing by the U.S. Food and Drug Administration, or FDA, with a Prescription Drug User Fee Act, or PDUFA, date of March 30, 2017. Our clinical pipeline also includes an investigational abaloparatide transdermal patch for potential use in postmenopausal women with 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 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. These results were published in the Journal of the American Medical Association, or JAMA, on August 16, 2016. 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. These data has been accepted for publication in a leading medical journal. 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 EMA which was validated and is currently undergoing active regulatory assessment by the Committee for Medicinal Products for Human Use of the EMA, or CHMP. The EMA has granted us an additional 3-month extension to the procedural timetable for response in the ongoing MAA assessment. As a result of this extension to the procedural timetable, we now anticipate that the CHMP may adopt an Opinion regarding the MAA in late 2016 or in 2017. In March 2016, we submitted an NDA to the FDA, which has been accepted for filing by the FDA with a PDUFA date of March 30, 2017. 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 2017.

**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 toward 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. In September 2016, we announced that data from this evaluation

showed that the pharmacokinetic profile of an optimized abaloparatide-TD patch with respect to Tmax, T1/2, and AUC was successfully modified so as to improve comparability to abaloparatide-SC. The results of this clinical evaluation will inform the design of a formal bioequivalence study that will be initiated following completion of activities related to manufacturing scale-up, production, and other activities required for the initiation of that study.

#### 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

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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 cohort was initiated in March 2016 to allow for an evaluation of additional safety, tolerability and preliminary efficacy. The Phase I Part B expansion cohort has completed enrollment with 20 patients at 400 mg daily. An abstract regarding this study has been accepted for presentation at the San Antonio Breast Cancer Symposium, or SABCS, in December 2016.

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. We continue to enroll patients in the European Phase I FES-PET trial - the first three patient dosing cohort at 400 mg has been enrolled and these patients have achieved a reduction equal to or greater than 75% in FES-PET signal intensity. An abstract regarding this study has been accepted for presentation at the SABCS in December 2016.

Radius has disclosed that multiple confirmed clinical responses have been reported from the patients dosed with 400 mg of RAD1901. To date, no dose limiting toxicities have been reported in the RAD1901 program.

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. An abstract on preclinical data has been accepted for presentation at the SABCS in December 2016.

In July 2016, the Company entered into a pre-clinical collaboration with Takeda Pharmaceutical Company Limited to evaluate the combination of investigational drug RAD1901 with investigational drug TAK-228, an oral mTORC 1/2 inhibitor in Phase 2b development for the treatment of breast, endometrial and renal cancer, with the goal of potentially exploring such combination in a clinical study. As previously reported, RAD1901 has demonstrated encouraging pre-clinical results in combination with Novartis' mTOR inhibitor, everolimus. Under the agreement, the Company and Takeda Oncology will each contribute resources and supply compound material necessary for studies to be conducted under the collaboration and will share third party out of pocket research and development expenses.

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, we plan to submit the results to an appropriate scientific meeting for presentation.

#### RAD140

RAD140 is a nonsteroidal selective androgen receptor modulator, or SARM. The androgen receptor, or AR, is highly expressed in many ER-positive, ER-negative, and triple-negative receptor breast cancers. Due to its receptor and tissue selectivity, potent activity, oral bioavailability, and long half-life, we believe RAD140 could have clinical potential in the treatment of breast cancer.

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In July 2016 we reported that RAD140 in preclinical xenograft models of breast cancer has demonstrated potent tumor growth inhibition when administered alone or in combinations with CDK4/6 inhibitors. It is estimated that 77% of breast cancers show expression of the androgen receptor. Our data suggest that RAD140 activity at the androgen receptor stimulates up-regulation of a tumor suppression pathway. An abstract on RAD140 has been accepted for presentation at the meeting Molecular Targets and Cancer Therapeutics Symposium of the European Organization for Research and Treatment of Cancer - National Cancer Institute - American Association for Cancer Research in November 2016. The Company expects to initiate a phase 1 study of RAD140 in women with AR-positive/ER-positive breast cancer in the first half of 2017.

