

Radius Health, Inc.  
Form 10-Q  
November 10, 2014  
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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, 2014.**

**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)

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

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

**950 Winter Street**  
**Waltham, Massachusetts**  
(Address of Principal Executive Offices)

**02451**  
(Zip Code)

**(617) 551-4000**

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

Number of shares of the registrant's Common Stock, \$.0001 par value per share, outstanding as of November 6, 2014: 32,923,834 shares

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**RADIUS HEALTH, INC.**  
**QUARTERLY REPORT FOR THE QUARTER ENDED SEPTEMBER 30, 2014**  
**ON FORM 10-Q**

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**CURRENCY AND CONVERSIONS**

In this report, references to dollar or \$ are to the legal currency of the United States, and references to euro or are to the single currency introduced on January 1, 1999 at the start of the third stage of European Economic and Monetary Union, pursuant to the Treaty establishing the European Communities, as amended by the Treaty on European Union and the Treaty of Amsterdam. Unless otherwise indicated, the financial information in this report has been expressed in U.S. dollars. Unless otherwise stated, the U.S. dollar equivalent information translating euros into U.S. dollars has been made, for convenience purposes, on the basis of the noon buying rate published by the Board of Governors of the Federal Reserve as of September 30, 2014, which was 1.00 = \$1.2628. Such translations should not be construed as a representation that the euro has been, could have been or could be converted into U.S. dollars at the rate indicated, any particular rate or at all.

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

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

(In thousands, except share and per share amounts)

	September 30, 2014 (unaudited)	December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,466	\$ 12,303
Marketable securities	52,048	
Prepaid expenses and other current assets	1,380	334
Total current assets	69,894	12,637
Property and equipment, net	790	76
Other assets	252	45
Total assets	\$ 70,936	\$ 12,758
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,309	\$ 300
Accrued expenses and other current liabilities	21,911	22,007
Current portion of note payable, net of discount	2,027	13,005
Total current liabilities	25,247	35,312
Note payable, net of current portion and discount	22,295	
Warrant liability		1,945
Commitments and contingencies		
Series B-2 Convertible Preferred Stock, \$.0001 par value; no shares and 655,000 shares authorized, no shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		
Series B Convertible Preferred Stock, \$.0001 par value; no shares and 980,000 shares authorized, no shares and 701,235 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		43,892
Series A-1 Convertible Preferred Stock, \$.0001 par value; no shares and 1,000,000 shares authorized, no shares and 939,612 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		78,737
Series A-2 Convertible Preferred Stock, \$.0001 par value; no shares and 983,213 shares authorized, no shares and 983,208 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		93,977
Series A-3 Convertible Preferred Stock, \$.0001 par value; no shares and 142,230 shares authorized, no shares and 142,227 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		12,232
Series A-4 Convertible Preferred Stock, \$.0001 par value; no shares and 4,000 shares authorized, no shares and 3,998 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		271

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Series A-5 Convertible Preferred Stock, \$.0001 par value; no shares and 7,000 shares authorized, no shares and 6,443 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively			525
Series A-6 Convertible Preferred Stock, \$.0001 par value; no shares and 800,000 shares authorized, no shares and 496,111 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively			23,168
Stockholders' equity (deficit):			
Common stock, \$.0001 par value; 200,000,000 shares and 100,000,000 shares authorized, 29,747,797 shares and 385,664 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		3	
Additional paid-in-capital		349,677	
Accumulated other comprehensive loss		(10)	
Accumulated deficit		(326,276)	(277,301)
Total stockholders' equity (deficit)		23,394	(277,301)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$	70,936	\$ 12,758

See accompanying notes to unaudited condensed financial statements.

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

(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>OPERATING EXPENSES:</b>				
Research and development	\$ 13,817	\$ 15,543	\$ 34,152	\$ 49,070
General and administrative	2,836	1,621	8,045	4,643
Loss from operations	(16,653)	(17,164)	(42,197)	(53,713)
<b>OTHER (EXPENSE) INCOME:</b>				
Other (expense) income, net		(2,607)	(506)	7,465
Loss on retirement of note payable			(203)	
Interest income	35	11	42	27
Interest expense	(802)	(582)	(1,653)	(1,938)
<b>NET LOSS</b>	<b>\$ (17,420)</b>	<b>\$ (20,342)</b>	<b>\$ (44,517)</b>	<b>\$ (48,159)</b>
<b>OTHER COMPREHENSIVE LOSS, NET OF TAX:</b>				
Unrealized loss from marketable securities	(11)	(3)	(10)	
<b>COMPREHENSIVE LOSS</b>	<b>\$ (17,431)</b>	<b>\$ (20,345)</b>	<b>\$ (44,527)</b>	<b>\$ (48,159)</b>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED</b>				
(Note 11):	\$ (17,420)	\$ (25,090)	\$ (53,517)	\$ (60,857)
<b>LOSS PER SHARE:</b>				
Basic	\$ (0.59)	\$ (65.05)	\$ (4.23)	\$ (159.09)
Diluted	\$ (0.59)	\$ (65.05)	\$ (4.23)	\$ (159.09)
<b>WEIGHTED AVERAGE SHARES:</b>				
Basic	29,746,426	385,688	12,651,628	382,541
Diluted	29,746,426	385,688	12,651,628	382,541

See accompanying notes to unaudited condensed financial statements.

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**Radius Health, Inc.**

**Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)**

(Unaudited, in thousands except share amounts)

	Series B-2		Series B		Series A-1		Convertible Preferred Stock		Series A-4		Series A-5		Series A-6			
	Shares	Amount	Shares	Amount	Shares	Amount	Series A-2	Series A-3	Shares	Amount	Shares	Amount	Shares	Amount		
Balance at December 31, 2013		\$ 701,235	\$ 43,892	939,612	\$ 78,737	983,208	\$ 93,977	142,227	\$ 12,232	3,998	\$ 271	6,443	\$ 525	496,111	\$ 23,168	
Net loss																
Unrealized gain from available-for-sale securities																
Issuance of preferred stock	448,060	152												186,847	10,109	
Accretion of dividends on preferred stock	685		1,515		3,084		3,246		470							
Issuance of warrants																
Exercise of warrants																
Exercise of options																
Stock-based compensation expense																
Issuance of common stock, net																
Conversion of convertible preferred stock into common stock	(448,060)	(37)	(701,235)	(45,407)	(939,612)	(81,821)	(983,208)	(97,223)	(142,227)	(12,702)	(3,998)	(271)	(6,443)	(525)	(682,958)	(33,277)
Reclassification of warrant liability to additional paid in capital																
Balance at September 30, 2014		\$	\$		\$		\$		\$		\$		\$		\$	

	Common Stock		Stockholders Equity (Deficit)			Total Stockholders Equity (Deficit) Amount
	Shares	Amount	Additional Paid-In-Capital Amount	Accumulated Comprehensive Income (Loss) Amount	Other Accumulated Deficit Amount	
Balance at December 31, 2013	385,664	\$	\$	\$	(277,301)	\$ (277,301)
Net loss					(44,517)	(44,517)
				(10)		(10)



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Unrealized gain from available-for-sale securities								
Issuance of preferred stock								
Accretion of dividends on preferred stock			(4,542)		(4,458)		(9,000)	
Issuance of warrants			41				41	
Exercise of warrants	20,435							
Exercise of options	1,168		3				3	
Stock-based compensation expense			2,560				2,560	
Issuance of common stock, net	7,012,744	1	50,437				50,438	
Conversion of convertible preferred stock into common stock	22,327,786	2	298,061				298,063	
Reclassification of warrant liability to additional paid in capital			3,117				3,117	
Balance at September 30, 2014	29,747,797	\$ 3	\$ 349,677	\$ (10)	(326,276)	\$	23,394	

See accompanying notes to unaudited condensed financial statements.

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

(Unaudited, in thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>CASH FLOWS USED IN OPERATING ACTIVITIES:</b>		
Net loss	\$ (44,517)	\$ (48,159)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	69	21
Amortization of premium (accretion of discount) on marketable securities, net	183	28
Stock-based compensation expense	2,560	1,247
Research and development expense settled in stock	2,717	10,568
Change in fair value of other current assets, warrant liability and other liability	505	(7,464)
Non-cash interest	212	307
Loss on retirement of note payable	57	
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(845)	1,813
Other long-term assets	(150)	
Accounts payable	1,009	2,134
Accrued expenses and other current liabilities	6,229	9,646
Net cash used in operating activities	(31,971)	(29,859)
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(714)	
Purchases of marketable securities	(53,305)	(17,070)
Sales and maturities of marketable securities	1,065	10,793
Net cash used in investing activities	(52,954)	(6,277)
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options		13
Proceeds from note payable, net	24,555	
Payments on note payable	(13,156)	(5,907)
Proceeds from the issuance of common stock, net	50,437	
Deferred financing costs	(116)	
Proceeds from the issuance of preferred stock, net	27,368	42,870
Net cash provided by financing activities	89,088	36,976
NET INCREASE IN CASH AND CASH EQUIVALENTS	4,163	840
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	12,303	18,653
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 16,466	\$ 19,493
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	\$ 1,138	\$ 1,426
<b>NON-CASH FINANCING ACTIVITIES:</b>		
Accretion of dividends on preferred stock	\$ 9,000	\$ 12,698
Fair value of Series A-6 convertible preferred stock issued as settlement of liability	\$ 10,109	\$
Fair value of warrants issued	\$ 1,552	\$ 1,356
Reclassification of preferred stock to common stock	\$ 298,063	\$

See accompanying notes to unaudited condensed financial statements.



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**Radius Health, Inc.**

**Notes to Financial Statements**

**(Unaudited)**

**1. Organization**

Radius Health, Inc. ( Radius or the Company ) is a science-driven biopharmaceutical company focused on developing new therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases. The Company's lead product candidate is the investigational drug abaloparatide (BA058), a bone anabolic for the treatment of osteoporosis delivered via subcutaneous injection, which the Company refers to as abaloparatide-SC and is currently in Phase 3 development. The Company is leveraging its investment in abaloparatide-SC to develop a line extension that is designed to improve patient convenience by enabling administration of abaloparatide through a short-wear-time patch, which the Company refers to as abaloparatide-TD. The Company has recently completed a successful Phase 2 proof of concept study of abaloparatide-TD.

The Company's current clinical product portfolio also includes the investigational drug RAD1901, a selective estrogen receptor down regulator/degrader ( SERD ) and RAD140, a nonsteroidal selective androgen receptor modulator ( SARM ). The Company is developing RAD1901 at higher doses for the treatment of metastatic breast cancer. At low doses, RAD1901 acts as a selective estrogen-receptor modulator ( SERM ). Low-dose RAD1901 has shown potential to be effective for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study. RAD140 resulted from an internal drug discovery program that began in 2005. RAD140 has demonstrated potent anabolic activity on muscle and bone in preclinical studies and has clinical potential in a number of indications including the treatment of weight loss due to cancer cachexia, sarcopenia, frailty and oncology.

The Company is subject to the risks associated with emerging companies with a limited operating history, including dependence on key individuals, a developing business model, the necessity of securing regulatory approval to market its investigational product candidates, market acceptance of the Company's product candidates, competition for its product candidates, 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, 2014, the Company had an accumulated deficit of \$326.3 million, and total cash, cash equivalents and marketable securities of \$68.5 million. On October 7, 2014, the Company completed a public offering whereby the Company sold 2,750,000 shares of common stock at a price of \$18.25 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$46.9 million. On October 7, 2014, the underwriters purchased an additional 378,524 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the over-allotment option, the Company received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately \$53.3 million.

The Company believes that the aggregate proceeds from the offering on October 7, 2014, together with its cash, cash equivalents and marketable securities as of September 30, 2014, will be sufficient to fund its operations into the fourth quarter of 2015. Accordingly, the Company expects to pursue strategic financing alternatives that could include, but are not limited to, partnering or other collaboration agreements, or additional financing opportunities, including the completion of a private placement or public offering in order to address its capital needs. However, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company fails to obtain additional future capital, it may be unable to complete its planned preclinical and clinical trials and obtain approval of any investigational product candidates from the U.S. Food and Drug Administration or other regulatory authorities. In addition, the Company could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive

business opportunities or discontinue operations entirely.

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

*Basis of Presentation* The accompanying unaudited condensed financial statements and the related disclosures of the Company have been prepared in accordance with accounting principles generally accepted in the United States ( GAAP ) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included.

When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three and nine months ended September 30, 2014 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2014. Subsequent events have been evaluated up to the date of issuance of these financials. For further information, refer to the financial statements and footnotes included in the Company's audited financial statements for the year ended December 31, 2013 included in the Company's Annual Report on Form 10-K/A, as filed with the Securities and Exchange Commission on April 3, 2014.

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*Significant Accounting Policies* The significant accounting policies identified in the Company's most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2013 relate to research and development costs, stock-based compensation, fair value measures, property and equipment, license agreements, impairment of long-lived assets and income taxes. There were no changes to significant accounting policies during the nine months ended September 30, 2014.

*Initial Public Offering*-On June 11, 2014, the Company completed its initial public offering whereby the Company sold 6,500,000 shares of common stock at a price of \$8.00 per share. The shares began trading on the NASDAQ Global Market on June 6, 2014. In connection with the offering, all outstanding shares of our convertible preferred stock converted into 19,465,132 shares of common stock and 2,862,654 shares of common stock were issued in satisfaction of accumulated dividends accrued on the preferred stock. In addition, all outstanding warrants to purchase shares of A-1 convertible preferred stock and warrants to purchase shares of series B-2 convertible preferred stock were converted into the right to purchase 149,452 shares of common stock and the Company's warrant liability was reclassified to equity.

On June 18, 2014 and June 25, 2014, the underwriters purchased an additional 512,744 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the initial public offering. As a result of the closing of the initial public offering and subsequent exercise of the over-allotment option, the Company received aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$50.4 million.

In connection with the completion of its initial public offering, the Company filed an amended and restated certificate of incorporation, which, among other things, changed the number of authorized shares of common stock to 200,000,000 shares.

*Reverse Stock Split* On April 24, 2014, the Company effected a reverse stock split of the Company's common stock. The number of authorized shares of the Company's common stock and the par value did not change. Pursuant to the stock split, every 2.28 shares of the Company's issued and outstanding common stock were automatically combined into one issued and outstanding share of the Company's common stock. All shares and per share amounts in the condensed financial statements and accompanying notes have been retroactively adjusted to give effect to the reverse stock split.

*Recently Adopted Accounting Standards* In July 2013, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* ( ASU 2013-11 ). ASU 2013-11 clarifies guidance and eliminates diversity in practice on the presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists at the reporting date. The amendments under ASU 2013-11 were effective for interim and annual fiscal periods beginning after December 15, 2013, with early adoption permitted. The Company adopted ASU 2013-11 on January 1, 2014. Its adoption did not have a material impact on the Company's results of operations, financial position, or cash flows.

In December 2013, the FASB issued Accounting Standards Update No. 2013-12, *Definition of a Public Business Entity* ( ASU 2013-12 ). ASU 2013-12 amends the Master Glossary of the FASB Accounting Standards Codification to include one definition of public business entity for future use in GAAP. ASU 2013-12 does not affect existing requirements but will be used in considering the scope of new financial guidance and will identify whether the guidance does or does not apply to public business entities. The Company adopted ASU 2013-12 on January 1, 2014. Its adoption did not have a material impact on the Company's results of operations, financial position or cash flows.

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*Accounting Standards Updates* In August 2014, the 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 plans to adopt ASU 2013-12 on January 1, 2015. We do not expect the adoption to have a material impact on the Company's results of operations, financial position or cash flows.

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

	September 30, 2014	December 31, 2013
Research costs - Nordic (1)	\$ 13,950	\$ 17,998
Research costs - other	5,413	1,599
Payroll and employee benefits	888	1,005
Professional fees	1,296	426
Vacation	151	69
Interest on notes payable	127	852
Other	86	58
Total accrued expenses and other current liabilities	\$ 21,911	\$ 22,007

(1) Includes amounts accrued ratably over the estimated per patient treatment period under the Nordic Work Statement NB-1 and Work Statement NB-3. Amounts do not include pass-through costs which are expensed as incurred or upon delivery. See note 9 for additional information.

**4. Loan and Security Agreement**

On May 30, 2014, the Company entered into a Loan and Security Agreement (the New 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 ( Initial Term Loan ).

The Company is required to make interest-only payments through June 1, 2015, and beginning on July 1, 2015, it is required to make payments of principal and accrued interest in equal monthly installments over a term of 36 months. If the Company consummates any one or more public or private stock offerings, equity raises or strategic partner arrangements resulting in the receipt of at least \$65.0 million in aggregate net cash proceeds on or prior to May 31, 2015, it will be permitted to make interest-only payments through December 1, 2015 rather than July 1, 2015, and beginning on January 1, 2016, the Company would be required to make principal and accrued interest payments in equal monthly installments over a term of 30 months.

In addition to the Initial Term Loan, the Company would have been able to request an additional term loan in an aggregate principal amount of \$9.0 million (the Original Term B Loan ) after the completion of this initial public offering if the net cash proceeds were at least \$65.0 million subject to certain customary conditions to funding. Given the net proceeds from the Company's initial public offering were less than \$65.0 million, it was not able to request the Original Term B Loan. The Initial Term Loan bears interest per annum at 9.85% plus one-month LIBOR (customarily defined). All principal and accrued interest on the initial term loan is due on June 1, 2018.



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The Company used approximately \$9.3 million of the Initial Term Loan to repay all the amounts owed under its credit facility with General Electric Capital Corporation and Oxford.

As security for its obligations under the New Credit Facility, the Company granted a security interest in substantially all of its existing and after-acquired assets except for our intellectual property and certain other customary exclusions.

On July 10, 2014, the Company entered into a first amendment to the New Credit Facility ( First Amendment ). Pursuant to the terms of the First Amendment, a second term loan of \$4.0 million was drawn on July 10, 2014. The terms of the First Amendment, among other things,

- provide 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 Modified Term B Loan ). All other terms applicable to the Original Term B Loan remain applicable to the Modified Term B Loan. The Original Term B Loan are replaced by the Modified Term B Loan. The Company borrowed the full amount of the Modified Term B Loan on July 10, 2014.

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- provide the Company the ability to borrow additional term loans in an aggregate amount of \$5.0 million (the Term C Loan ) at any time through December 31, 2014. In order to draw the Term C Loan, the Company must, in addition to other customary conditions, either (a) close public or private stock offerings, equity raises or strategic partner arrangements resulting in \$13.0 million in aggregate net proceeds after the closing of the First Amendment, or (b) as it relates specifically to RAD1901, complete both the maximum tolerable dose trial and enroll the first patient in the breast cancer brain metastasis trial.