## 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.

No significant amount of the research and development expenses in relation to our product candidates is 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 September 30, 2016 were approximately \$210.7 million. We began tracking program expenses for abaloparatide-TD in 2007, and program expenses from inception to September 30, 2016 were approximately \$38.2 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to September 30, 2016 were approximately \$49.5 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to September 30, 2016 were approximately \$7.6 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 and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months		Nine Months	
	Ended		Ended September	
	September 30,		30,	
	2016	2015	2016	2015
Abaloparatide-SC	\$2,358	\$4,993	\$14,748	\$15,468
Abaloparatide-TD	855	585	4,545	1,287
RAD1901	8,605	1,607	21,865	5,047
RAD140	699	26	1,826	26

## 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 versus general and administrative expenses). We expect to record additional non-cash stock-based compensation expense in the future, which may be significant as we expand our commercial team.

#### Interest Income and Interest Expense

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

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Interest expense for the three and nine months ended September 30, 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 and nine months ended September 30, 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 September 30, 2016 and September 30, 2015 (in thousands, except percentages)

	Three Months Ended		Change		
	September 30, 2016	September 30, 2015	\$	%	
Operating expenses:					
Research and development	\$27,453	\$18,217	\$9,236	51	%
General and administrative	19,240	8,456	10,784	128	%
Loss from operations	(46,693 )	(26,673 )	20,020	75	%
Other (expense) income:					
Other (expense) income, net	(78 )	1	79	7,900	%
Loss on retirement of note payable	—	(1,572 )	(1,572 )	(100 )	%
Interest income (expense), net	585	(20 )	605	3,025	%
Net loss	\$(46,186)	\$(28,264)	17,922	63	%

Research and development expenses— For the three months ended September 30, 2016, research and development expense was \$27.5 million compared to \$18.2 million for the three months ended September 30, 2015, an increase of \$9.2 million, or 51%. 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 42 research and development employees as of September 30, 2015 to 101 research and development employees as of September 30, 2016.

General and administrative expenses— For the three months ended September 30, 2016, general and administrative expense was \$19.2 million compared to \$8.5 million for the three months ended September 30, 2015, an increase of \$10.8 million, or 128%. This increase was primarily the result of an increase of approximately \$3.8 million in professional support costs and legal fees during the three months ended September 30, 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, including stock-based compensation, due to an increase in headcount from

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21 general and administrative employees as of September 30, 2015 to 90 general and administrative employees as of September 30, 2016.

Interest income (expense), net—For the three months ended September 30, 2016, interest income, net of interest expense, was \$0.6 million compared to interest expense, net of interest income, of \$20 thousand for the three months ended September 30, 2015, a change of \$0.6 million, or 3,025%. This change was primarily a result of no interest expense recorded for the three months ended September 30, 2016 due to repayment of our Credit Facility on August 4, 2015.

Nine Months Ended September 30, 2016 and September 30, 2015 (in thousands, except percentages)

	Nine Months Ended		Change	
	September 30, 2016	September 30, 2015	\$	%
Operating expenses:				
Research and development	\$81,827	\$46,054	\$35,773	78 %
General and administrative	50,079	19,212	30,867	161 %
Loss from operations	(131,906 )	(65,266 )	66,640	102 %
Other (expense) income:				
Other (expense) income, net	(174 )	(127 )	47	37 %
Loss on retirement of note payable	—	(1,572 )	(1,572 )	(100)%
Interest income (expense), net	1,996	(1,321 )	3,317	251 %
Net loss	\$(130,084)	\$(68,286)	61,798	90 %

Research and development expenses— For the nine months ended September 30, 2016, research and development expense was \$81.8 million compared to \$46.1 million for the nine months ended September 30, 2015, an increase of \$35.8 million, or 78%. 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 42 research and development employees as of September 30, 2015 to 101 research and development employees as of September 30, 2016.

General and administrative expenses— For the nine months ended September 30, 2016, general and administrative expense was \$50.1 million compared to \$19.2 million for the nine months ended September 30, 2015, an increase of \$30.9 million, or 161%. This increase was primarily the result of an increase of approximately \$9.1 million in professional support costs and legal fees during the nine months ended September 30, 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, including stock-based compensation, due to an increase in headcount from 21 general and administrative employees as of September 30, 2015 to 90 general and administrative employees as of September 30, 2016.