The future principal payments under the New Credit Facility, as amended, are as follows, as of September 30, 2014 (in thousands):

Years ending December 31,	
2014	\$
2015	4,167
2016	8,333
2017	8,333
2018	4,167
	\$ 25,000

On May 30, 2014, pursuant to the Loan and Security Agreement with Solar and Oxford, the Company issued to Solar and Oxford warrants to purchase an aggregate of up to 10,258 shares of its series B-2 convertible preferred stock ( Series B-2 ) at an exercise price equal to \$61.42 per share. The warrants were initially classified as liabilities in the Company's balance sheet and were re-measured at their estimated fair value through completion of the Company's initial public offering. The changes in fair value are recorded as other (expense) income in the statement of operations. Upon the closing of its initial public offering at a price of \$8.00 per share and the automatic conversion of the Series B-2 into common stock, these warrants became exercisable for up to 78,760 shares of common stock. Subsequent to the initial public offering, the Company's warrant liability was reclassified to equity. On July 10, 2014, pursuant to the First Amendment and closing of the Modified Term B Loan, the Company issued both Solar and Oxford warrants to purchase up to 4,706 shares of common stock, each at a price per share equal to \$12.75.

These warrants are immediately exercisable for cash or by net exercise and will expire five years from their issuance.

The initial fair value of the warrants issued in connection with Initial Term Loan was \$0.3 million and was recorded as a discount to the Initial Term Loan. The initial fair value of the warrants issued in connection with the First Amendment was \$41 thousand and was recorded as a discount to the Modified Term B Loan. The Company also paid Solar and Oxford a facility fee of \$0.3 million and reimbursed certain costs associated with the Loan and Security Agreement of approximately \$0.1 million, both of which were also recorded as a discount to the Initial Term Loan. The discount is being amortized to interest expense over the 48 month period that the Initial Term Loan is expected to be outstanding using the effective interest method.

**5. Convertible Preferred Stock**

Below is a summary of the rights, preferences, and privileges of the Series B convertible preferred stock ( Series B ), Series B-2 convertible preferred stock ( Series B-2 ), Series A-1 convertible preferred stock ( Series A-1 ), Series A-2 convertible preferred stock ( Series A-2 ), Series A-3 convertible preferred stock ( Series A-3 ), Series A-4 convertible preferred stock ( Series A-4 ), Series A-5 convertible preferred stock ( Series A-5 )

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and Series A-6 convertible preferred stock ( Series A-6 ) (the Series A-1, Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6, collectively, the Series A Preferred Stock ) prior to the conversion of all outstanding convertible preferred stock into common stock upon completion of the Company s initial public offering on June 11, 2014.

On February 14, 2014, the Company entered into a Series B-2 Convertible Preferred Stock and Warrant Purchase Agreement (the Series B-2 Purchase Agreement ), pursuant to which the Company was able to raise up to approximately \$40.2 million through the issuance of (1) up to 655,000 shares of its Series B-2 and (2) warrants to acquire up to 718,201 shares of its common stock with an exercise price of \$14.004 per share. In February and March 2014, the Company consummated closings under the Series B-2 Purchase Agreement, whereby, in exchange for aggregate gross proceeds to the Company of approximately \$27.5 million, the Company issued an aggregate of 448,060 shares of Series B-2 and warrants to purchase up to a total of 491,293 shares of its common stock.

*Conversion* Any holder of the Company s preferred stock had the right, at any time or from time to time, to convert any or all of its shares of preferred stock into fully paid and non-assessable shares of the Company s common stock for each share of preferred stock converted based upon the then in effect Conversion Price ( Conversion Feature ). If the Company issued or sold any shares of its Common Stock (as defined by the Company s certificate of incorporation) or options to purchase or other rights to subscribe for such

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convertible or exchangeable securities, in each case other than Excluded Stock (as defined by the Company's certificate of incorporation), for a consideration per share less than the then in effect conversion price ( Dilutive Issuance ) of the Company's Series A-1, A-2, A-3, B, or B-2 preferred stock, respectively, the Conversion Price for such series in effect immediately prior to each such Dilutive Issuance would automatically be reduced in accordance with the provisions set forth in the Certificate of Designations. Upon issuance of each series of the Company's preferred stock, the respective Conversion Prices were greater than the fair value of the Company's common stock at the respective commitment dates. Therefore, the Conversion Feature was not considered to be a beneficial conversion feature that would require the Company to record a deemed dividend on the preferred stock. Each holder of Series B and Series B-2 shares had the right, at their option at any time, to convert any such shares of preferred stock into such number of fully paid shares of common stock as determined by dividing the original purchase price of \$61.42 by the conversion price ( Series B Optional Conversion ). The conversion price of the Series B and Series B-2 as of June 6, 2014 was \$14.004 per share and \$8.00 per share, respectively, (the Series B Conversion Price ), which represented a conversion ratio of one share of Series B or Series B-2 into approximately 4.386 and 7.678 shares of common stock, respectively.

Each holder of Series A-1, Series A-2 and Series A-3 had the right, at their option at any time, to convert any such shares of preferred stock into such number of fully paid shares of common stock as determined by dividing the original purchase price of \$81.42 by the conversion price ( Optional Conversion ). The original conversion price of the Series A-1, Series A-2 and Series A-3 was \$18.564 per share (the Conversion Price ), which represented a conversion ratio of one share of Series A-1, Series A-2 or Series A-3 into approximately 4.386 shares of common stock. The issuance of the Series B in April and May of 2013 and the Series B-2 in February and March of 2014 resulted in an adjustment to the Conversion Price of the Series A-1, Series A-2 and Series A-3 (the Anti-Dilution Adjustment ). As a result of the Anti-Dilution Adjustment, the conversion price of each share of Series A-1, Series A-2 and Series A-3 was reduced to \$16.970, which represented a conversion ratio of one share of Series A-1, Series A-2 or Series A-3 into approximately 4.798 shares of common stock. This reduction of the Conversion Price did not create a beneficial conversion feature that would require the Company to record a deemed dividend on the Series A-1, Series A-2 or Series A-3 preferred stock.

Each holder of Series A-4, Series A-5 and Series A-6 had the right, at their option at any time, to convert any such shares of preferred stock into such number of fully paid shares of common stock as determined by dividing the original purchase price of \$81.42 by the conversion price. The Conversion Price of the Series A-4, Series A-5 and Series A-6 as of June 6, 2014 was \$18.564 per share, which represented a conversion ratio of one share of Series A-4, Series A-5 or Series A-6 into approximately 4.386 shares of common stock.

Upon an optional conversion, the holders of the converted Series B-2, Series B and Series A Preferred Stock were entitled to payment of all accrued, whether or not declared, but unpaid dividends in shares of the common stock of the Company at the then effective Conversion Price.

Each share of the Series B, Series B-2 and Series A Preferred Stock was automatically convertible into fully paid and non-assessable shares of common stock at the applicable conversion price (as described above) in effect upon, in the case of the Series A and Series B Preferred Stock, upon (1) a vote of the holders of at least 70% of the outstanding shares of Series B, Series B-2, Series A-1, Series A-2 and Series A-3 to convert all shares of Series B, Series B-2 and Series A Preferred Stock or (2) the common stock becoming listed for trading on a national stock exchange, and in the case of the Series B-2 Preferred Stock, upon (1) a vote of the holders of at least 70% of the outstanding shares of Series B-2 to convert all shares of Series B-2 Preferred Stock, (2) the closing of a firm commitment underwritten public offering on or prior to June 30, 2014 or (3) after June 30, 2014, the common stock becoming listed for trading on a national stock exchange ( Special Mandatory Conversion ). Upon a Special Mandatory Conversion, all accrued, whether or not declared, but unpaid dividends were to be paid in cash or shares of common stock (calculated based on the then effective conversion price) at the discretion of the Company's Board of Directors.

In the event of a conversion upon the closing of a firm commitment underwritten public offering on or prior to June 30, 2014 in which the public offering price per share is less than the Series B-2 Conversion Price, then the Series B-2 Conversion Price was automatically reduced to the price equal to the public offering price.

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*Redemption* Unless redemption was waived by a requisite stockholder vote or consent, the shares of Series B, Series B-2 and Series A Preferred Stock were automatically redeemable upon an event of sale of the Company. The shares of Series B, Series B-2 and Series A Preferred Stock were not redeemable at the option of the holder.

*Dividends* Holders of shares of Series B and Series B-2 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrued on a daily basis commencing on the date of issuance of the shares of Series B and Series B-2. Dividends were payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series B and Series B-2 were also entitled to dividends declared or paid on any shares of common stock.

Following payment in full of required dividends to the holders of Series B and Series B-2, holders of shares of Series A-1 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrued on a daily basis commencing on the date of issuance of the shares of Series A-1. Dividends were payable, as accrued, upon liquidation, event of sale, and conversion to

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common stock, as described above. The holders of shares of Series A-1 were also entitled to dividends declared or paid on any shares of common stock.

Following payment in full of required dividends to the holders of Series B, Series B-2 and Series A-1, holders of Series A-2 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrued on a daily basis commencing on the date of issuance of the shares of Series A-2. Dividends were payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series A-2 were also entitled to dividends declared or paid on any shares of common stock.

Following payment in full of required dividends to the holders of Series B, Series B-2, Series A-1 and Series A-2, holders of Series A-3 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrued on a daily basis commencing on the date of issuance of the shares of Series A-3. Dividends were payable, as accrued, upon liquidation, event of sale and conversion to common stock, as described above. The holders of shares of Series A-3 were also entitled to dividends declared or paid on any shares of common stock.

Without regard to the payment of required dividends to the holders of Series B, Series B-2, Series A-1, Series A-2 and Series A-3, holders of Series A-5 were entitled to receive the Series A-5 Special Accruing Dividend (as defined in the Company's certificate of incorporation) paid in shares of Series A-6 as described in note 9. Dividends were payable, as accrued, upon liquidation, event of sale and conversion to common stock, as described above. The holders of shares of Series A-5 were also entitled to dividends declared or paid on any shares of common stock.

Following payment in full of required dividends to the holders of Series B, Series B-2, Series A-1, Series A-2, Series A-3 and Series A-5, holders of Series A-4 and Series A-6 were entitled to receive, when, if and as declared by the Board of Directors, dividends on any shares of Series A-4 Stock or Series A-6 Stock, as the case may be, out of funds legally available for that purpose, at a rate to be determined by the Board of Directors if and when they may so declare any dividend on the Series A-4 Stock or A-6 Stock, as the case may be. Dividends were payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series A-4 and Series A-6 were also entitled to dividends declared or paid on any shares of common stock.

As of June 6, 2014, the Company had accrued dividends of \$3.9 million, \$18.1 million, \$21.2 million and \$3.1 million on Series B, Series A-1, Series A-2 and Series A-3, respectively. As of June 11, 2014 the Company had accrued dividends of \$0.7 million on Series B-2. Upon completion of the Company's initial public offering, all accrued dividends were paid in shares of common stock at the then effective Conversion Price.

*Voting* The holders of Series B, Series B-2 and Series A Preferred Stock were entitled to vote together with the holders of the common stock as one class on an as-if converted basis. In addition, as long as the shares of Series A-1 were outstanding, the holders of Series A-1, voting as a separate class, had the right to elect two members of the Company's Board of Directors.

*Liquidation* The shares of Series B and Series B-2 ranked equally to other shares of Series B and Series B-2, and ranked senior to the Series A-1 and all other classes of Series A Preferred Stock. The shares of Series A-1 ranked senior to all other classes of Series A Preferred Stock. Series A-2 ranked junior to Series A-1 and senior to Series A-3, Series A-4, Series A-5 and Series A-6. Series A-3, Series A-5 and Series A-6 ranked equally but junior to Series A-1 and Series A-2 and senior to Series A-4. Series A-4 ranked senior to the Company's common stock.

In the event of a liquidation, dissolution, or winding-up of the Company, the holders of Series B and Series B-2 were entitled to be paid first out of the assets available for distribution, before any payment is made to the Series A Preferred Stock. Payment to the holders of Series B was to consist of two (2) times the original purchase price of \$61.42, plus all accrued but unpaid dividends. Payment to the holders of Series B-2 was to consist of one and a half (1.5) times the original purchase price of \$61.42, plus all accrued but unpaid dividends. After such distribution to the holders of Series B and Series B-2, the holders of Series A-1 would have been entitled to be paid out of the remaining assets available for distribution, before any payment is made to the Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6. Payment to the holders of Series A-1 was to consist of the original purchase price of \$81.42, plus all accrued but unpaid dividends. After the distribution to the holders of Series A-1, the holders of Series A-2 would have been entitled to receive an amount per share equal to the original purchase price per share of \$81.42, plus any accrued but unpaid dividends. After the distribution to the holders Series A-1 and Series A-2, the holders of Series A-3, Series A-5 and Series A-6, would have been entitled to receive an amount per share equal to the original purchase price per share of \$81.42, plus any accrued but unpaid or declared and unpaid dividends, as appropriate. After the distribution to the holders Series A-1, Series A-2, Series A-3, Series A-5 and Series A-6, the holders of Series A-4 would have been entitled to receive an amount per share equal to the original purchase price per share of \$81.42, plus any declared and unpaid dividends. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series B, the assets would have been distributed ratably among the holders of Series B in proportion to their aggregate liquidation preference amounts. If the assets of the Company were insufficient to pay the full preferential amounts to the

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holders of Series A-1, the assets would have been distributed ratably among the holders of Series A-1 in proportion to their aggregate liquidation preference amounts. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series A-2, the assets would have been distributed ratably among the holders of Series A-2 in proportion to their aggregate liquidation preference amounts. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series A-3, Series A-5 and Series A-6, the assets would have been distributed ratably among the holders of Series A-3, Series A-5 and Series A-6 in proportion to their aggregate liquidation preference amounts. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series A-4, the assets would have been distributed ratably among the holders of Series A-4 in proportion to their aggregate liquidation preference amounts. After all liquidation preference payments have been made to the holders of the Series B, Series B-2 and Series A Preferred Stock, the holders of the Series B, Series B-2 and Series A-1, Series A-2 and Series A-3 were to participate in the distribution of the remaining assets with the holders of the Company's common stock on an as-if converted basis.

In the event of, and simultaneously with, the closing of an event of sale of the Company (as defined in the Company's Amended Certificate of Incorporation), the Company was to redeem all of the shares of Series B, Series B-2 and Series A Preferred Stock then outstanding at the Special Liquidation Price, as defined. If the event of sale involved consideration other than cash, the Special Liquidation Price could have been paid with such consideration having a value equal to the Special Liquidation Price. The Special Liquidation Price was to be equal to an amount per share, which would be received by each holder of the Preferred Stock if, in connection with the event of sale, all the consideration paid in exchange for the assets or the shares of capital stock of the Company was actually paid to and received by the Company, and the Company was immediately liquidated thereafter and its assets distributed pursuant to the liquidation terms above.

**6. Marketable Securities**

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

	September 30, 2014			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	\$ 2,135	\$	\$	\$ 2,135
Money market funds	14,331			14,331
Total	\$ 16,466	\$	\$	\$ 16,466
Marketable securities:				
Domestic corporate debt securities	43,561		(13)	43,548
Domestic corporate commercial paper	8,497	3		8,500
Total	\$ 52,058	\$ 3	\$ (13)	\$ 52,048

	December 31, 2013			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	\$ 2,710	\$	\$	\$ 2,710
Money market fund	9,593			9,593
Total	\$ 12,303	\$	\$	\$ 12,303



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There were no debt securities that had been in an unrealized loss position for more than 12 months as of September 30, 2014 or December 31, 2013. There were 18 debt securities in an unrealized loss position for less than 12 months at September 30, 2014 and there were no debt securities that had been in an unrealized loss position for less than 12 months at December 31, 2013. The aggregate unrealized loss on these securities as of September 30, 2014 was less than \$14 thousand and the fair value was \$29.8 million. 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, 2014.

The contractual term to maturity of all marketable securities held by the Company as of September 30, 2014 is less than one year.

Table of Contents**7. 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 balance sheets as of September 30, 2014 and December 31, 2013 (in thousands):

	September 30, 2014			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Cash and cash equivalents:				
Cash	\$ 2,135	\$	\$	\$ 2,135
Money market funds (1)	14,331			14,331
Total	\$ 16,466	\$	\$	\$ 16,466
Marketable securities:				
Domestic corporate debt securities (2)		43,548		43,548
Domestic corporate commercial paper (2)		8,500		8,500
Total	\$	\$ 52,048	\$	\$ 52,048

	December 31, 2013			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Cash and cash equivalents:				
Cash	\$ 2,710	\$	\$	\$ 2,710
Money market funds (1)	9,593			9,593
	\$ 12,303	\$	\$	\$ 12,303
<b>Liabilities</b>				
Warrant liability (3)	\$	\$	\$ 1,945	\$ 1,945
Stock liability (3)			5,328	5,328
	\$	\$	\$ 7,273	\$ 7,273

- (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.
- (3) Fair value is determined using the probability-weighted expected return model ( PWERM ), as discussed below. Changes in the fair value of the Level 3 assets and liabilities are recorded as other (expense) income in the condensed statement of operations.

The stock liability represents the accrued balance of the research and development expense related to the stock dividends that were issuable to Nordic Bioscience Clinical Development VII A/S ( Nordic ) in shares of Series A-6 (or in shares of common stock if the Company lists its common stock on a national exchange) as of December 31, 2013, for services rendered which is being recognized ratably over the estimated per patient treatment period under the three work statements executed with Nordic (the Nordic Work Statements ) (see note 9). The fair value of the stock liability was based upon the fair value of the Series A-6 as determined using

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PWERM, which considered the value of the Company's various classes of preferred stock. The fair value of the Company's various classes of preferred stock was determined through an analysis of the future values for equity assuming various future outcomes. Accordingly, share value was based upon the probability weighted present value of expected future net cash flows, considering each of the possible future events, discount rate as determined using the capital asset pricing model, as well as the rights and preferences of each share class. PWERM is complex as it requires numerous assumptions relating to potential future outcomes of equity. Accordingly, the valuation of the Company's stock liability was determined using Level 3 inputs. Upon completion of the Company's initial public offering, any payments owed by the Company to Nordic in relation to the Nordic Work Statements were changed from the right to receive shares of Series A-6 to the right to receive a total cash payment from the Company of \$4.3 million.

The warrant liability as of December 31, 2013, represents the liability for the warrants issued to the placement agent in connection with the Company's Series A-1 financing, to the investors in the Series B financing in April and May 2013, and to the lenders in connection with the Company's Loan and Security Agreement executed with Oxford and General Electric Capital Corporation in May 2011. The warrant liability was calculated using the Black-Scholes option pricing method. This method of valuation includes using inputs such as the fair value of the Company's common stock or preferred stock, historical volatility, the term of the warrant and risk free interest rates. Prior to its initial public offering, the fair value of the Company's shares of common stock and preferred stock is estimated using PWERM, as described above. Accordingly, the valuation of the warrant liability at December 31, 2013, was determined using Level 3 inputs. Upon completion of the Company's initial public offering, the outstanding warrants to purchase shares of A-1 convertible preferred stock were converted into the right to purchase shares of common stock and the Company's warrant liability was reclassified to equity.