Interest income (expense), net— For the nine months ended September 30, 2016, interest income, net of interest expense, was \$2.0 million compared to interest expense, net of interest income, of \$1.3 million for the nine months ended September 30, 2015, a change of \$3.3 million, or 251%. This change was primarily a result of no interest expense recorded for the nine months ended September 30, 2016 due to repayment of our Credit Facility on August 4, 2015.

## Liquidity and Capital Resources

From inception to September 30, 2016, we have incurred an accumulated deficit of \$575.8 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-term marketable securities balance as of September 30, 2016 was \$369.8 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

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sufficient capital to fund our development plans, U.S. commercial scale-up and other operational activities into 2018. We expect to finance the future commercial launch preparations and 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, the incurrence of debt or other alternative financing arrangements. However, there is no guarantee that any of these 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.

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 SEC 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):

	Nine Months Ended		Change	
	September 30, 2016	September 30, 2015	\$	%
Net cash (used in) provided by:				
Operating activities	\$(103,074)	\$(60,066)	\$43,008	72 %
Investing activities	139,519	(256,490)	396,009	154 %
Financing activities	2,442	456,710	(454,268)	(99)%
Net increase in cash and cash equivalents	\$38,887	\$140,154	\$(101,267)	(72)%

## Cash Flows from Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2016 was \$103.1 million, which was primarily the result of a net loss of \$130.1 million, partially offset by \$19.9 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of \$7.0 million. The \$130.1 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 \$19.9 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$18.7 million and amortization of premiums (discounts) on marketable securities of \$0.8 million.

Net cash used in operating activities during the nine months ended September 30, 2015 was \$60.1 million, which was primarily the result of a net loss of \$68.3 million and net changes in working capital of \$4.7 million, partially offset by \$12.9 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The \$68.3 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 \$12.9 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$10.0 million, loss on retirement of note payable of \$1.6 million and amortization of premiums (discounts) on marketable securities of \$1.0 million.

#### Cash Flows from Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2016 was \$139.5 million, which was primarily the result of \$367.1 million of net proceeds received from the sale or maturity of marketable securities, partially offset by \$225.5 million of purchases of marketable securities.

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Net cash used in investing activities during the nine months ended September 30, 2015 was \$256.5 million, which was primarily the result of \$420.7 million of purchases of marketable securities, partially offset by \$164.5 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 nine months ended September 30, 2016 was \$2.4 million, as compared to \$456.7 million net cash provided by financing activities during the nine months ended September 30, 2015. Net cash provided by financing activities during the nine months ended September 30, 2016 consisted of \$2.4 million of proceeds received from exercises of stock options.

Net cash provided by financing activities during the nine months ended September 30, 2015 consisted of \$482.3 million of net proceeds received from a public offering in January and July of 2015 and \$1.0 million of proceeds received from the exercise of stock options, partially offset by the repayment of our credit facility.

### Contractual Obligations

#### Supply and Manufacturing Agreements

On June 23, 2016, we entered into a Supply Agreement, or the Ypsomed Supply Agreement, with Ypsomed AG, or Ypsomed, effective as of September 30, 2015, pursuant to which Ypsomed agreed to supply a disposable pen injection device customized for injection of abaloparatide, or the Device, for commercial purposes. We agreed to purchase a minimum number of Devices at prices per Device that decrease with an increase in quantity supplied, subject to adjustment based on actual supply amounts. In addition, we agreed to make milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the Device and to pay a one-time capacity fee. All costs and payments under the Ypsomed Supply Agreement are delineated in Swiss Francs. The Ypsomed Supply Agreement has an initial term of three years from the earlier of the date of delivery of the first commercial Devices for regulatory approval and June 1, 2017, after which, it automatically renews for two-year terms until terminated. During the initial term of the Ypsomed Supply Agreement, we estimate that we will be obligated to make total minimum payments to Ypsomed of approximately CHF 3.9 million (\$4.0 million) in the aggregate, including the milestone payments and one-time capacity fee.

On June 28, 2016, we entered into a Commercial Supply Agreement, or the Vetter Supply Agreement, with Vetter Pharma International, GmbH, or Vetter, effective as of January 1, 2016, pursuant to which Vetter has agreed to formulate the drug product containing the active pharmaceutical ingredient, or API, of abaloparatide, to fill cartridges with the drug product, to assemble the pen delivery device, and to package the pen for commercial distribution. Based on forecasts of demand to be provided by us, we agreed to purchase the cartridges and pens in specified batch sizes at a price per unit. For labeling and packaging services, we agreed to pay a per unit price dependent upon the number of pens loaded with cartridges that are labeled and packaged. These prices are subject to an annual price adjustment. The Vetter Supply Agreement has an initial term of five years, which began on January 1, 2016, after which, it automatically renews for two-year terms until terminated.