The following table provides a roll-forward of the fair value of the assets, where fair value is determined using Level 3 inputs (in thousands):

Balance at December 31, 2013	\$	
Issuance of shares of Series A-6 - prepayment		1,220
Nordic amendment		(1,220)
Balance at September 30, 2014	\$	

The following table provides a roll-forward of the fair value of the liabilities, where fair value is determined using Level 3 inputs (in thousands):

Balance at December 31, 2013	\$	7,273
Issuance of shares of Series A-6		(8,889)
Additions accrued shares of Series A-6		2,717
Additions warrants		1,511
Change in fair value		505
Warrant liability reclassified to equity		(3,117)
Balance at September 30, 2014	\$	

Additions represent the value of the asset or liability for additional accrued shares of stock that were issuable to Nordic for services rendered in connection with the Company's Phase 3 Clinical Trial of abaloparatide-SC (see note 9), as well as the value of any new warrants issued during the period. The issuance of shares of Series A-6 represents the release of the quarterly stock dividends of Series A-6 accrued under the Nordic Work Statements (see note 9). The Nordic amendment represents amounts that were originally payable in shares of Series A-6, but converted to the right to receive cash upon completion of the Company's initial public offering and no longer require fair value measurement at September 30, 2014 (see note 9).

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The fair value of the Company's note payable is determined using current applicable rates for similar instruments as of the balance sheet date. The carrying value of the Company's note payable approximated its fair value as of September 30, 2014, as the Company's interest rate is near current market rates. The fair value of the Company's notes payable was determined using Level 3 inputs.

### 8. License Agreements

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 in all countries, except Japan and (subject to certain co-marketing and co-promotion rights retained by Ipsen) France. With respect to France, if Ipsen exercises its co-marketing and co-promotion rights, then Ipsen may elect to receive a percentage of the aggregate revenue from the sale of products by both parties in

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France (subject to a mid-double digit percentage cap), and Ipsen shall bear a corresponding percentage of the costs and expenses incurred by both parties with respect to such marketing and promotion efforts in France; Ipsen shall also pay Radius a mid-single digit royalty on Ipsen's allocable portion of aggregate revenue from the sale of products by both parties in France. Abaloparatide is subject to the Ipsen Agreement. Ipsen also granted the Company an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen also granted the Company an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling the Company to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan and (subject to certain co-marketing and co-promotion rights retained by Ipsen) France.

In consideration for these licenses, the Company made a nonrefundable, non-creditable payment of \$250,000 to Ipsen, which was expensed during 2005. The Ipsen Agreement provides for further payments in the range of 10.0 million to 36.0 million (\$12.6 million to \$45.5 million) to Ipsen upon the achievement of certain development and commercialization milestones specified in the Ipsen Agreement, and for the payment of fixed 5% royalties on net sales of any product by the Company or its sub-licensees on a country-by-country basis until the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country of any product that includes the compound licensed from Ipsen or any analog thereof, whichever is longer.

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 sub-licensees 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 last to expire of its patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country, whichever is longer. In January 2006, we entered into a Pharmaceutical Development Agreement with Ipsen as contemplated by the Ipsen Agreement. In connection with the Ipsen Agreement and Pharmaceutical Development Agreement, the Company recorded \$0.1 million and less than \$0.1 million in costs during the three months ended September 30, 2014 and 2013, respectively, and \$0.4 million and \$0.2 million during the nine months ended September 30, 2014 and 2013, respectively, which were incurred by Ipsen and charged to the Company for the manufacture of the clinical supply of the licensed compound.

## 9. Research Agreements

*Abaloparatide-SC Phase 3 Clinical Trial* On March 29, 2011, the Company and Nordic entered into a Clinical Trial Services Agreement, a Work Statement NB-1 (the "Work Statement NB-1") under such Clinical Trial Services Agreement and a related Stock Issuance Agreement, as amended to date (the "Stock Issuance Agreement"). Pursuant to the Work Statement NB-1, Nordic is managing the Phase 3 Clinical Trial (the "Phase 3 Clinical Trial") of abaloparatide-SC and is being compensated for such services in a combination of cash and shares of stock.

In December 2011, the Company entered into an amendment to the Work Statement NB-1 (the "First Amendment"). Pursuant to the original terms of the Work Statement NB-1, the study was to be conducted in 10 countries at a specified number of sites within each country. The terms of the First Amendment (1) provided for two additional countries (the United States and India) in which the trial would be conducted, (2) specified a certain number of sites within each such additional country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect the addition of such countries and sites within the study's parameters. Payments to be made by the Company to Nordic under the First Amendment are denominated in both euros and U.S. dollars and total up to 717,700 (\$906,312) and \$289,663, respectively, for the 15 additional study sites in India contemplated by the First Amendment and up to 1.2 million (\$1.6 million) and \$143,369, respectively, for the five additional study sites in the United States contemplated by the First Amendment.

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In June 2012, the Company entered into a second amendment to the Work Statement NB-1 (the "Second Amendment"). Pursuant to the original terms of the Work Statement NB-1, as amended by the First Amendment, the study was to be conducted in 12 countries at a specified number of sites within each country. The terms of the Second Amendment (1) increased the overall number of sites by adding sites in Europe, Brazil and Argentina and removing other sites, (2) specified a certain number of sites within each country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect additional services to be provided at existing sites and the addition of the new study sites within the study's parameters. The Second Amendment also provided that cash payments to Nordic under the Clinical Trial Services Agreement as well as the payment of shares of stock under the related Stock Issuance Agreement will each be reduced by an amount of 11,941 (\$15,079) per subject for any subjects enrolled in India or the United States. Such reductions are applied in pro rata monthly installments. Payments to be made by the Company to Nordic under the Second Amendment in connection with the additional services provided at existing sites and the conduct of the study at the new study sites are denominated in both euros and U.S. dollars and total of up to 3.7 million (\$4.7 million) and \$205,540, respectively.

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In March 2014, the Company entered into a fourth amendment to the Work Statement NB-1 (the Fourth Amendment ). Pursuant to the terms of the Fourth Amendment, the Company agreed to pay to Nordic an additional performance incentive, or a Performance Incentive Payment, of \$500,000 for every 50 patients that, subsequent to March 28, 2014, complete all end-of-study procedures, up to a maximum aggregate amount of additional payments equal to \$5.0 million. Any Performance Incentive Payment would have been paid in cash in the event that the Company's initial public offering of its common stock was completed prior to May 31, 2014. If an initial public offering was not completed prior to May 31, 2014, any Performance Incentive Payments would have been paid through the issuance to Nordic of shares of capital stock of the Company under the same model for equity-based compensation contemplated by the Company's existing outstanding work statements under the Clinical Trial Services Agreement. On May 19, 2014, the Company entered into a fifth amendment to Work Statement NB-1, which amended the date prior to which an initial public offering must be completed to June 30, 2014. As the Company completed an initial public offering of its common stock on June 11, 2014, all Performance Incentive Payments will be paid in cash.

Pursuant to the Work Statement NB-1, the Company is required to make certain per patient payments denominated in both euros and U.S. dollars for each patient enrolled in the Phase 3 Clinical Trial followed by monthly payments for the duration of the study and final payments in two equal euro-denominated installments and two equal U.S. dollar-denominated installments. Changes to the Clinical Trial schedule may alter the timing, but not the aggregate amounts of the payments.

The Work Statement NB-1, as amended on December 9, 2011, June 18, 2012, March 28, 2014 and May 19, 2014, provides for a total of up to approximately 41.2 million (\$52.0 million) of euro-denominated payments and a total of up to approximately \$3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus Performance Incentive Payments of up to \$5.0 million. These payments may be adjusted based upon actual sites opened, work performed or number of patients enrolled.

Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase the equivalent of 371,864 of Series A-5 at \$8.142 per share, and 64,430 shares of Series A-5 were sold to Nordic on May 17, 2011 for proceeds of \$525,154. These shares were exchanged for an aggregate of 6,443 shares of the Company's Series A-5 pursuant to an Agreement and Plan of Merger (the Merger ) entered into in April 2011 by and among the Company, which was formerly known as MPM Acquisition Corp., (a public-reporting, Form 10 shell company at the time), RHI Merger Corp., a Delaware corporation and wholly owned subsidiary of the Company ( MergerCo ), and Radius Health, Inc., a privately-held Delaware corporation ( Former Operating Company ). Pursuant to the Merger, MergerCo merged with and into the Former Operating Company, with the Former Operating Company remaining as the surviving entity and a wholly-owned subsidiary of the Company.

The Stock Issuance Agreement provided that Nordic was entitled to receive quarterly stock dividends, payable in shares of Series A-6 or shares of common stock if the Company's preferred stock had been converted in accordance with its amended certificate of incorporation, having an aggregate value, under the Work Statement NB-1, of up to 36.8 million (\$46.5 million) (the Nordic Accruing Dividend ). In the event Nordic sold the shares of Series A-5 or in the event the shares of Series A-5 were converted into common stock in accordance with the Company's amended certificate of incorporation, this right to receive the Nordic Accruing Dividend would terminate, but a right to receive an equivalent number of shares of Series A-6 or common stock, as applicable, would remain with Nordic as a contractual right under the Stock Issuance Agreement.

On March 28, 2014, the Company entered into Amendment No. 2 to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011 (the Second Stock Issuance Agreement Amendment ), with Nordic. The Second Stock Issuance Agreement Amendment required that the Company's Board of Directors declare, as soon as reasonably practical, a stock dividend of twenty nine (29) shares of its Series A-6 for each share of the Company's then outstanding Series A-5, all of which were held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in relation to Work Statement NB-1 and Work Statement NB-3. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, the Company's Board of Directors declared and issued a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance



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Agreement Amendment further provided that in the event an initial public offering of the Company's common stock occurred prior to May 31, 2014, any payments owed by the Company to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, excluding Performance Incentive Payments, for all periods of time after 2014, would be changed from the right to receive stock to the right to receive a total cash payment from the Company of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, the Company entered into Amendment No. 3 to the Stock Issuance Agreement, which amended the date prior to which an initial public offering must occur to June 30, 2014. The Second Stock Issuance Agreement Amendment also stipulated that all consideration to be paid to Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an initial public offering be payable in cash. As the Company completed an initial public offering on June 11, 2014, Nordic no longer has the right to receive stock from the Company and agreed to be paid in cash for all periods after the consummation of the initial public offering.

Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock was being accounted for as a liability in the Company's balance sheet, based upon the fair value of the Series A-6 as determined using

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PWERM. Changes in the fair value from the date of accrual to the date of issuance of the Series A-6 shares were recorded as a gain or loss in other (expense) income in the statement of operations.

The Company recognizes research and development expense for the amounts due to Nordic under the Work Statement NB-1, First Amendment and Second Amendment ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 3 Clinical Trial, or a twenty-month period. The Company recognizes research and development expense for the amounts due to Nordic under the Fourth Amendment on a per patient basis when the End-of-Study visit and all other required procedures are completed. The Company recorded \$1.2 million and \$7.6 million of research and development expense during the three months ended September 30, 2014 and 2013, respectively and \$8.1 million and \$25.5 million during the nine months ended September 30, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Study.

As of September 30, 2014, the Company had a liability of \$9.5 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

*Abaloparatide-SC Phase 3 Clinical Extension Study* In February 2013, the Company entered into a Work Statement NB-3 (the Work Statement NB-3 ) under the Clinical Trial Services Agreement and the related Stock Issuance Agreement. Pursuant to Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the 18-month abaloparatide-SC Phase 3 Clinical Trial (the Extension Study ) and will be compensated for such services in a combination of cash and shares of stock. Under the terms of a Letter of Intent that the Company entered into with Nordic on October 22, 2012 setting forth the parties' obligations to negotiate in good faith to enter into Work Statement NB-3, the Company was required to make an initial payment of 806,468 (\$1.0 million).

In March 2014, the Company entered into an amendment to the Work Statement NB-3 (the NB-3 Amendment ). The NB-3 Amendment was effective as of February 28, 2014 and provides that Nordic will perform a Period 2 extension study (the Second Extension ), to evaluate an additional eighteen months of standard-of-care osteoporosis management following the Period 1 extension of six months upon completion of the Phase 3 clinical trial of the Company's abaloparatide-SC product. Payments in cash to be made by the Company to Nordic under the NB-3 Amendment are denominated in both euros and U.S. dollars and total up to approximately 3.0 million (\$3.7 million) and \$527,740, respectively. In addition, the Company agreed to issue to Nordic shares of the Company's series A-6 having a value of up to approximately 3.0 million (\$3.7 million) and \$527,740 as additional payment for the services to be provided under the NB-3 Amendment, with the issuance of such shares to be made pursuant to the terms of an Amendment No. 2, entered into by the Company with Nordic on March 28, 2014, to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011.

Payments in cash to be made to Nordic under the Work Statement NB-3, as amended by the NB-3 Amendment, are denominated in both euros and U.S. dollars and total up to 7.5 million (\$9.5 million) and \$1.1 million, respectively. In addition, the Company will issue to Nordic, shares of the Company's Series A-6 having a value of up to 7.5 million (\$9.5 million) and \$0.8 million, as additional payment for services to be provided under the Work Statement NB-3 and the Services Agreement.

The Stock Issuance Agreement provided that, beginning with the quarter ended March 31, 2013, Nordic was entitled to receive quarterly stock dividends in connection with services performed under the Work Statement NB-3, payable in shares of Series A-6 or shares of common stock if the Company's preferred stock automatically converted into common stock in accordance with its amended certificate of incorporation, having an aggregate value of up to 7.5 million (\$9.5 million) and \$0.8 million. In the event Nordic sold the shares of Series A-5 or in the event the shares of Series A-5 were converted into common stock in accordance with the Company's amended certificate of incorporation, this right to receive the Nordic Accruing Dividend would terminate, but a right to receive an equivalent number of shares of Series A-6 or common stock, as applicable,

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would remain with Nordic as a contractual right under the Stock Issuance Agreement.

On March 28, 2014, the Company entered into Amendment No. 2 to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011 (the "Second Stock Issuance Agreement Amendment"), with Nordic. The Second Stock Issuance Agreement Amendment required that the Company's Board of Directors declare, as soon as reasonably practical, a stock dividend of twenty nine (29) shares of its Series A-6 for each share of the Company's then outstanding Series A-5, all of which were held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in relation to Work Statement NB-1 and Work Statement NB-3. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, the Company's Board of Directors declared and issued a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment further provided that in the event an initial public offering of the Company's common stock occurred prior to May 31, 2014, any payments owed by the Company to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, excluding Performance Incentive Payments, for all periods of time after 2014, would be changed from the right to receive stock to the right to receive a total cash payment from the Company of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, the Company entered into Amendment No. 3 to the Stock Issuance Agreement, which amended the date prior to which an initial public offering must occur to June 30, 2014. The Second Stock Issuance Agreement Amendment also stipulated that all consideration to be paid to

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Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an initial public offering be payable in cash. As the Company completed an initial public offering on June 11, 2014, Nordic no longer has the right to receive stock from the Company and agreed to be paid in cash for all periods after the consummation of the initial public offering.

Prior to the issuance of the shares of Series A-6 to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock was being accounted for as a liability in the Company's balance sheet, based upon the fair value of the Series A-6 as determined using PWERM. Changes in the fair value from the date of accrual to the date of issuance of the Series A-6 shares are recorded as a gain or loss in other (expense) income in the statement of operations.

On December 6, 2013, the Company entered into a Letter of Intent (the "Letter of Intent") with Nordic, which provided that the Company and Nordic would continue to negotiate the definitive terms of the NB-3 Amendment, which provides for an additional 18 months of standard-of-care treatment for those patients enrolled in the Extension Study being performed under Work Statement NB-3. The NB-3 Amendment was executed on March 28, 2014 and provides for payment by the Company to Nordic of both cash and equity compensation in consideration of the services provided by Nordic, with the equity portion of such compensation to be made pursuant to an Amendment No. 2 to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011. Pursuant to the Letter of Intent, the Company was required to make an initial payment of \$222,573 (\$0.3 million) and agreed to commence payment of the cash compensation due in consideration of the services being provided by Nordic under the Amendment.

The Company recognizes research and development expense for the amounts due to Nordic under the Work Statement NB-3 and Amendment ratably over the estimated per patient treatment periods beginning upon enrollment, or over a nine-month and nineteen-month period, respectively. The Company recorded \$2.3 million and \$1.3 million of research and development expense during the three months ended September 30, 2014 and 2013, respectively, and \$7.7 million and \$2.6 million for the nine months ended September 30, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Extension Study and Second Extension.

As of September 30, 2014, the Company had a liability of \$4.5 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

*Abaloparatide-TD Phase 2 Clinical Trial* On July 26, 2012, the Company entered into a Letter of Intent (the "Phase 2 Letter of Intent") with Nordic, which provided that the Company and Nordic would, subject to compliance by the Company with certain requirements of its Certificate of Incorporation and applicable securities laws, negotiate in good faith to enter into (1) a Work Statement NB-2 (the "Work Statement NB-2"), a draft of which is attached to the Phase 2 Letter of Intent, and (2) an amendment to the Amended and Restated Stock Issuance Agreement.

In February 2013, the Company executed the final Work Statement NB-2 under the Clinical Trial Services Agreement and the related Stock Issuance Agreement. Pursuant to the Work Statement NB-2, Nordic would provide clinical trial services relating to the Phase 2 Clinical Trial and would be compensated for such services in a combination of cash and shares of stock. Payments in cash to be made by the Company to Nordic under the Work Statement NB-2 were denominated in both euros and U.S. dollars and totaled up to \$3.6 million (\$4.5 million) and \$0.3 million, respectively. In addition, the Company would issue to Nordic shares of its Series A-6 stock having a value of up to \$2.9 million, as additional payment for services to be provided under the Work Statement NB-2 and the Clinical Trial Services Agreement.

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As of December 31, 2013, 32,215 shares of Series A-6 were due to Nordic under Work Statement NB-2, or, after the automatic conversion into common stock of the Company's preferred stock, 141,294 shares the Company's common stock. In December 2013, Nordic requested that all 32,215 shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-2 be issued. Accordingly, the Company's Board of Directors declared a dividend to Nordic of all 32,215 shares of Series A-6 accrued under Work Statement NB-2 on December 31, 2013, which constituted all shares of Series A-6 due under Work Statement NB-2.

The Company recognized research and development expense for the amounts due to Nordic under the Work Statement NB-2 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 2 Clinical Trial, or a nine-month period. The Company recorded no expense and \$0.6 million of research and development expense during the three months ended September 30, 2014 and 2013, respectively, and nil and \$4.1 million during the nine months ended September 30, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Phase 2 Clinical Trial. As of September 30, 2014, all obligations due to Nordic under Work Statement NB-2 had been paid.

The Company is also responsible for certain pass-through costs in connection with the Phase 3 Clinical Trial, Extension Study and Phase 2 Clinical Trial. Pass through costs are expensed as incurred or upon delivery. The Company recognized research and development expense of \$0.3 million and \$1.3 million for pass-through costs during the three months ended September 30, 2014 and 2013, respectively, and \$0.8 million and \$3.3 million during the nine months ended September 30, 2014 and 2013, respectively.

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A summary of stock option activity during the nine months ended September 30, 2014 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, 2013	1,667	\$ 7.05		
Granted	1,894	8.25		
Exercised	(1)	2.46		
Cancelled	(1,182)	8.63		
Expired	(1)	3.42		
Options outstanding at September 30, 2014	2,377	\$ 7.22	8.12	\$ 32,756
Options exercisable at September 30, 2014	968	\$ 5.52	6.23	\$ 14,974
Options vested or expected to vest at September 30, 2014	2,299	\$ 7.18	8.08	\$ 31,761

The weighted-average grant-date fair value per share of options granted during the three and nine months ended September 30, 2014 was \$8.36 and \$4.80, respectively, and the total grant-date fair value of stock options that vested during the nine months ended September 30, 2014 was approximately \$1.9 million. As of September 30, 2014, there was approximately \$6.2 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.

**11. 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,	
	2014	2013	2014	2013
<b>Numerator:</b>				
Net loss	\$ (17,420)	\$ (20,342)	\$ (44,517)	\$ (48,159)
Accretion of Preferred Stock		(4,748)	(9,000)	(12,698)
Loss attributable to common stockholders - basic and diluted	\$ (17,420)	\$ (25,090)	\$ (53,517)	\$ (60,857)
<b>Denominator:</b>				
Weighted-average number of common shares used in loss per share - basic and diluted (1)	29,746,426	385,688	12,651,628	382,541
Loss per share - basic and diluted	\$ (0.59)	\$ (65.05)	\$ (4.23)	\$ (159.09)

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(1) Common shares adjusted for 2.28:1 stock split that was affected April 24, 2014.

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, 2014 and 2013, all of the Company's classes of preferred stock, options to purchase common stock and warrants outstanding were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Convertible preferred stock		7,108,324	5,157,682	6,203,960
Options to purchase common stock	2,599,770	1,699,830	2,449,476	1,705,552
Warrants	1,379,551	783,898	1,235,074	465,559

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**12. 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.



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

***Cautionary Statement***

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

- *the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;*
- *the success of our clinical studies for our product candidates;*
- *our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards;*
- *our expectations regarding federal, state and foreign regulatory requirements;*
- *the therapeutic benefits and effectiveness of our product candidates;*
- *the safety profile and related adverse events of our product candidates;*
- *our ability to manufacture sufficient amounts of abaloparatide, RAD1901, and RAD140 for commercialization activities with target characteristics following regulatory approvals;*
- *our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates;*
- *our expectations as to future financial performance, expense levels and liquidity sources;*
- *our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;*
- *anticipated trends and challenges in our potential markets; and*
- *our ability to attract and motivate key personnel.*

*The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements. These important factors include our financial performance, our ability to attract and retain customers, our development activities and those factors we discuss in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K/A filed with the Securities and Exchange Commission, or the SEC, on April 3, 2014 under the caption Risk Factors. You should read these factors and the other cautionary statements made in this*

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*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 risk 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, or Radius.

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**Executive Overview**

We are a science-driven biopharmaceutical company focused on developing new therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases. Our lead product candidate is the investigational drug abaloparatide (BA058), a bone anabolic for the potential treatment of osteoporosis delivered via subcutaneous injection, which we refer to as abaloparatide-SC. We are currently in Phase 3 development of abaloparatide-SC and plan to announce top-line 18-month fracture data from this study in late December 2014. If the results meet the study endpoints, we plan to submit a new drug application, or NDA, in the United States, and a marketing authorization application, or MAA, in Europe, in mid-2015. We hold worldwide commercialization rights to abaloparatide-SC, other than in Japan, and subject to a regulatory review and a favorable regulatory outcome, we anticipate our first commercial sales of abaloparatide-SC will take place in 2016. We are leveraging our investment in abaloparatide-SC to develop a line extension that is designed to improve patient convenience by enabling administration of abaloparatide through a short-wear-time patch, which we refer to as abaloparatide-TD. We have recently completed a successful Phase 2 proof of concept study of abaloparatide-TD.

Our current clinical product portfolio also includes the investigational drug RAD1901, a selective estrogen receptor down-regulator/degrader, or SERD, and RAD140, a nonsteroidal selective androgen receptor modulator, or SARM. We are developing RAD1901 at higher doses for the potential treatment of metastatic breast cancer, and intend to advance its development with the initiation of Phase 1 clinical trials, including a maximum tolerated dose study that has commenced patient dosing and a Phase 1b clinical trial in metastatic breast cancer patients, which is expected to commence in late 2014. The precise patient population will be defined in the study protocol and determined in conjunction with our investigators. At lower doses, RAD1901 acts as a selective estrogen-receptor modulator, or SERM. Low-dose RAD1901 has shown potential to be effective for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study. We intend to commence a Phase 2b clinical trial in vasomotor symptoms in the second half of 2015. RAD140 resulted from an internal drug discovery program that began in 2005. RAD140 has demonstrated potent anabolic activity on muscle and bone in preclinical studies and has clinical potential in a number of indications including the treatment of weight loss due to cancer cachexia, sarcopenia, frailty and oncology.

***Abaloparatide***

Abaloparatide is a synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a potential bone anabolic treatment for osteoporosis. Osteoporosis is a disease that affects nearly 10 million people in the United States, with an additional approximately 43 million people at increased risk for the disease. It is characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. Anabolic agents, like Forteo (teriparatide), are used to increase bone mineral density, or BMD, and to reduce the risk of fracture. We believe abaloparatide has the potential to increase BMD and bone quality to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis. We are developing two formulations of abaloparatide:

- *Abaloparatide-SC* is an injectable subcutaneous formulation of abaloparatide. In August 2009, we announced positive Phase 2 data from a study that showed abaloparatide-SC produced faster and greater BMD increases at the spine and the hip with substantially less hypercalcemia than Forteo, which is the only approved subcutaneous injectable anabolic agent for the treatment of osteoporosis in the United States. The abaloparatide-SC Phase 2 manuscript has been accepted for publication in the *Journal of Clinical Endocrinology and Metabolism* and an online version is expected to be available in November 2014. A subsequent Phase 2 clinical trial announced in January 2014 confirmed the results of our first clinical trial as data from the second study showed that abaloparatide-SC produced BMD increases from baseline in the spine and hip that were comparable to our earlier Phase 2 clinical trial. In April 2011, we commenced a Phase 3 clinical trial of abaloparatide-SC. Enrollment was completed in March 2013. The last patient, last visit for the 18-month anabolic treatment portion of the Phase 3 clinical trial occurred during October 2014 and all continuing patients are now enrolled in the 6-month standard-of-care extension study. We plan to announce top-line 18-month data, including efficacy and safety data for each treatment group included in the 18-month anabolic phase, in late December 2014. Assuming the study meets its endpoints, we plan to use the results from this Phase 3 clinical trial to support a new drug

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application, or NDA, with the U.S. Food and Drug Administration, or FDA, and believe we could obtain approval of the NDA in 2016.

- *Abaloparatide-TD* is a line extension of abaloparatide-SC in the form of a convenient, short-wear-time (approximately five minutes) transdermal patch. Data from a recent Phase 2 clinical trial showed abaloparatide-TD produced a statistically significant mean percent increase from baseline in BMD as compared to placebo at the lumbar spine and at the hip. These Phase 2 results demonstrated proof of concept by achieving a dose-dependent increase in BMD. Following additional formulation development work, we intend to advance an optimized abaloparatide-TD product in additional clinical studies and in a Phase 3 bridging study in order to submit an application for regulatory approval. We hold worldwide commercialization rights to abaloparatide-TD technology.

In April 2011, we began the dosing of subjects in a pivotal Phase 3 clinical trial managed by Nordic Bioscience Clinical Development VII A/S, or Nordic, at certain clinical sites operated by the Center for Clinical and Basic Research, a leading global clinical research organization, or CRO, with extensive experience in global osteoporosis registration studies. We designed this Phase 3 study to enroll a total of 2,400 patients to be randomized equally to receive daily doses of one of the following: 80 micrograms ( $\mu\text{g}$ ) of abaloparatide, a matching placebo, or the approved dose of 20  $\mu\text{g}$  of Forteo for 18 months. The study also includes a 6-month extension period in order to obtain 24-months of fracture data, as requested by the FDA. We plan to submit the NDA with the 24-month fracture data. The study was designed to evaluate whether abaloparatide is superior to placebo for prevention of vertebral fracture. The study was also designed to evaluate whether abaloparatide is superior to Forteo for greater BMD improvement at major skeletal sites and for a lower

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occurrence of hypercalcemia, a condition in which the calcium level in a patient's blood is above normal. We plan to announce top-line fracture data, including efficacy and safety data for each treatment group included in the 18-month anabolic phase, in late December 2014. We will remain blinded at the patient and site level until such time as the 6-month standard-of-care extension study is completed. Following completion of this Phase 3 clinical trial, if the results from this study indicate that the study endpoints were met, we intend to submit for regulatory approval in the United States and Europe in mid-2015. With standard review time and a favorable regulatory outcome, we expect to begin commercial sales in 2016.

On May 9, 2014, we submitted a breakthrough therapy designation request to the FDA for abaloparatide-SC for the treatment of postmenopausal osteoporosis. Abaloparatide-SC was selected for clinical development on the basis of its demonstrated marked effects on increasing bone mass in non-clinical models. The recently completed analyses of two abaloparatide Phase 2 clinical trials have confirmed these non-clinical results, demonstrating potentially important clinical benefits relative to current anabolic therapies, including faster and greater increases in hip (non-vertebral) and spine (vertebral) BMD. We believe these results could support a breakthrough therapy designation. In July 2014, the FDA responded to our request and indicated that abaloparatide-SC would be considered for a breakthrough therapy designation if clinical evidence, such as the results of our Phase 3 clinical trial, demonstrate that patients dosed with abaloparatide-SC show substantial improvement in treatment of postmenopausal osteoporosis, or safety, over existing therapies. Once we have evaluated the results from the Phase 3 clinical trial, a decision will be made on whether or not to re-submit our request for breakthrough designation with focus on areas highlighted by the FDA.

***RAD1901***

RAD1901 is a SERD that we believe crosses the blood-brain barrier and that we are evaluating for the potential treatment of metastatic breast cancer. RAD1901 has been shown to bind with good selectivity to the estrogen receptor and to have both estrogen-like and estrogen-antagonistic effects in different tissues. In many cancers, hormones, like estrogen, stimulate tumor growth and a desired therapeutic goal is to block this estrogen-dependent growth while inducing apoptosis of the cancer cells. SERDs are an emerging class of endocrine therapies that directly induce estrogen receptor, or ER, degradation, enabling them to remove the estrogen growth signal in ER-dependent tumors without allowing ligand-independent resistance to develop. There is currently only one SERD, Faslodex (fulvestrant), approved in the United States for the treatment of hormone-receptor positive metastatic breast cancer. In 2012, the worldwide market for Faslodex exceeded \$650.0 million. However, for patients with brain metastases, there are no approved targeted therapies that cross the blood-brain barrier. If successfully developed, we believe there is a significant opportunity for RAD1901 to be the first ER-targeted therapy that crosses the blood-brain barrier to more effectively treat ER-positive metastatic breast cancer and potentially reduce both intracranial and extracranial tumors.

In June 2014, we initiated a Phase 1 maximum tolerated dose, or MTD, study of RAD1901 in healthy volunteers. The study is designed to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also to use 18F-estradiol positron emission tomography, or FES-PET, imaging to provide a pharmacodynamic assessment of estrogen receptor turnover following administration of RAD1901. Levels of RAD1901 in cerebrospinal fluid samples taken from study subjects will be measured to confirm that RAD1901 has crossed the blood-brain barrier. Based upon initial study results, FES-PET imaging of RAD1901 has demonstrated potent SERD activity. As of September 30, 2014, 40 subjects had completed dose escalation in the ongoing MTD study, and FES-PET imaging had been completed in a total of six subjects across two different doses. Each of these six subjects demonstrated, based on FES-PET imaging, suppression of the FES-PET signal to background levels after six days of dosing. In addition, RAD1901, at the doses that showed suppression of the FES-PET signal, was well tolerated in these six patients. We expect to report additional results from the MTD study of RAD1901 and to commence a Phase 1b clinical study of RAD1901 for metastatic breast cancer in late 2014.

In March 2014, we submitted to the FDA an application for orphan drug product designation of RAD1901 for the treatment of breast cancer brain metastases. In June 2014, we received a request from the FDA for additional data with respect to our orphan drug designation application. We plan to meet with the FDA and are working to provide them with the data requested.

We are also developing RAD1901 at lower doses as a selective estrogen receptor modulator, or SERM, for the potential treatment of vasomotor symptoms. Historically, hormone replacement therapy, or HRT, with estrogen (with or without the addition of progesterone) was considered the most efficacious approach to relieving menopausal symptoms such as hot flashes. However, because of the concerns about the potential long-term risks and contraindications associated with HRT, we believe a significant need exists for new therapeutic treatment options to treat vasomotor symptoms. In a Phase 2 proof of concept study, RAD1901 at lower doses demonstrated a reduction in the frequency and severity of moderate and severe hot flashes. We intend to commence a Phase 2b trial in vasomotor symptoms in the second half of 2015.

Our efforts and resources are focused primarily on developing abaloparatide-SC, abaloparatide-TD, RAD1901 and our other pharmaceutical product candidates, raising capital and recruiting personnel. We have no product sales to date and we will not receive any revenue from product sales unless and until we receive regulatory approval for abaloparatide-SC from the FDA, or equivalent foreign regulatory bodies. However, developing pharmaceutical products is a lengthy and very expensive process. Accordingly, our success depends not only on demonstrating the safety and efficacy of abaloparatide, but also on our ability to finance the development of these products, which will require substantial additional funding to complete development and submit applications seeking

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marketing approval. Our ability to raise this additional financing will depend on our ability to execute on the abaloparatide development plan, manage and coordinate, on a cost-effective basis, the required components of the NDA submission for abaloparatide-SC and scale-up abaloparatide-SC and abaloparatide-TD manufacturing capacity. In addition, we currently have no sales or distribution capabilities and thus our ability to market abaloparatide once approved may depend in part on our ability to enter into and maintain collaborative relationships, which will depend on the strength of our clinical data, our access to capital and other factors.

***Recent Financings***

On June 11, 2014, we completed our initial public offering whereby we sold 6,500,000 shares of our common stock at a price of \$8.00 per share. The shares began trading on the NASDAQ Global Market on June 6, 2014. In connection with the completion of the offering, all outstanding shares of our convertible preferred stock converted into 19,465,132 shares of common stock, and 2,862,654 shares of common stock were issued in satisfaction of accumulated dividends accrued on the preferred stock. In addition, all outstanding warrants to purchase shares of A-1 convertible preferred stock and warrants to purchase shares of series B-2 convertible preferred stock were converted into the right to purchase 149,452 shares of common stock and our warrant liability was reclassified to equity. On June 18, 2014 and June 25, 2014, the underwriters purchased an additional 512,744 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the initial public offering. As a result of the closing of the initial public offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$50.4 million.

On October 7, 2014, we completed an additional public offering whereby we sold 2,750,000 shares of common stock at a price of \$18.25 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$46.9 million. On October 7, 2014, the underwriters purchased an additional 378,524 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately \$53.3 million.

***Future Financing Needs***

We expect to finance the future development costs of abaloparatide-SC, abaloparatide-TD and RAD1901 with our existing cash and cash equivalents and marketable securities, or through strategic financing opportunities, future offerings of our equity, or the incurrence of debt. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, progress on securing third-party collaborators, as well as ongoing assessments of such product candidate's commercial potential and our ability to fund this product development.

The successful development of our product candidates is subject to numerous risks and uncertainties associated with developing drugs, including, but not limited to, the variables listed below. A change in the outcome of any of these variables with respect to the development of any of our product candidates could mean a significant change in the cost and timing associated with the development of that product candidate.

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. We have not submitted an NDA to the FDA or comparable applications to foreign regulatory authorities. Obtaining approval of a product candidate is an extensive, lengthy, expensive and uncertain process, and any approval of

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abaloparatide-SC may be delayed, limited or denied for many reasons, including:

- we may not be able to demonstrate that abaloparatide is safe and effective as a treatment for osteoporosis to the satisfaction of the FDA or other foreign regulatory authorities;
- the results of our clinical studies may not meet the level of statistical or clinical significance required for marketing approval;
- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the CRO that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA or other foreign regulatory authorities may not find the data from preclinical studies and clinical studies sufficient to demonstrate that abaloparatide's clinical and other potential benefits outweigh its safety risks;
- the FDA or other foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;
- the FDA or other foreign regulatory authorities may not agree with our proposed labeling and may require labeling that undermines or otherwise significantly impairs the commercial value of the product if it were to be approved with such labeling;



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- the FDA or other foreign regulatory authorities may not accept data generated at our clinical study sites;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions; or
- the FDA or other foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

In addition, the FDA or other foreign regulatory authorities may change their approval policies or adopt new regulations. For example, on February 15, 2012, we received a letter from the FDA stating that, after internal consideration, the agency believes that a minimum of 24-months of fracture data is necessary for approval of new products for the treatment of postmenopausal osteoporosis, and our ongoing abaloparatide-SC pivotal Phase 3 clinical trial is designed to produce fracture data based on an 18-month primary endpoint. Based on our discussions with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from a 6-month extension of the abaloparatide 80 µg and placebo groups in our Phase 3 clinical trial. In the extension study, patients are receiving an approved alendronate (generic Fosamax) therapy for osteoporosis management. We plan to submit the NDA with the 24-month fracture data. We cannot be certain that the FDA, or other regulatory authorities, will be supportive of this plan, will not change this approval policy again, or adopt other approval policies or regulations that adversely affect any NDA that we may submit.

**Financial Overview**

*Research and Development Expenses*

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

None of the research and development expenses in relation to our product candidates are currently borne by third parties. Our lead product candidate is 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, 2014 were approximately \$170.8 million. We began tracking program expenses for abaloparatide-TD in 2007, and program expenses from inception to September 30, 2014 were approximately \$30.6 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to September 30, 2014 were approximately \$16.9 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to September 30, 2014 were approximately \$5.2 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs.

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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.