On July 13, 2016, we entered into a Manufacturing Services Agreement, or the Manufacturing Agreement, with Lonza Sales Ltd, or Lonza, effective as of June 28, 2016, pursuant to which Lonza has agreed to manufacture the commercial supply of the API for abaloparatide. In accordance with forecasts provided by us, we agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by Lonza. We are also required to purchase a



minimum number of batches annually. The Manufacturing Agreement has an initial term of six years, after which, it automatically renews for three-year terms until terminated.

#### Research and Development Agreements

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

We 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

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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.

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 (\$4.6 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 (\$13.3 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. As of September 30, 2016, services related to the Second Extension Period are ongoing. All obligations due to Nordic in relation to the Extension Study were 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 nineteen-month period, respectively. We recorded \$0.7 million and \$1.5 million for the three months ended September 30, 2016 and 2015, respectively, and \$2.6 million and \$4.1 million for the nine months ended September 30, 2016 and 2015, respectively, for per patient costs incurred.

As of September 30, 2016, we had a liability of \$2.2 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 \$4.4 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, FDA approval for our NDA and EMA approval of our MAA. The range of milestone payments that could be paid under the agreement is €10.0 million to €36.0 million (\$11.2 million to \$40.4 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 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

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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, subject to reduction based on the expiration or lapse of the licensed patents, no data protection coverage for the commercial product, and sales of generic products. Unless sooner terminated, our license with Eisai expires on a country-by-country basis upon (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 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. The latest valid claim is expected to expire, barring any extension thereof, on August 18, 2026. 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, subject to limitation, 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, or Section 382, 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. We have completed studies through December 31, 2015, to determine whether any ownership change has occurred since our formation and have determined that transactions have resulted in two ownership changes, as defined under Section 382. There could be additional ownership changes in the future that could further limit the amount of net operating loss and tax credit carryforwards that we can utilize.

A full valuation allowance has been provided against our net operating loss carryforwards and other deferred tax assets, 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.



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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% adverse change in the dollar/euro or dollar/Swiss Franc 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 September 30, 2016, we had cash, cash equivalents and short-term marketable securities of \$369.8 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 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 a change in market interest rates on our investments. We carry our investments based on publicly available information. As of September 30, 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.

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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 September 30, 2016.

Changes in Internal Control over Financial Reporting

During the three months ended September 30, 2016, we implemented a new enterprise resource planning (“ERP”) system. As appropriate, we are modifying the design and documentation of internal control processes and procedures relating to the new system and interfaces to simplify and synchronize our existing internal control over financial reporting.

With the exception of the ERP implementation described above, there were no changes in our internal control over financial reporting during the third quarter of 2016, which were identified in connection with management’s evaluation required by paragraph (d) of Rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II— OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

In addition to the other information set forth in this report, you should carefully consider the risk 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 although we may disclose changes to such factors or disclose additional factors from time to time in our future filings with the Securities and Exchange Commission.



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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.

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SIGNATURES

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

RADIUS HEALTH, INC.

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

Date: November 3, 2016

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

Date: November 3, 2016

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## EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
3.1	Restated Certificate of Incorporation, filed on June 11, 2014	8-K	001-35726	3.1	6/13/2014	
3.2	Amended and Restated By-Laws	8-K	001-35726	3.2	6/13/2014	
10.1†	Manufacturing Services Agreement, dated July 13, 2016, by and between the Company and Lonza Sales Ltd					*
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a)					*
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a)					*
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
101.INS	XBRL Instance Document	10-Q	001-35726	101.INS	11/3/2016	
101.SCH	XBRL Taxonomy Extension Schema Document	10-Q	001-35726	101.SCH	11/3/2016	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	10-Q	001-35726	101.CAL	11/3/2016	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	10-Q	001-35726	101.DEF	11/3/2016	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	10-Q	001-35726	101.LAB	11/3/2016	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	10-Q	001-35726	101.PRE	11/3/2016	

\* 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.