We estimate that future development costs for abaloparatide-SC may exceed \$44.0 million, including \$10.0 million for clinical costs, \$23.0 million for license and milestone payments and NDA submission fees, \$10.0 million for manufacturing costs and \$1.0 million for preclinical costs. For abaloparatide-TD, we estimate that future development costs may exceed \$44.0 million, including \$35.0 million for clinical costs, \$8.0 million for manufacturing costs, and \$1.0 million for preclinical costs and NDA submission fees.

Our current strategy is to commence a Phase 1b clinical study of RAD1901 for the potential treatment of metastatic breast cancer in late 2014. However, due to its early stage of development, we are not yet able to determine the possible marketing approval timeline or future development costs at this time. We intend to initiate a Phase 2b clinical study of RAD1901 for the potential treatment of vasomotor symptoms in the second half of 2015. We are currently designing the trial and have not finalized the full development plan. In addition, we are currently evaluating alternative development options for RAD140 and anticipate selecting a therapeutic area of focus during 2015. Therefore, it is currently not possible to project the future development costs or possible marketing approval timelines at this time.

The following table sets forth our research and development expenses related to abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140 for the three and nine months ended September 30, 2014 and 2013 (in thousands):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Abaloparatide-SC	\$ 10,132	11,815	\$ 26,779	35,753
Abaloparatide-TD	523	2,942	992	10,867
RAD1901	1,027		1,402	
RAD140				

*General and Administrative Expenses*

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

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

*Interest Income and Interest Expense*

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

Interest expense reflects interest due under our loan and security agreement, entered into on May 23, 2011 with General Electric Capital Corporation, or GECC, as agent and lender, and Oxford Finance, as a lender, or the Original Credit Facility, and our loan and security agreement entered into on May 30, 2014 with Solar Capital Ltd., or Solar, as agent and lender, and Oxford Finance as, as lender, or the New Credit Facility. Under the Original Credit Facility, we drew \$12.5 million under an initial and second term loan during the year ended December 31, 2011 and an additional \$12.5 million under a third term loan during the year ended December 31, 2012. Under the New 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 May 30, 2014, we used approximately \$9.3 million of the New Credit Facility to repay all the amounts owed under the Original Credit Facility.

*Other (Expense) Income*

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For the three and nine months ended September 30, 2014 and 2013, other (expense) income reflects changes in the fair value of our warrant liability and the series A-6 convertible preferred stock liability and stock asset from the date of the initial accrual to the reporting date as discussed in note 7 to our condensed financial statements for the three and nine months ended September 30, 2014.

### **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, or

GAAP. 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, 2013. 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, 2014. 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, 2013, as amended.

Table of Contents**Results of Operations***Three Months Ended September 30, 2014 and September 30, 2013 (in thousands, except percentages)*

	Three Months Ended September 30,		Change	
	2014	2013	\$	%
Operating expenses:				
Research and development	\$ 13,817	\$ 15,543	\$ (1,726)	-11%
General and administrative	2,836	1,621	1,215	75%
Loss from operations	(16,653)	(17,164)	(511)	-3%
Other (expense) income:				
Other income (expense), net		(2,607)	(2,607)	-100%
Interest (expense) income, net	(767)	(571)	196	34%
Net Loss	\$ (17,420)	\$ (20,342)	\$ (2,922)	-14%

*Research and development expenses* For the three months ended September 30, 2014, research and development expense was \$13.8 million compared to \$15.5 million for the three months ended September 30, 2013, a decrease of \$1.7 million, or 11%. This decrease is primarily a result of a decrease in the total professional contract service costs associated with the development of abaloparatide-SC and abaloparatide-TD, partially offset by an increase in professional contract service costs associated with the development of RAD1901. During the three months ended September 30, 2014, we incurred professional contract service costs associated with the development of abaloparatide-SC, abaloparatide-TD and RAD1901 of \$10.1 million, \$0.5 million and \$1.0 million, respectively, compared to \$11.8 million, \$2.9 million and zero, respectively, for the three months ended September 30, 2013. The decrease in contract service costs associated with the development of abaloparatide-SC is primarily a result of fewer patients enrolled in the Phase 3 clinical trial as of September 30, 2014, as compared to the three months ended September 30, 2013. We expect that costs associated with the development of abaloparatide-SC will continue to decrease over the course of the clinical trial as patients complete treatment under the 18-month fracture study and 6-month extension study. In addition, there will be variability from quarter to quarter in the costs for abaloparatide-SC, driven primarily by the euro/dollar exchange rate, which is more fully described below under Research and Development Agreements. The decrease in contract service costs associated with the development of abaloparatide-TD is a result of the completion of the Phase 2 clinical trial in September 2013. We expect that the costs associated with the development of abaloparatide-TD will increase as we begin to advance an optimized abaloparatide-TD product in additional clinical studies, followed by a Phase 3 bridging study. The increase in contract service costs associated with the development of RAD1901 is a result of the initiation of various preclinical and manufacturing activities in 2014. We expect that the costs associated with the development of RAD1901 will increase as we begin to advance RAD1901 through various preclinical and clinical studies, including a Phase 1b study in metastatic breast cancer, which is expected to commence in late 2014, and a Phase 2b study in vasomotor symptoms, which is expected to commence in the second half of 2015.

*General and administrative expenses* For the three months ended September 30, 2014, general and administrative expense was \$2.8 million compared to \$1.6 million for the three months ended September 30, 2013, an increase of \$1.2 million, or 75%. This increase was primarily the result of higher legal fees and consulting support costs of approximately \$0.6 million during the three months ended September 30, 2014. This increase can also be attributed to higher compensation costs, including non-cash stock-based compensation expense, due to an overall increase in employee headcount.

*Other income (expense), net* For the three months ended September 30, 2014, there was no other income, net of other expense, as compared to other expense, net of other income during the three months ended September 30, 2013 of \$2.6 million. Other income, net of other expense, primarily reflects changes in the fair value of the stock liability, other liability and warrant liability as discussed in notes 7 and 9 to the financial statements included in our condensed financial statements for the three and nine months ended September 30, 2014. There was no other income,

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net of expense, recorded for the three months ended September 30, 2014, as, following our initial public offering on June 6, 2014, the warrant liability was reclassified to equity. The \$2.6 million of other expense, net of income, as of September 30, 2013 was primarily due to an increase in the fair value of our stock liability and other liability as a result of an increase in the fair value of the underlying convertible preferred stock from June 30, 2013 to September 30, 2013.

*Interest (expense) income* For the three months ended September 30, 2014, interest expense, net of interest income, was \$0.8 million compared to \$0.6 million for the three months ended September 30, 2013, an increase of \$0.2 million, or 34%. This increase was primarily a result of higher average debt outstanding during the three months ended September 30, 2014 as compared to the three months ended September 30, 2013.

Table of Contents*Nine Months Ended September 30, 2014 and September 30, 2013 (in thousands, except percentages)*

	Nine Months Ended September 30,		Change	
	2014	2013	\$	%
<b>Operating expenses:</b>				
Research and development	\$ 34,152	\$ 49,070	\$ (14,918)	-30%
General and administrative	8,045	4,643	3,402	73%
Loss from operations	(42,197)	(53,713)	(11,516)	-21%
<b>Other (expense) income:</b>				
Other (expense) income, net	(506)	7,465	7,971	107%
Loss on retirement of note payable	(203)		203	100%
Interest (expense) income, net	(1,611)	(1,911)	(300)	-16%
Net Loss	\$ (44,517)	\$ (48,159)	\$ (3,642)	-8%

*Research and development expenses* For the nine months ended September 30, 2014, research and development expense was \$34.2 million compared to \$49.1 million for the nine months ended September 30, 2013, a decrease of \$14.9 million, or 30%. This decrease is primarily a result of a decrease in the total professional contract service costs associated with the development of abaloparatide-SC and abaloparatide-TD, partially offset by an increase in professional contract services costs associated with the development of RAD1901. During the nine months ended September 30, 2014, we incurred professional contract service costs associated with the development of abaloparatide-SC, abaloparatide-TD and RAD1901 of \$26.8 million, \$1.0 million and \$1.4 million, respectively, compared to \$35.8 million, \$10.9 million and zero, respectively, for the nine months ended September 30, 2013. The decrease in contract service costs associated with the development of abaloparatide-SC is primarily a result of fewer patients enrolled in the Phase 3 clinical trial as of September 30, 2014, as compared to the nine months ended September 30, 2013. We expect that costs associated with the development of abaloparatide-SC will continue to decrease over the course of the clinical trial as patients complete treatment under the 18-month fracture study and 6-month extension study. In addition, there will be variability from quarter to quarter in the costs for abaloparatide-SC, driven primarily by the euro/dollar exchange rate, which is more fully described below under Research and Development Agreements. The decrease in contract service costs associated with the development of abaloparatide-TD is a result of the completion of the Phase 2 clinical trial (which began dosing patients in September 2012) in September 2013. The increase in contract service costs associated with the development of RAD1901 is a result of the initiation of various preclinical and manufacturing activities in 2014.

*General and administrative expenses* For the nine months ended September 30, 2014, general and administrative expense was \$8.0 million compared to \$4.6 million for the nine months ended September 30, 2013, an increase of \$3.4 million, or 73%. This increase was primarily due to an increase in compensation costs, including an increase of \$1.1 million in non-cash stock-based compensation expense as a result of the issuance of new option awards during the period, as well as the acceleration of vesting for a portion of our Chief Executive Officer's outstanding option awards, in accordance with his employment agreement, upon completion of our initial public offering. This increase can also be attributed to higher legal fees and consulting support costs of approximately \$1.3 million during the nine months ended September 30, 2014.

*Other (expense) income, net* For the nine months ended September 30, 2014, other expense, net of other income, was \$0.5 million, as compared to other income, net of expense during the nine months ended September 30, 2013 of \$7.5 million. Other expense, net of other income, primarily reflects changes in the fair value of the stock asset, stock liability, other liability and warrant liability as discussed in notes 7 and 9 to our financial statements included in our condensed quarterly financial statements for the three and nine months ended September 30, 2014. The \$0.5 million of other expense, net of income, for the nine months ended September 30, 2014 was primarily due to an increase in the fair value of our warrant liability as a result of an overall increase in the fair value of the underlying common stock from December 31, 2013 to June 6, 2014. Following our initial public offering on June 6, 2014, our warrant liability was reclassified to equity. The \$7.5 million of other income, net of other expense, as of September 30, 2013 was primarily due to a decrease in the fair value of our stock liability and other liability as a result of a decrease in the fair value of the underlying convertible preferred stock from December 31, 2012 to September 30, 2013.

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*Loss on retirement of note payable* For the nine months ended September 30, 2014, loss on retirement of note payable was \$0.2 million. This loss was a result of the prepayment of our Original Credit Facility on May 30, 2014.

*Interest (expense) income* For the nine months ended September 30, 2014, interest expense, net of interest income, was \$1.6 million compared to \$1.9 million for the nine months ended September 30, 2013, a decrease of \$0.3 million, or 16%. This decrease was



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primarily a result of lower average debt outstanding during the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013.

***Liquidity and Capital Resources***

From inception to September 30, 2014, we have incurred an accumulated deficit of \$326.3 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 marketable securities balance as of September 30, 2014 was \$68.5 million. We have financed our operations since inception primarily through the private sale of preferred stock as well as the receipt of \$5.0 million in fees associated with an option agreement. In addition, on June 11, 2014, we completed our initial public offering. As a result of the closing of the initial public offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$50.4 million. On October 7, 2014, we completed an additional public offering whereby we sold 2,750,000 shares of common stock at a price of \$18.25 per share. As a result of the closing of the additional offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$53.3 million. We have also borrowed \$25.0 million under our Original Credit Facility in three term loans and \$25.0 million under our New Credit Facility.

We believe that the aggregate proceeds from the offering on October 7, 2014, together with our cash, cash equivalents and marketable securities as of September 30, 2014, will be sufficient to fund our operations into the fourth quarter of 2015. Accordingly, we plan to pursue strategic financing alternatives that could include, but are not limited to, partnering or other collaboration agreements, or the completion of an additional public offering. 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 activities and our clinical trials. 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 product candidates from the FDA and other foreign regulatory authorities.

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 September 30,		Change	
	2014	2013	\$	%
Net cash (used in) provided by:				
Operating activities	\$ (31,971)	\$ (29,859)	\$ 2,112	7%
Investing activities	(52,954)	(6,277)	46,677	744%
Financing activities	89,088	36,976	52,112	141%
Net increase (decrease) in cash and cash equivalents	\$ 4,163	\$ 840		

***Cash Flows from Operating Activities***

Net cash used in operating activities during the nine months ended September 30, 2014 was \$32.0 million, which was primarily the result of a net loss of \$44.5 million, partially offset by \$6.3 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net

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changes in working capital of \$6.2 million. The \$44.5 million net loss was primarily due to expenses incurred in connection with our ongoing Phase 3 clinical trial of abaloparatide-SC. The \$6.3 million net non-cash adjustments to reconcile net loss to net cash used in operations included \$2.7 million of research and development expenses settled in stock, stock-based compensation expense of \$2.6 million and a \$0.5 million increase in the fair value of our warrant liability and stock liability as a result of an increase in the fair value of the underlying convertible preferred stock and common stock from December 31, 2013 to September 30, 2014.

Net cash used in operating activities for the nine months ended September 30, 2013 was \$29.9 million, which was primarily the result of a net loss of \$48.2 million, partially offset by net changes in working capital of \$13.6 million and \$4.7 million net non-cash adjustments to reconcile net loss to net cash used in operations. The \$48.2 million net loss was primarily due to expenses incurred in connection with our ongoing Phase 3 clinical study of abaloparatide-SC and our Phase 2 clinical study of abaloparatide-TD, which finished dosing patients during the three months ended September 30, 2013. The \$4.7 million net non-cash adjustments to reconcile net loss to net cash used in operations included \$10.6 million of research and development expenses settled in stock and stock-based compensation expense of \$1.2 million, partially offset by a \$7.5 million reduction in the fair value of our warrant liability, stock liability and other liability as a result of a decline in the fair value of the underlying convertible preferred stock from December 31, 2012 to September 30, 2013.

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*Cash Flows from Investing Activities*

Net cash used in investing activities during the nine months ended September 30, 2014 was \$53.0 million, which was primarily the result of \$53.3 million of purchases of marketable securities. Net cash used during the nine months ended September 30, 2013 was \$6.3 million, which was primarily the result of \$17.1 million of purchases of marketable securities, partially offset by \$10.8 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. All of our marketable securities have contractual maturities of less than one year. Due to the short-term nature of our marketable securities, we would not expect our operational results or cash flows to be significantly affected by a change in market interest rates.

On January 7, 2014, we entered into a letter agreement with Vetter Pharma International GMBH, or Vetter that authorized Vetter to begin purchasing and installing dedicated equipment that will be utilized in the formulation and filling of abaloparatide-SC. In accordance with the letter agreement, the total capital expenditures are not to exceed 0.6 (\$0.8 million) without our prior written consent. We expect that all equipment will be purchased and installed in 2014 and funded by our existing cash and cash equivalents.

*Cash Flows from Financing Activities*

Net cash provided by financing activities during the nine months ended September 30, 2014 was \$89.1 million, as compared to \$37.0 million net cash provided by financing activities during the nine months ended September 30, 2013.

Net cash provided by financing activities during the nine months ended September 30, 2014 consisted of \$50.4 million of net proceeds from our initial public offering, \$27.4 million of net proceeds from the issuance of our series B-2 convertible preferred stock in February and March of 2014, and \$24.6 million of net proceeds from our New Credit Facility, partially offset by payments under our Original Credit Facility of \$13.2 million.

Net cash provided by financing activities for the nine months ended September 30, 2013 consisted of \$42.9 million of net proceeds from the issuance of our series B convertible preferred stock in April and May of 2013, partially offset by payments under our Original Credit Facility of \$5.9 million.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as potential collaboration agreements and equity and debt financing. Through September 30, 2014, almost all of our financing has been through our initial public offering, private placements of preferred stock and borrowings under our Original Credit Facility and New Credit Facility. In addition, on October 7, 2014, we completed an additional public offering. As a result of the additional public offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately \$53.3 million. In subsequent periods, we plan to seek to raise additional capital in order to continue operating our business. We can give no assurances that any additional capital that we are able to obtain, if any, will be sufficient to meet our needs. Our future capital requirements will depend on

many factors, including the scope and progress made in our research and development activities and our clinical studies. We may also need additional funds for possible future strategic acquisitions of businesses, products or technologies complementary to our business. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition and results of operations. Additional equity financing may be dilutive to the holders of our common stock and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

***Preferred Stock Financings***

*Series B-2 Financing*-On February 14, 2014, we entered into a Series B-2 Convertible Preferred Stock and Warrant Purchase Agreement, or Purchase Agreement, pursuant to which we were able to raise up to approximately \$40.2 million through the issuance of (1) up to 655,000 series B-2 Shares convertible preferred stock, or Series B-2, par value \$.0001 per share, and (2) warrants to acquire up to 718,201 shares of our common stock, at an exercise price of \$14.004 per share.

Shares of our Series B-2 were convertible, in whole or in part, at the option of the holder at any time into shares of common stock, on an approximately 4.386-for-one basis at an initial effective conversion price of \$14.004 per share. Shares of our Series B-2 were automatically convertible into shares of our common stock upon the closing of an initial public offering on or prior to June 30, 2014 at a conversion rate determined by dividing the initial purchase price of \$61.42 per share by the lower of (1) \$14.004 per share and (2) the initial public offering price, or upon listing of the common stock on a national securities exchange after June 30, 2014 at the then applicable conversion rate. Holders of shares of Series B-2 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrue on a daily basis commencing on the date of issuance of the shares of Series B-2. Dividends were

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payable, as accrued, upon liquidation, event of sale, and conversion to common stock, including upon mandatory conversion of the Series B-2 upon the closing of our initial public offering on or prior to June 30, 2014 or upon listing of the common stock on a national securities exchange after June 30, 2014. The holders of shares of Series B-2 were also entitled to dividends declared or paid on any shares of common stock.

Shares of Series B-2 ranked senior in payment to any other dividends payable on any and all series of preferred stock and upon liquidation, or an event of sale, each share of Series B-2 ranked equally with each other share of Series B-2 and Series B, senior to all shares of Series A-1, Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6 and senior to all shares of common stock. In the event of a liquidation, dissolution, or winding-up of the Company, the holders of the Series B-2 were entitled to be paid first out of the assets available for distribution, before any payment was made to the Series A-1, Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6. Payment to the holders of Series B-2 was to consist of one and a half (1.5) times the original issuance price of \$61.42, plus all accrued but unpaid dividends.

On February 14, 2014, February 19, 2014, February 24, 2014, March 14, 2014 and March 28, 2014, we consummated closings under the Series B-2 Purchase Agreement, whereby, in exchange for aggregate proceeds to us of approximately \$27.5 million, we issued an aggregate of 448,060 Series B-2 Shares and warrants to purchase up to a total of 491,293 shares of our common stock.

Each share of Series B-2 had the right to that number of votes per share as is equal to the number shares of common stock into which such share of Series B-2 was then convertible.

The warrants issuable pursuant to the Purchase Agreement are exercisable for a period of five years from issuance.

The issuances in February and March 2014 of the Series B-2 and accompanying warrants under the Purchase Agreement resulted in an additional adjustment to the Conversion Price of the Series A-1, Series A-2 and Series A-3. As a result of the Anti-Dilution Adjustment, the effective conversion price of each share of Series A-1, Series A-2 and Series A-3 was reduced to \$16.970. Accordingly, each share of Series A-1, Series A-2 and Series A-3 was convertible into approximately 4.798 shares of common stock.

Upon completion of our initial public offering, all shares of Series B-2 were converted into shares of our common stock at a conversion rate of 7.678, which is equal to the initial purchase price, divided by the initial public offering price of \$8.00 per share.

***Research and Development Agreements***

***Abaloparotide-SC Phase 3 Clinical Trial*** On March 29, 2011, we and Nordic entered into a Clinical Trial Services Agreement, a Work Statement NB-1 under the Clinical Trial Services Agreement and a related Stock Issuance Agreement, as amended to date, or the Stock Issuance Agreement. Pursuant to the Work Statement NB-1, Nordic is managing the Phase 3 clinical trial, or the Phase 3 Clinical Trial, of abaloparotide-SC and is being compensated for such services in a combination of cash and shares of stock.

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In December 2011, we entered into an amendment to the Work Statement NB-1 or the First Amendment. Pursuant to the original terms of the Work Statement NB-1, the study was to be conducted in 10 countries at a specified number of sites within each country. The terms of the First Amendment (1) provided for two additional countries (the United States and India) in which the trial would be conducted, (2) specified a certain number of sites within each such additional country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect the addition of such countries and sites within the study's parameters. Payments to be made by us to Nordic under the First Amendment are denominated in both euros and U.S. dollars and total up to 717,700 (\$906,312) and \$289,663, respectively, for the 15 additional study sites in India contemplated by the First Amendment and up to 1.2 million (\$1.6 million) and \$143,369, respectively, for the five additional study sites in the United States contemplated by the First Amendment.

In June 2012, we entered into a second amendment to the Work Statement NB-1, or the Second Amendment. Pursuant to the original terms of the Work Statement NB-1, as amended by the First Amendment, the study was to be conducted in 12 countries at a specified number of sites within each country. The terms of the Second Amendment (1) increased the overall number of sites by adding sites in Europe, Brazil and Argentina and removing other sites, (2) specified a certain number of sites within each country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect additional services to be provided at existing sites and the addition of the new study sites within the study's parameters. The Second Amendment also provided that cash payments to Nordic under the Clinical Trial Services Agreement as well as the payment of shares of stock under the related Stock Issuance Agreement will each be reduced by an amount of 11,941 (\$15,079) per subject for any subjects enrolled in India or the United States. Such reductions are applied in pro rata monthly installments. Payments to be made by us to Nordic under the Second Amendment in connection with the additional services provided at existing sites and the conduct of the study at the new study sites are denominated in both euros and U.S. dollars and total of up to 3.7 million (\$4.7 million) and \$205,540, respectively.

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In March 2014, we entered into a fourth amendment to the Work Statement NB-1, or the Fourth Amendment. Pursuant to the terms of the Fourth Amendment, we agreed to pay to Nordic an additional performance incentive payment, or a Performance Incentive Payment, of \$500,000 for every 50 patients that, subsequent to March 28, 2014, complete all end-of-study procedures, up to a maximum aggregate amount of additional payments equal to \$5.0 million. Any Performance Incentive Payment would have been paid in cash in the event that the initial public offering of our common stock was completed prior to May 31, 2014. If an initial public offering was not completed prior to May 31, 2014, any Performance Incentive Payments would have been paid through the issuance to Nordic of shares of our capital stock under the same model for equity-based compensation contemplated by our existing outstanding work statements under the Clinical Trial Services Agreement. On May 19, 2014, we entered into a fifth amendment to Work Statement NB-1, which amended the date prior to which an initial public offering must be completed to June 30, 2014. As we completed an initial public offering of our common stock on June 11, 2014, all Performance Incentive Payments will be paid in cash.

Pursuant to the Work Statement NB-1, we are required to make certain per patient payments denominated in both euros and U.S. dollars for each patient enrolled in the Phase 3 Clinical Trial followed by monthly payments for the duration of the study and final payments in two equal euro-denominated installments and two equal U.S. dollar-denominated installments. Changes to the Clinical Trial schedule may alter the timing, but not the aggregate amounts of the payments.

The Work Statement NB-1, as amended on December 9, 2011, June 18, 2012, March 28, 2014 and May 19, 2014, provides for a total of up to approximately 41.2 million (\$52.0 million) of euro-denominated payments and a total of up to approximately \$3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus Performance Incentive Payments of up to \$5.0 million. These payments may be adjusted based upon actual sites opened, work performed or number of patients enrolled.

Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase the equivalent of 371,864 of series A-5 convertible preferred stock at \$8.142 per share, and 64,430 shares of series A-5 convertible preferred stock were sold to Nordic on May 17, 2011 for proceeds of \$525,154. These shares were exchanged in a merger of the former operating company with a subsidiary of ours in May 2011 (see note 9 to our condensed quarterly financial statements for the nine months ended September 30, 2014) for an aggregate of 6,443 shares of our series A-5 convertible preferred stock.

The Stock Issuance Agreement provided that Nordic was entitled to receive quarterly stock dividends, payable in shares of series A-6 convertible preferred stock or shares of common stock if our preferred stock had been converted in accordance with our amended certificate of incorporation, having an aggregate value, under the Work Statement NB-1, of up to 36.8 million (\$46.5 million), or the Nordic Accruing Dividend. In the event Nordic sold the shares of series A-5 convertible preferred stock or in the event the shares of series A-5 convertible preferred stock were converted into common stock in accordance with our amended certificate of incorporation, this right to receive the Nordic Accruing Dividend will terminate, but a right to receive an equivalent number of shares of series A-6 convertible preferred stock or common stock, as applicable, would remain with Nordic as a contractual right under the Stock Issuance Agreement.

On March 28, 2014, we entered into Amendment No. 2 to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011, or the Second Stock Issuance Agreement Amendment, with Nordic. The Second Stock Issuance Agreement Amendment required that our Board of Directors declare, as soon as reasonably practical, a stock dividend of twenty nine (29) shares of our Series A-6 for each share of our then outstanding Series A-5, all of which were held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in relation to Work Statement NB-1 and Work Statement NB-3. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, our Board of Directors declared and issued a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment further provided that in the event an initial public offering of our common stock occurred prior to May 31, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, excluding Performance Incentive Payments, for all periods of time after 2014 would change

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from the right to receive stock to the right to receive a total cash payment from us of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, we entered into Amendment No. 3 to the Stock Issuance Agreement, which amended the date prior to which an initial public offering must occur to June 30, 2014. The Second Stock Issuance Agreement Amendment also stipulated that all consideration to be paid to Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an initial public offering shall be payable in cash. As the Company completed an initial public offering on June 11, 2014, Nordic no longer has the right to receive stock from the Company and agreed to be paid in cash for all periods after the consummation of the initial public offering.

Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock was being accounted for as a liability on our balance sheet, based upon the fair value of the Series A-6 as determined using PWERM. Changes in the fair value from the date of accrual to the date of issuance of the Series A-6 shares were recorded as a gain or loss in other (expense) income in the statement of operations.



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We recognize research and development expense for the amounts due to Nordic under the Work Statement NB-1, First Amendment and Second Amendment ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 3 Clinical Trial, or a twenty-month period. We recognize research and development expense for the amounts due to Nordic under the Fourth Amendment on a per patient basis when the End-of-Study visit and all other required procedures are completed. We recorded \$1.2 million and \$7.6 million of research and development expense during the three months ended September 30, 2014 and 2013, respectively, and \$8.1 million and \$25.5 million for the nine months ended September 30, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Trial.

As of September 30, 2014, we had a liability of \$9.5 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

*Abaloparatide-SC Phase 3 Clinical Extension Study* In February 2013, we entered into the Work Statement NB-3, or the Work Statement NB-3, under the Clinical Trial Services Agreement and the related Stock Issuance Agreement. Pursuant to the Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the 18-month abaloparatide-SC Phase 3 Clinical Trial, or the Extension Study, and will be compensated for such services in a combination of cash and shares of stock. Under the terms of a Letter of Intent that we entered into with Nordic on October 22, 2012 setting forth the parties' obligations to negotiate in good faith to enter into Work Statement NB-3, we were required to make an initial payment of \$806,468 (\$1.0 million).

In March 2014, we entered into an amendment to the Work Statement NB-3, or the NB-3 Amendment. The NB-3 Amendment was effective as of February 28, 2014 and provides that Nordic will perform a Period 2 extension study, or the Second Extension, to evaluate an additional eighteen months of standard-of-care osteoporosis management following the Period 1 extension of six months upon completion of the Phase 3 clinical study of our abaloparatide-SC product. Payments in cash to be made by us to Nordic under the NB-3 Amendment are denominated in both euros and U.S. dollars and total up to approximately \$3.0 million (\$3.7 million) and \$527,740, respectively. In addition, we agreed to issue to Nordic shares of our Series A-6 having a value of up to the sum of approximately \$3.0 million (\$3.7 million) and \$527,740 as additional payment for the services to be provided under the NB-3 Amendment, with the issuance of such shares to be made pursuant to the terms of an Amendment No. 2, entered into by us with Nordic on March 28, 2014, to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011.

Payments in cash to be made to Nordic under the Work Statement NB-3, as amended by the NB-3 Amendment, are denominated in both euros and U.S. dollars and total up to \$7.5 million (\$9.5 million) and \$1.1 million, respectively. In addition, we will issue to Nordic shares of our series A-6 convertible preferred stock having a value of up to \$7.5 million (\$9.5 million) and \$0.8 million, as additional payment for services to be provided under the Work Statement NB-3 and the Services Agreement.

The Stock Issuance Agreement provided that, beginning with the quarter ended March 31, 2013, Nordic is entitled to receive quarterly stock dividends in connection with services performed under the Work Statement NB-3, payable in shares of series A-6 convertible preferred stock, or shares of common stock if our preferred stock automatically converted into common stock in accordance with our amended certificate of incorporation, having an aggregate value of up to \$7.5 million (\$9.5 million) and \$0.8 million. In the event Nordic sold the shares of series A-5 convertible preferred stock or in the event the shares of series A-5 convertible preferred stock were converted into common stock in accordance with our amended certificate of incorporation, this right to receive the Nordic Accruing Dividend would terminate, but a right to receive an equivalent number of shares of series A-6 convertible preferred stock or common stock, as applicable, would remain with Nordic as a contractual right under the Stock Issuance Agreement.

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On March 28, 2014, we entered into Amendment No. 2 to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011, or the Second Stock Issuance Agreement Amendment, with Nordic. The Second Stock Issuance Agreement Amendment required that our Board of Directors declare, as soon as reasonably practical, a stock dividend of twenty nine (29) shares of our Series A-6 for each share of our then outstanding Series A-5, all of which were held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in relation to Work Statement NB-1 and Work Statement NB-3. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, our Board of Directors declared and issued a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment further provided that in the event an initial public offering of our common stock occurred prior to May 31, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, excluding Performance Incentive Payments, for all periods of time after 2014 would change from the right to receive stock to the right to receive a total cash payment from us of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, we entered into Amendment No. 3 to the Stock Issuance Agreement, which amended the date prior to which an initial public offering must occur to June 30, 2014. The Second Stock Issuance Agreement Amendment also stipulated that all consideration to be paid to Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an initial public offering shall be payable in cash. As the Company completed an initial public offering on June 11, 2014, Nordic no longer has the right to receive stock from the Company and agreed to be paid in cash for all periods after the consummation of the initial public offering.

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Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock was being accounted for as a liability on our balance sheet, based upon the fair value of the Series A-6 as determined using PWERM. Changes in the fair value from the date of accrual to the date of issuance of the Series A-6 shares are recorded as a gain or loss in other (expense) income in the statement of operations.

On December 6, 2013, we entered into a Letter of Intent, or the Letter of Intent, with Nordic, which provided that we and Nordic would continue to negotiate the definitive terms of the NB-3 Amendment. Pursuant to the Letter of Intent, we were required to make an initial payment of 222,573 (\$0.3 million) and agreed to commence payment of the cash compensation due in consideration of the services being provided by Nordic under the NB-3 Amendment. The Letter of Intent terminated in accordance with its terms on February 28, 2014 (pursuant to an extension mutually agreed to by the Company and Nordic).

We recognize research and development expense for the amounts due to Nordic under the Work Statement NB-3 and Amendment ratably over the estimated per patient treatment periods beginning upon enrollment or over a nine-month and nineteen-month period, respectively. We recorded \$2.3 million and \$1.3 million of research and development expense during the three months ended September 30, 2014 and 2013, respectively, and \$7.7 million and \$2.6 million during the nine months ended September 30, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Extension Study and Second Extension.

As of September 30, 2014, we had a liability of \$4.5 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

*Abaloparotide-TD Phase 2 Clinical Trial* On July 26, 2012, we entered into a Letter of Intent, or the Phase 2 Letter of Intent, with Nordic, which provides that we and Nordic will, subject to compliance by us with certain requirements of our Certificate of Incorporation and applicable securities laws, negotiate in good faith to enter into (1) a Work Statement NB-2, or the Work Statement NB-2, a draft of which is attached to the Phase 2 Letter of Intent, and (2) an amendment to the Amended and Restated Stock Issuance Agreement.

In February 2013, we executed the final Work Statement NB-2 under the Clinical Trial Services Agreement and the related Stock Issuance Agreement. Pursuant to the Work Statement NB-2, Nordic agreed to provide clinical trial services relating to the Phase 2 Clinical Trial and to be compensated for such services in a combination of cash and shares of stock. Payments in cash to be made by us to Nordic under Work Statement NB-2 were denominated in both euros and U.S. dollars and totaled up to 3.6 million (\$4.5 million) and \$0.3 million, respectively. In addition, we agreed to issue to Nordic shares of our series A-6 preferred stock having a value of up to \$2.9 million, as additional payment for services to be provided under the Work Statement NB-2 and the Clinical Trial Services Agreement.

As of December 31, 2013, 32,215 shares of Series A-6 were due to Nordic under Work Statement NB-2, or, after the automatic conversion into common stock of the Company's preferred stock, 141,294 shares the Company's common stock. In December 2013, Nordic requested that all 32,215 shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-2 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 32,215 shares of Series A-6 accrued under Work Statement NB-2 on December 31, 2013, which constituted all shares of Series A-6 due under Work Statement NB-2.

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We recognized research and development expense for the amounts due to Nordic under the Work Statement NB-2 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 2 Clinical Trial, or a nine-month period. We recorded no expense and \$0.6 million of research and development expense during the three months ended September 30, 2014 and 2013, respectively, and nil and \$4.1 million during the nine months ended September 30, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Phase 2 Clinical Trial. As of September 30, 2014, all obligations due to Nordic under Work Statement NB-2 had been paid.

We are also responsible for certain pass-through costs in connection with the Phase 3 Clinical Trial, Extension Study and Phase 2 Clinical Trial. Pass-through costs are expensed as incurred or upon delivery. We recognized research and development expense of \$0.3 million and \$1.3 million for pass through costs during three months ended September 30, 2014 and 2013, respectively, and \$0.8 million and \$3.3 million during the nine months ended September 30, 2014 and 2013 respectively.

### *License Agreement Obligations*

#### *Abaloparatide*

In September 2005, we exclusively licensed the worldwide rights (except Japan) to abaloparatide and analogs from an affiliate of Ipsen Pharma SAS, or Ipsen, including US Patent No. 5,969,095, (effective filing date March 29, 1996, statutory term expires March 29, 2016) entitled *Analogs of Parathyroid Hormone* that claims abaloparatide and US Patent No. 6,544,949, (effective filing date March 29, 1996, statutory term expires March 29, 2016) entitled *Analogs of Parathyroid Hormone* that claims methods of

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treating osteoporosis using abaloparatide and pharmaceutical compositions comprising abaloparatide, and the corresponding foreign patents and continuing patent applications. We believe that European Patent No. 0847278, which was included in the license from Ipsen and claimed the composition of matter of abaloparatide, has lapsed due to Ipsen's failure to pay annuities. While we are seeking to address the lapse of right, we believe that the data and market exclusivity provided in Europe for a new chemical entity, coupled with the need for a potential competitor to conduct clinical trials will likely provide a longer barrier to entry than the patent protection provided by the original European patent term, which would have expired in 2016, plus a five year maximum Supplemental Protection Certificate.

We also have rights to joint intellectual property related to abaloparatide, including rights to the jointly derived intellectual property contained in US Patent No. 7,803,770, (effective filing date October 3, 2007, statutory term extended to March 26, 2028 with 175 days of patent term adjustment due to delays in patent prosecution by the United States Patent and Trademark Office, or USPTO), US Patent No. 8,148,333 (effective filing date October 3, 2007, statutory term extended to November 8, 2027 with 36 days of patent term adjustment due to delays in patent prosecution by the USPTO) and related patents and patent applications both in the United States and worldwide that cover the method of treating osteoporosis using the Phase 3 Clinical Trial dosage strength and form. A corresponding European application is pending with claims to the intended therapeutic formulation for abaloparatide-SC. Examination has been requested, but substantive examination has not yet commenced. Upon grant, this patent could be validated in any designated contracting or extension states and potentially could be considered for a Supplemental Protection Certificate depending upon the timing of its grant. Related cases granted in the United States, Australia, China, Japan, Mexico, New Zealand, Russia, Singapore, and Ukraine, and currently pending in Brazil, Canada, China, Europe, Hong Kong, India, Israel, Norway, Singapore, and South Korea will have a normal un-extended patent expiration date of 2027. Patent applications which cover various aspects of abaloparatide for microneedle application are pending in the United States, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Russia, Singapore, South Korea, and Ukraine. Any claims that might issue from these applications will have a normal expiration date no earlier than 2032.

In consideration for the rights to abaloparatide and in recognition of certain milestones having been met to date, we have paid to Ipsen an aggregate amount of \$1.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. The range of milestone payments that could be paid under the agreement is 10.0 million to 36.0 million (\$12.6 million to \$45.5 million). Should abaloparatide be approved and subsequently become commercialized, we or our sublicensees will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product 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 our 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 contains other customary clauses and terms as are common in similar agreements in the industry.

Prior to executing the license agreement for abaloparatide with Radius, Ipsen licensed the Japanese rights for abaloparatide to Teijin Limited, or Teijin, a Japanese pharmaceutical company. It is our understanding that Teijin has fully enrolled a Phase 2 study of abaloparatide which is expected to report results in mid-2015.

*RAD1901*

In June 2006, we exclusively licensed the worldwide rights (except Japan) to RAD1901 from Eisai Co. Ltd., or Eisai. In particular, we have licensed US Patent No. 7,612,114 (effective filing date December 25, 2003, statutory term extended to August 18, 2026 with 967 days of patent

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term adjustment due to delays by the USPTO) and US Patent No. 8,399,520 (effective filing date December 25, 2003, statutory term expires December 25, 2023). 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 \$1.5 million. The range of milestone payments that could be paid under the agreement is \$1.0 million to \$20.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. Should RAD1901 be approved and subsequently become commercialized, we will be obligated to pay to Eisai a royalty in a variable mid-single digit range based on net sales of the product on a country by country basis for a period that expires on the later of (1) 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, unless it is sooner terminated. The latest valid claim is expected to expire, barring any extension thereof, on August 18, 2026. The

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royalty rate shall then be subject to reduction and the royalty obligation will expire at such time as sales of lawful generic version of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. We were also granted the right to sublicense with prior written approval from Eisai, but subject to a right of first negotiation held by Eisai if we seek to grant sublicenses limited to particular Asian countries. 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 contains other customary clauses and terms as are common in similar agreements in the industry.

***Net Operating Loss Carryforwards***

As of December 31, 2013, we had federal and state net operating loss carryforwards of approximately \$263.6 million and \$229.4 million, respectively. If not utilized, the net operating loss carryforwards will expire at various dates through 2033.

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

**Off-Balance Sheet Arrangements**

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

**New Accounting Standards**

Refer to note 2, *Basis of Presentation and Significant Accounting Policies - Accounting Standards Updates and Basis of Presentation and Significant Accounting Policies - Recently Adopted Accounting Standards*, in Notes to Condensed Financial Statements, for a discussion of new accounting standards.





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

Our primary exposure to market risk is foreign currency exposure. A substantial portion of our abaloparatide development costs are denominated in euro and an immediate 10 percent adverse change in the dollar/euro exchange rate will result in increased costs and would have a material adverse effect on our financial statements and require us to raise additional capital to complete the development of our products. We do not hedge our foreign currency exchange rate risk.

We are also exposed to market risk related to changes in interest rates. As of September 30, 2014 and December 31, 2013, we had cash, cash equivalents, and marketable securities of \$68.5 million and \$12.3 million, respectively, consisting of money market funds, domestic corporate debt securities, domestic corporate commercial paper, and cash equivalents. 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 short-term marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10 percent 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 short-investments until maturity, and therefore we would not expect our operating results or cash flows to be affected by any significant degree by the effect of a change in market interest rates on our investments. We carry our investments based on publicly available information. As of September 30, 2014 and December 31, 2013, we do not have any hard to value investment securities or securities for which a market is not readily available or active.

On May 30, 2014, we entered into a Loan and Security Agreement with Solar Capital Ltd., as collateral agent and a lender, and Oxford Finance LLC, as a lender, pursuant to which Solar and Oxford agreed to make available to us \$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, or the Initial Term Loan. A second term loan was made on July 10, 2014 in an aggregate principal amount equal to \$4.0 million, or the Second Term Loan. The Initial Term Loan and Second Term Loan bear interest per annum at 9.85% plus one-month LIBOR (customarily defined) and mature on June 1, 2018. Changes in interest rates can cause interest charges to fluctuate under our Loan and Security Agreement, as amended. As of September 30, 2014, principal payable under the Initial Term Loan was \$25.0 million. A 10% increase in current interest rates would have resulted in less than \$0.1 million in additional cash interest expense for the three months ended September 30, 2014.

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 Exchange Act 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, 2014.

**Changes in Internal Control over Financial Reporting**

There have not been any changes in our internal control over financial reporting during the three months ended September 30, 2014 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**

*Set forth below and elsewhere in this Quarterly Report on Form 10-Q and in other documents we file with the SEC are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Quarterly Report on Form 10-Q. Because of the following important factors, as well as other variables affecting our operating results, past financial performance should not be considered as a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods.*

**Risks Related to Our Business**

**Risks Related to Our Financial Position and Need for Capital**

*We currently have no product revenues and we will need to raise additional capital, which may not be available on favorable terms, if at all, in order to continue operating our business.*

To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or FDA, and other foreign regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Currently, our only product candidates are abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140, and none of these product candidates is approved by the FDA or other foreign regulatory authorities for sale. Therefore, for the foreseeable future, we will have to fund our operations and capital expenditures with our existing cash and cash equivalents and marketable securities, or through strategic financing opportunities, future offerings of our equity, or the incurrence of debt. We believe that our existing resources will be sufficient to fund our planned operations into the fourth quarter of 2015. We have based this estimate on assumptions that may prove to be wrong, and we could use up our available capital resources sooner than we currently expect. If we fail to obtain additional capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any product candidates from the FDA and other foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts for any product candidate that is approved, forego attractive business opportunities or discontinue our operations entirely. Any additional sources of financing may not be available or may not be available on favorable terms and will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies.

*We are not currently profitable and may never become profitable.*

We have a history of net losses and expect to incur substantial losses and have negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability. We had net losses of \$44.5 million for the nine months ended September 30, 2014 and \$60.7 million and \$69.1 million for the years ended December 31, 2013 and 2012, respectively. As of September 30, 2014, we had an accumulated deficit of \$326.3 million. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical development and clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. Accordingly, unless and until we generate revenues and become profitable, we will need to raise additional capital to continue to operate our business. Our failure to achieve or maintain profitability or to raise additional capital could negatively impact the value of our securities.

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***Our credit facility imposes significant restrictions on our business, and if we default on our obligations, the lenders would have a right to foreclose on substantially all our assets.***

In May 2014, we entered into our new \$30.0 million credit facility with Solar Capital Ltd., as collateral agent and lender, and Oxford Finance LLC, as lender. We drew \$21.0 million under our new credit facility on May 30, 2014, and used approximately \$9.3 million to repay our existing credit facility. Pursuant to an amendment to the credit facility, we drew an additional \$4.0 million on July 10, 2014. Our new credit facility contains a number of covenants that impose significant operating and financial restrictions on us, including covenants that limit our ability to:

- dispose of our business or certain assets;
- change our business, management, ownership or business locations;
- incur additional debt or liens;
- make certain investments or declare dividends;
- acquire or merge with another entity;
- enter into licensing agreements;
- engage in transactions with affiliates; or
- encumber our intellectual property.

Our credit facility may limit our ability to finance future operations or capital needs or to engage in, expand or pursue our business activities. It may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

We have pledged substantially all of our assets other than our intellectual property to secure our obligations under our credit facility. If we default on our obligations and are unable to obtain a waiver for such a default, the lenders would have a right to accelerate the debt and terminate all commitments under our credit facility. They would also have the right to foreclose on the pledged assets, including our cash and cash equivalents. Any such action on the part of lenders against us would significantly harm our business and our ability to operate.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

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

*We are a company with a limited operating history upon which to base an investment decision.*

We are a company with a limited operating history and have not demonstrated an ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- continuing to undertake preclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing further in our securities.

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*Our financial results may fluctuate from quarter to quarter, which makes our results difficult to predict and could cause our results to fall short of expectations.*

Our financial results may fluctuate as a result of a number of factors, many of which are outside of our control. For these reasons, comparing our financial results on a period-to-period basis may not be meaningful, and you should not rely on our past results as an indication of our future performance. Our revenues, if any, may fluctuate from quarter to quarter and our future quarterly and annual expenses as a percentage of our revenues may be significantly different from those we have recorded in the past or which we expect for the future. Our financial results in some quarters may fall below expectations. Any of these events as well as the various risk factors listed in this Risk Factors section could adversely affect our financial results and cause our stock price to fall.

**Risks Related to the Discovery, Development and Commercialization of Our Product Candidates**

*We are heavily dependent on the success of abaloparatide-SC which is under clinical development. We cannot be certain that abaloparatide-SC will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.*

Abaloparatide-SC is our only product candidate in late-stage clinical development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop marketable drug products. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other foreign regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market abaloparatide-SC in the United States unless and until we receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in foreign countries. In addition, the approval of abaloparatide-TD as a line extension to abaloparatide-SC is dependent on the earlier approval of abaloparatide-SC. We have not submitted an NDA to the FDA or comparable applications to regulatory authorities in other countries. 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, including:

- we may not be able to demonstrate that abaloparatide is safe and effective as a treatment for osteoporosis to the satisfaction of the FDA or other foreign regulatory authorities;
- the results of our clinical studies may not meet the level of statistical or clinical significance required for marketing approval;
- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- any clinical research organizations, or CROs, that we have retained or may in the future retain, to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA or other foreign regulatory authorities may not find the data from preclinical studies and clinical studies sufficient to demonstrate that abaloparatide's clinical and other benefits outweigh its safety risks;
- the FDA or other foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;

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

- the FDA or other foreign regulatory authorities may not accept data generated at our clinical study sites;
- the FDA or other foreign regulatory authorities may not agree with our proposed labeling and may require labeling that undermines or otherwise significantly impairs the commercial value of the product if it were to be approved with such labeling;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions; or
- the FDA or other foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

In addition, the FDA or other foreign regulatory authorities may change its approval policies or adopt new regulations. For example, on February 15, 2012, we received a letter from the FDA stating that, after internal consideration, the agency believes that a minimum of 24-month fracture data are necessary for approval of new products for the treatment of postmenopausal osteoporosis. Our ongoing abaloparatide-SC pivotal Phase 3 Clinical Trial is designed to produce fracture data based on an 18-month primary endpoint. Based on our discussions with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from a 6-month extension of the abaloparatide 80 µg and placebo groups in our Phase 3 study, which groups will receive an approved alendronate (generic Fosamax) therapy for osteoporosis management. We plan to submit our NDA with the 24-month fracture data. We cannot be certain that the FDA will be supportive of this plan, will not change



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this approval policy again or will not adopt other approval policies or regulations that adversely affect any NDA that we may submit, the occurrence of any of which may further delay FDA approval.

Before we submit an NDA to the FDA for abaloparatide-SC as a proposed treatment for osteoporosis, we must complete our pivotal Phase 3 study based upon 18-month fracture data and the 6-month extension study, a carcinogenicity study in rats, and bone quality studies in rats and monkeys. We also may need to complete several additional studies, including, but not limited to, a thorough QT Phase 1 study, a Phase 1 pharmacokinetic, or PK, study in renal patients, a Phase 1 absolute bioavailability PK study and several drug interaction studies. Not all of these studies have commenced and the results of these studies will have an important bearing on the approval of abaloparatide. In addition to fracture and bone mineral density, or BMD, our pivotal Phase 3 study will measure a number of other potential safety indicators, including blood calcium levels, orthostatic hypotension, nausea, dizziness and anti-abaloparatide antibodies which may have an important bearing on the approval of abaloparatide.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140, or any product candidate we may acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its indicated use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for proposed uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review, such as the request we received from the FDA with respect to providing a minimum of 24-month fracture data for approval of abaloparatide. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We may never obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire any product candidate.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates for sale outside the United States.

*Clinical trials are very expensive, time-consuming and difficult to design and implement.*

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. A substantial portion of our abaloparatide development costs are denominated in euros and any adverse movement in the dollar/euro exchange rate will result in increased costs and require us to raise additional capital to complete the development of our products. The clinical trial process is also time consuming. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- changes in government regulation, administrative action or changes in FDA or other foreign regulatory authority policy with respect to clinical trials that change the requirements for approval;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- failure of sites to comply with requirements for conducting clinical trials;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

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In addition, we, the FDA, or other equivalent regulatory authorities and ethics committees with jurisdiction over our studies may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or other or other foreign regulatory authorities find deficiencies in our regulatory submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for existing or future clinical trials. Any such unexpected expenses or delays in our clinical trials could increase our need for additional capital, which may not be available on favorable terms or at all.

***Most of our investigational product candidates are in early stages of clinical trials.***

Except for abaloparatide-SC and abaloparatide-TD, each of our other product candidates (i.e., RAD1901 and RAD140) is in the early stages of development and requires extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit an NDA or equivalent application to foreign regulatory authorities for regulatory approval for any of our product candidates or whether any such NDA or equivalent application would be accepted for filing by FDA or approved if filed.

***The results of clinical trials may not support our product candidate claims.***

Even if our clinical trials are completed as planned, we cannot be certain that the results will support regulatory approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. For example, our Phase 3 trial of abaloparatide-SC for fracture prevention may not replicate the positive efficacy results for BMD seen in our two Phase 2 trials. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for proposed uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our NDAs to the FDA or equivalent application to foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date have involved small patient populations. Because of the small sample sizes, the results of these clinical trials may not be indicative of future results.

In addition, third parties could conduct clinical trials using the product candidates we license. We would have no control over how these trials are conducted and the results could potentially contradict the results we have obtained, or will obtain from the clinical trials we conduct.

***If serious adverse or undesirable side effects are identified during the development of our product candidates, we may need to abandon our development of some of our product candidates.***

All of our product candidates are still in preclinical or clinical development. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval, if ever. If our product candidates result in undesirable side effects or have characteristics that are unexpected, we may need to abandon their development.

***Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when***

*and if any of them are approved.*

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices, or cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if we obtain marketing approval of a product candidate, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and, if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;

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- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary or mandatory recall of products and related publicity requirements;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

***The commercial success of any product candidates that we may develop will depend upon the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.***

Even if the FDA or other foreign regulatory authority approves one or more of our product candidates, physicians and patients may not accept and use them. Acceptance and use of any of our products will depend upon a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drug;
- cost-effectiveness of our product relative to competing products;
- availability of coverage and reimbursement for our product from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these drugs to gain market acceptance would harm our business and would require us to seek additional financing.

*We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.*

Because we have limited financial and managerial resources, we narrowly focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

*If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.*

We may not be able to initiate or continue clinical trials for some of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other foreign regulatory authorities. In addition, many of our competitors have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

#### **Risks Related to Our Dependence on Third Parties**

*Our drug development program depends upon third-party researchers, investigators and collaborators who are outside our control.*

We depend upon independent researchers, investigators and collaborators, to conduct our preclinical and clinical trials under agreements with us. These third parties are not our employees and we cannot control the amount or timing of resources that they

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devote to our programs. These third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA or foreign regulatory authority applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist competitors at our expense, our competitive position would be harmed.

***If a regulatory or governmental authority determines that a financial interest in the outcome of the Phase 3 study of abaloparatide-SC by any of the entities managing our Phase 3 clinical trial affected the reliability of the data from the Phase 3 clinical trial, our ability to use the data for our planned regulatory submissions could be compromised, which could harm our business and the value of our common stock.***

The Phase 3 clinical trial and subsequent extension studies of abaloparatide-SC are being managed by Nordic at certain clinical sites operated by the Center for Clinical and Basic Research, or CCBR, a leading global CRO with extensive experience in global osteoporosis registration studies. Nordic controls, and holds an ownership interest in, the local CCBR clinical sites. The clinical trial investigators are employees of CCBR and may also hold an equity interest in the local CCBR clinical trials.

In consideration of Nordic's management of our Phase 3 clinical trial and subsequent extension studies, we have agreed to make various cash payments to Nordic denominated in both euros and U.S. dollars over the course of the Phase 3 study equal to a total of up to approximately 48.6 million (\$61.4 million) and a total of up to approximately \$4.4 million plus up to an additional \$5.0 million in aggregate performance incentive payments, payable in cash or stock depending on the timing of the closing of an underwritten offering of shares of our common stock. We also agreed to sell shares of capital stock to Nordic that were exchanged in the Merger for 6,443 shares of our series A-5 convertible preferred stock for proceeds of approximately \$0.5 million. These shares of our series A-5 convertible preferred stock automatically converted into 28,258 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market. Pursuant to the terms of our agreements with Nordic, we were required to issue to Nordic shares of stock with an aggregate value of up to approximately 44.3 million (\$55.9 million) and \$0.8 million in consideration of Nordic's management of the Phase 3 clinical trial. These shares of stock accrued at a quarterly rate based on the progress of the Phase 3 clinical trial and were issuable at a price per share equal to the greater of (1) the fair market value of our common stock as of the applicable accrual date or (2) \$81.42 and rounding down the resulting quotient to the nearest whole number. On each of December 31, 2013 and March 31, 2014, our Board of Directors declared a stock dividend to pay all shares of stock that had accrued as of such dates and that are anticipated to accrue through December 31, 2014, representing an aggregate of 682,958 shares of our Series A-6 convertible preferred stock that automatically converted into 2,995,453 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market. Following the completion of our initial public offering of shares of our common stock on June 11, 2014, or our IPO, all compensation remaining payable to Nordic in consideration of their management of our Phase 3 clinical trial became payable in cash.

The fair market value of our common stock may be subject to wide fluctuations in response to various factors, many of which are beyond our control, including any negative outcome of the Phase 3 study. Accordingly, the shares of stock that we have issued to Nordic in consideration of Nordic's management of the Phase 3 clinical trial may be less than the full value originally anticipated under our agreements with Nordic, assuming Nordic did not expect the fair market value of our stock to fluctuate widely over the term of such agreements. As a result, the total consideration that Nordic will receive in cash and stock may be viewed to be below the market price paid by other companies for comparable clinical trial services.

Because of the potential decrease in the value of the common stock issued to Nordic upon a negative outcome of the Phase 3 study, Nordic, CCBR and the clinical trial investigators may be viewed as having a financial interest in the outcome of the study. We have obtained written acknowledgments from the clinical trial investigators certifying that they have no financial interest in the outcome of the Phase 3 clinical trial. However, if the FDA, the European Medicines Agency, or EMA, or any other similar regulatory or governmental authority determines that Nordic, CCBR or the clinical trial investigators have a financial interest that affected the reliability of the data from the Phase 3 clinical trial, we

could be subject to additional regulatory scrutiny and the utility of the Phase 3 clinical trial for purposes of our planned regulatory submissions could be compromised, which could have a material adverse effect on our business and the value of our common stock.

*We will rely exclusively on third parties to formulate and manufacture our product candidates.*

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We have entered into agreements with contract manufacturers to manufacture abaloparatide for use in clinical trial activities. These contract manufacturers are currently our only source for the production and formulation of abaloparatide. We may not have sufficient clinical supplies of abaloparatide but believe that our contract manufacturers will be able to produce sufficient supply of abaloparatide to complete all of the planned abaloparatide



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clinical studies. If our contract manufacturers are unable to produce, in a timely manner, adequate clinical supplies to meet the needs of our clinical studies, we would be required to seek new contract manufacturers that may require us to modify our finished product formulation and modify or terminate our clinical studies for abaloparatide. Any modification of our finished product or modification or termination of our Phase 3 Clinical Trial could adversely affect our ability to obtain necessary regulatory approvals and significantly delay or prevent the commercial launch of the product if it were to be approved, which would materially harm our business and impair our ability to raise capital.

We depend on a number of single source contract manufacturers to supply key components of abaloparatide. For example, we depend on Lonza Group Ltd., or Lonza, which produces supplies of bulk drug product of abaloparatide to support the abaloparatide-SC and abaloparatide-TD clinical studies and any potential commercial launch. We also depend on Vetter Pharma Fertigung GmbH & Co, or Vetter, and Ypsomed AG, or Ypsomed, for the production of finished supplies of abaloparatide-SC and we depend on 3M for the production of abaloparatide-TD. Because of our dependence on Vetter for the fill and finish part of the manufacturing process for abaloparatide-SC, we are subject to the risk that Vetter may not have the capacity from time to time to produce sufficient quantities of abaloparatide to meet the needs of our clinical studies or be able to scale to commercial production of abaloparatide. Because the manufacturing process for abaloparatide-TD requires the use of 3M's proprietary technology, 3M is our sole source for finished clinical trial supplies of abaloparatide-TD. To date, we have not entered into a commercial supply agreement with 3M. If we were not able to negotiate commercial supply terms with 3M, as we depend on 3M for production of abaloparatide-TD, we would be unable to commercialize this product if it were to be approved. Or, if we are forced to accept unfavorable terms for our future relationship with 3M, our business and financial condition would be materially harmed.

While we are currently in discussions, to date, we have not entered into a long-term agreement with any of Lonza, Vetter or Ypsomed, each of whom currently produces abaloparatide or related components on a purchase order basis for us. Accordingly, Lonza, Vetter and Ypsomed could terminate their relationship with us at any time and for any reason. We may not be able to negotiate long-term agreements on acceptable terms, or at all. If our relationship with any of these contract manufacturers is terminated, or if they are unable to produce abaloparatide or related components in required quantities, on a timely basis or at all, or if we are forced to accept unfavorable terms for our future relationship, our business and financial condition would be materially harmed. If any of our current product candidates or any product candidates we may develop or acquire in the future receive FDA or foreign regulatory authority approval, we will rely on one or more third-party contractors to manufacture our drugs or related components. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs or related components in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with cGMP, and other government regulations and corresponding foreign standards and failure to comply with cGMP or corresponding foreign standards can result in compliance actions that may limit a manufacturer's production or prohibit a manufacturer from producing some or all products at a facility. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

*If we are not able to establish additional collaborations, we may have to alter our development plans.*

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we

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may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

**Risks Related to Marketing and Sale of Our Products**

*We have no experience selling, marketing or distributing products and currently do not have the internal capability to do so.*

We currently have no sales, marketing or distribution capabilities. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborators' strategic interest in the products under development and such collaborators' ability to successfully market and sell any such products. We intend to build an internal sales force to market and sell our products to specialists and to pursue collaborative arrangements to market and sell our products to primary care physicians. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and we cannot assure you that their efforts will be successful. In addition, we cannot assure you that we will be able to establish or maintain relationships with such third party collaborators or that we would be able to market and sell our products in the United States or overseas through an in-house sales force in lieu of such relationships.

*If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.*

The market for our product candidates is characterized by intense competition and rapid technological advances. If any of our product candidates receives FDA or other foreign regulatory authority approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have compounds already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;

- obtaining FDA and other foreign regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling approved drugs.

*Developments by competitors may render our products or technologies obsolete or non-competitive.*

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Some of the drugs that we are attempting to develop, such as abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140 will have to compete against existing therapies if they are approved. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies doing business in different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business. These risks could render our products or technologies obsolete or non-competitive.

*Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.*

Our ability to commercialize our drugs, alone or with collaborators, will depend in large part on the extent to which coverage and reimbursement will be available from:

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- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if one of our product candidates is approved by the FDA or other foreign regulatory authority, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover the costs of our drug. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our product candidates, once approved, market acceptance of our products could be reduced.

*We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.*

The testing and marketing of medical products entail an inherent risk of product liability. Even if one of our investigational product candidates is approved by the FDA or other foreign regulatory authority, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators.

### **Risks Related to Our Intellectual Property**

*If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.*

We are a party to a number of intellectual property license agreements with third parties and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that any future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The occurrence of such events could materially harm our business.

*If our efforts to protect our intellectual property related to abaloparatide-SC, abaloparatide-TD, RAD1901 and/or RAD140 fail to adequately protect these assets or if we are unable to secure all necessary intellectual property, we may lose the ability to license or successfully commercialize one or more of these candidates.*

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

Our commercial success is significantly dependent on intellectual property related to our product portfolio. We are either the licensee or assignee of numerous issued and pending patent applications that cover various aspects of our assets, including abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140.

Patents covering abaloparatide as a composition of matter have been issued in the United States (US Patent No. 5,969,095) and several additional countries. Because the abaloparatide composition of matter patent was filed in 1996, it is expected to have a normal expiration in approximately 2016 in the United States (this date does not include the possibility of Hatch-Waxman patent term extension, which could extend the expiration in the United States into the first quarter of 2021 if an application for extension is made and the maximum extension is granted by the United States Patent and Trademark Office, USPTO), and additional countries where it has issued. We believe that European Patent No. 0847278, which was included in the license from Ipsen and claimed the composition of matter of abaloparatide, has lapsed due to Ipsen's failure to pay annuities. While we are seeking to address the lapse of right, we believe that the data and market exclusivity provided in Europe for a new chemical entity, coupled with the need for a potential competitor to conduct clinical trials, will likely provide a longer barrier to entry than the patent protection provided by the original European patent term, which would have expired in 2016, plus a five year maximum Supplemental Protection Certificate.

We and Ipsen are also co-assignees to US Patent No. 7,803,770 that we believe provides exclusivity until 2028 in the United States (absent any Hatch-Waxman patent term extension) for the method of treating osteoporosis with the intended therapeutic dose for abaloparatide-SC.

We and Ipsen Pharma SAS, or Ipsen, are also co-assignees to US Patent No. 8,148,333 that we believe provides exclusivity until 2027 in the United States (absent any Hatch-Waxman patent term extension) for the intended therapeutic formulation for abaloparatide-SC.

We and 3M are co-assignees to several foreign and corresponding U.S. patent applications with the earliest priority date of April 22, 2011, which cover various aspects of abaloparatide for microneedle application. Any issued claims resulting from these applications

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will expire no earlier than 2032. However, pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of claimed inventions are not always predictable. Additional intellectual property covering abaloparatide-TD technology exists in the form of proprietary information protected as trade secrets. These can be accidentally disclosed to, independently derived by or misappropriated by competitors, possibly reducing or eliminating the exclusivity advantages of this form of intellectual property, thereby allowing those competitors more rapid entry into the marketplace with a competitive product thus reducing our advantage with abaloparatide-TD. In addition, trade secrets may in some instances become publicly available through required disclosures in regulatory files. Alternatively, competitors may sometimes reverse engineer a product once it becomes available on the market. Even where a competitor does not use an identical technology for the delivery of abaloparatide, it is possible that they could achieve an equivalent or even superior result using another technology. Such occurrences could lead to either one or more alternative competitor products becoming available on the market and/or one or more generic competitor products on the market gaining market share and causing a corresponding decrease in market share and/or price for abaloparatide-TD.

Patents covering RAD1901 as a composition of matter, as well as the use of RAD1901 for the treatment of estrogen-dependent breast cancer, have been issued in the United States, Canada and Australia and are pending in Europe and India. The RAD1901 composition of matter patents in the United States expire in 2023 and 2026 (absent any Hatch-Waxman patent term extension). Additional patent applications relating to methods of treating vasomotor symptoms and clinical dosage strengths using RAD1901 have been filed. Pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of any claimed invention before a patent office are not always predictable. As a result, we could encounter challenges or difficulties in building, maintaining and/or defending our intellectual property both in the United States and abroad.

Patent applications covering RAD140 and other SARM compounds have been granted in the United States, Europe, Canada, Mexico, Japan and Australia, and are pending in the United States and elsewhere. The RAD140 composition of matter case expires in 2029 in the United States (absent any Hatch-Waxman patent term extension) and additional countries if and when it issues.

Since patents are technical legal documents that are frequently subject to intense litigation pressure, there is risk that even if one or more patents related to our products does issue and is asserted that the patent(s) will be found invalid, unenforceable and/or not infringed when subject to said litigation. Finally, the intellectual property laws and practices can vary considerably from one country to another and also can change with time. As a result, we could encounter challenges or difficulties in building, maintaining and defending our intellectual property both in the United States and abroad.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to patents issued or licensed to us, including interference proceedings before the USPTO. Third parties may assert infringement claims against us. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. For example, we are aware of a provisional patent application recently filed with the USPTO that could be relevant to the use of RAD1901 to treat indications for which we are developing RAD1901. If a patent issues from this patent application with claims covering the use of RAD1901 to treat indications for which we are developing RAD1901, including metastatic breast cancer, we may need to license the patent in order to commercialize RAD1901 specifically for the treatment of such indications. We are evaluating whether to enter into negotiations for such license. We cannot assure you that we will be able to secure a license on reasonable terms, if at all. If we need a license of such patent in order to commercialize RAD1901 and are unable to secure one on reasonable terms, our business would be materially harmed.

*If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.*

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain these patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.



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The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States, prior to March 16, 2013, the first to make the claimed invention was entitled to the patent (a first-to-invent system), while outside the United States, the first to file a patent application is entitled to the patent (a first-to-file system). With the implementation of the Leahy-Smith America Invents Act, the United States now has a first-to-file system for patent applications filed on or after March 16, 2013. We may become involved in opposition, interference or derivation proceedings challenging our patent rights or the patent rights of others. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Any challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***Payments, fees, submissions and various additional requirements must be met in order for pending patent applications to advance in prosecution and issued patents to be maintained. Rigorous compliance with these requirements is essential to procurement and maintenance of patents integral to our product portfolio.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will come due for payment periodically throughout the lifecycle of patent applications and issued patents. In order to help ensure that we comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents for which we are an assignee or co-assignee, we employ competent legal help and related professionals as needed to comply with those requirements. Our outside patent counsel uses Computer Packages, Inc. for patent annuity payments. We depend on Eisai and/or Ipsen to comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents we have licensed. Failure to meet a required fee payment, document production or procedural requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances the defect can be cured through late compliance but there are situations where the failure to meet the required event cannot be cured. Any failures could compromise the intellectual property protection around our preclinical or clinical candidates and possibly weaken or eliminate our ability to protect our eventual market share for that product.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to our patented technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to our trade secrets, such as our corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for any breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by a competitor, our competitive position would be harmed.

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***If we infringe the rights of third parties, we could be prevented from selling products and could be forced to pay damages and defend against litigation.***

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing drug candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, which could result in a substantial diversion of our financial and management resources.

***We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute these types of claims, and we may be reliant on them to do so.

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities, delaying the development of our product candidates. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Litigation or other proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct any litigation or proceedings. Some of our competitors may be able to sustain the costs of any litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

#### **Risks Related to Legislation and Administrative Actions**

*Healthcare reform may have a material adverse effect on our industry and our results of operations.*

From time to time, legislation is implemented to reign in rising healthcare expenditures. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA. PPACA includes a number of provisions affecting the pharmaceutical industry, including annual, non-deductible fees on any entity that manufactures or imports some types of branded prescription drugs and biologics, beginning in 2011, and increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program. In addition, among other things, PPACA also establishes a

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new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research. Congress has proposed a number of legislative initiatives to alter PPACA, including possible repeal of PPACA. At this time, it remains unclear whether there will be any changes made to particular provisions of PPACA or its entirety. In addition, other legislative changes have been proposed and adopted since PPACA was enacted. Most recently, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which may result in such changes as aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, starting in 2013. The full impact on our business of PPACA and the Budget Control Act is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the pharmaceutical industry generally or our business in particular.

***We are subject to healthcare laws, regulation and enforcement, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.***

We are subject to several healthcare regulations and enforcement by the federal government and the states and foreign countries in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of various electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- the federal transparency requirements under PPACA, which require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;
- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

***We may be exposed to liability claims associated with the use of hazardous materials and chemicals.***

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

#### **Risks Related to Employee Matters and Managing Growth**

*We may not successfully manage our growth.*

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we may be required to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage this growth effectively, our business would be harmed.

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***We may enter into or seek to enter into business combinations and acquisitions which may be difficult to integrate, disrupt our business, divert management attention or dilute stockholder value.***

We may enter into business combinations and acquisitions. We have limited experience in making acquisitions, which are typically accompanied by a number of risks, including:

- the difficulty of integrating the operations and personnel of the acquired companies;
- the potential disruption of our ongoing business and distraction of management;
- the potential for unknown liabilities and expenses;
- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

If we are not successful in completing acquisitions that we may pursue in the future, we would be required to reevaluate our business strategy and we may have incurred substantial expenses and devoted significant management time and resources in seeking to complete the acquisitions. In addition, we could use substantial portions of our available cash as all or a portion of the purchase price, or we could issue additional securities as consideration for these acquisitions, which could cause our stockholders to suffer significant dilution.

***We rely on key executive officers and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.***

We are highly dependent on our chief executive officer and our principal scientific, regulatory and medical advisors. We do not have key person life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

***If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.***

We will need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

## Risks Relating to Our Securities

*Our stock price may be volatile, and the value of an investment in our common stock may decline.*

The trading price of our common stock may be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- results of clinical trials of our product candidates or those of our competitors;
- our operating performance and the operating performance of similar companies;
- the success of competitive products;
- the overall performance of the equity markets;
- the number of shares of our common stock publicly owned and available for trading;
- threatened or actual litigation;
- changes in laws or regulations relating to our products, including changes in the structure of healthcare payment systems;
- any major change in our board of directors or management;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- large volumes of sales of our shares of common stock by existing stockholders;
- general political, economic and market conditions; and
- the other factors described in this Risk factors section.

In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the companies whose shares trade in the stock market. These fluctuations may be even more pronounced in the trading market for our stock shortly following the initial public offering. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's



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securities. Such litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources and harm our business, operating results and financial condition.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our credit facility preclude us from paying cash dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

As a public company listed on the NASDAQ Global Market, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company and prior to the listing of our common stock on the NASDAQ Global Market. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission, or the SEC, and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and are making some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and in the future will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm at such time as we no longer qualify as a smaller reporting company. Despite our efforts, there is a risk that our independent registered public accounting firm will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. Material weaknesses in our internal control over financial reporting could also result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business.

***Our directors, executive officers and principal stockholders have substantial control over us and could delay or prevent a change in corporate control.***

Our directors, executive officers and holders of more than five percent of our common stock, together with their affiliates, beneficially own a significant portion of our outstanding common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or

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substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

*Future sales of shares of our common stock by stockholders could depress the price of our common stock.*

As of September 30, 2014, we had 29,747,797 shares of common stock outstanding and on October 7, 2014 we issued 3,128,524 shares of common stock in a public offering. Of these shares, only the shares sold in our initial public offering or subsequent public offering are freely tradable. The holders of substantially all of our other shares of common stock have signed lock-up agreements under which they have agreed not to sell, transfer or dispose of, directly or indirectly, any shares of our common stock or any securities into or exercisable or exchangeable for shares of our common stock without the prior written consent of Jefferies and Cowen and Company for a period ending on the later of 180 days, subject to a possible extension under certain circumstances, after June 5, 2014, or, in the case of our directors, executive officers and their affiliates, 90 days, subject to possible extension under certain

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circumstances, after October 2, 2014. After the expiration of the applicable lock-up period, these shares may be sold in the public market, subject to prior registration or qualification for an exemption from registration, including, in the case of shares held by affiliates, compliance with the volume restrictions of Rule 144. To the extent that any of these stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the contractual lock-ups and other legal restrictions on resale lapse, the trading price of our common stock could decline significantly.

In addition, the 4,249,328 shares of our common stock reserved for issuance under our equity incentive plans as of September 30, 2014, which includes 2,377,693 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2014, will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the price of our common stock could decline substantially.

***If securities or industry analysts cease to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

***Anti-takeover provisions contained in our restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt.***

Our restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- a staggered board of directors;
- authorizing the board to issue, without stockholder approval, preferred stock with rights senior to those of our common stock;
- authorizing the board to amend our bylaws and to fill board vacancies until the next annual meeting of the stockholders;
- prohibiting stockholder action by written consent;
- limiting the liability of, and providing indemnification to, our directors and officers;
- eliminating the ability of our stockholders to call special meetings; and
- requiring advance notification of stockholder nominations and proposals.

Section 203 of the Delaware General Corporation Law, or DGCL, prohibits, subject to some exceptions, business combinations between a Delaware corporation and an interested stockholder, which is generally defined as a stockholder who becomes a beneficial owner of 15% or more of a Delaware corporation's voting stock, for a three-year period following the date that the stockholder became an interested stockholder.

These and other provisions in our restated certificate of incorporation and our amended and restated bylaws under Delaware law could discourage potential takeover attempts, reduce the price that investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

*Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.*

As of December 31, 2013, we had \$263.6 million of federal and \$229.4 million of state net operating loss carryforwards available to offset future taxable income. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code has previously occurred. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

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

*Use of Proceeds from the Sale of Registered Securities*

On June 5, 2014, the Securities and Exchange Commission, or SEC, declared effective our Registration Statement on Form S-1 (File No. 333-194150), as amended, or Registration Statement, filed in connection with the initial public offering of our common stock. Pursuant to the Registration Statement, we registered the offer and sale of 7,475,000 shares of common stock with an aggregate offering price of approximately \$59.8 million.

There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus, dated June 5, 2014, filed with the SEC pursuant to Rule 424(b) relating to our Registration Statement.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

None.

**Item 5. Other Information**

None.

Table of Contents**Item 6. Exhibits.**

The following is an index of the exhibits included in this report:

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		Filing Date	Filed/ Furnished Herewith
			File No.	Exhibit		
3.1	Restated Certificate of Incorporation, as amended and restated as of June 11, 2014	8-K	001-35726	3.1	6/13/14	
3.2	Amended and Restated By-Laws of Radius Health Inc.	8-K	001-35726	3.2	6/13/14	
10.1	First Amendment to Loan and Security Agreement, dated July 10, 2014, by and among Radius Health, Inc., Solar Capital Ltd., and Oxford Finance LLC	8-K	001-35726	10.3	7/11/14	
10.2	Warrant to Purchase Stock, dated July, 10, 2014, issued by Radius Health, Inc. to Oxford Finance LLC	8-K	001-35726	10.2	7/11/14	
10.3	Warrant to Purchase Stock, dated July, 10, 2014, issued by Radius Health, Inc. to Solar Capital Ltd.	8-K	001-35726	10.1	7/11/14	
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)/14d-14(a)					*
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)/14d-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					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

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\* Filed herewith.

\*\* Furnished herewith.

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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 10, 2014

By:

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

Date: November 10, 2014