

Radius Health, Inc.  
Form 10-Q  
November 14, 2013  
[Table of Contents](#)

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

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended September 30, 2013.

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 000-53173

**Radius Health, Inc.**

(Exact name of registrant as specified in its charter)

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

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

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

**201 Broadway**  
**Sixth Floor**  
**Cambridge, Massachusetts**  
(Address of Principal Executive Offices)

**02142**  
(Zip Code)

**(617) 551-4700**

(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, \$0.0001 par value per share, outstanding as of November 14, 2013: 879,370 shares

Table of Contents

**RADIUS HEALTH, INC.**  
**QUARTERLY REPORT FOR THE QUARTER ENDED SEPTEMBER 30, 2013**  
**ON FORM 10-Q**

**INDEX**

**PART I FINANCIAL INFORMATION**

<u>Item 1.</u>	<u>Financial Statements (Unaudited)</u>	2
	<u>Condensed Balance Sheets as of September 30, 2013 and December 31, 2012</u>	2
	<u>Condensed Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2013 and 2012</u>	3
	<u>Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit for the nine months ended September 30, 2013</u>	4
	<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2013 and 2012</u>	5
	<u>Notes to Unaudited Financial Statements</u>	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	33
<u>Item 4.</u>	<u>Controls and Procedures</u>	34

**PART II OTHER INFORMATION** 35

<u>Item 1.</u>	<u>Legal Proceedings</u>	35
<u>Item 1A.</u>	<u>Risk Factors</u>	35
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and the Use of Proceeds</u>	52
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	52
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	52
<u>Item 5.</u>	<u>Other Information</u>	52
<u>Item 6.</u>	<u>Exhibits</u>	53

**SIGNATURES** 54

---

Table of Contents

**CURRENCY AND CONVERSIONS**

In this report, references to dollar or \$ are to the legal currency of the United States, and references to euro or are to the single currency introduced on January 1, 1999 at the start of the third stage of European Economic and Monetary Union, pursuant to the Treaty establishing the European Communities, as amended by the Treaty on European Union and the Treaty of Amsterdam. Unless otherwise indicated, the financial information in this report has been expressed in U.S. dollars. Unless otherwise stated, the U.S. dollar equivalent information translating euros into U.S. dollars has been made, for convenience purposes, on the basis of the noon buying rate published by the Board of Governors of the Federal Reserve as of September 30, 2013, which was 1.00 = \$1.3535. 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 Unaudited****Radius Health, Inc.****Condensed Balance Sheets**

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

	September 30, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 19,493	\$ 18,653
Marketable securities	10,250	4,000
Prepaid expenses and other current assets	242	2,463
Total current assets	29,985	25,116
Property and equipment, net	91	139
Other assets	45	45
Total assets	\$ 30,121	\$ 25,300
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS</b>		
<b>DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 2,684	\$ 550
Accrued expenses and other current liabilities	22,943	8,740
Current portion of note payable, net of discount	10,837	7,800
Total current liabilities	36,464	17,090
Note payable, net of current portion and discount	4,369	13,005
Warrant liability	2,499	830
Other liabilities	22,186	24,387
Commitments and contingencies		
Series B Convertible Preferred Stock, \$.0001 par value; 980,000 shares authorized, 701,235 shares and no shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	43,024	
Series A-1 Convertible Preferred Stock, \$.0001 par value; 1,000,000 shares authorized, 939,612 shares issued and outstanding at September 30, 2013 and December 31, 2012	76,987	71,957
Series A-2 Convertible Preferred Stock, \$.0001 par value; 983,213 shares authorized, 983,208 shares issued and outstanding at September 30, 2013 and December 31, 2012	92,094	86,714
Series A-3 Convertible Preferred Stock, \$.0001 par value; 142,230 shares authorized, 142,227 shares issued and outstanding at September 30, 2013 and December 31, 2012	11,960	11,182
Series A-4 Convertible Preferred Stock, \$.0001 par value; 4,000 shares authorized, 3,998 shares issued and outstanding at September 30, 2013 and December 31, 2012	271	271
Series A-5 Convertible Preferred Stock, \$.0001 par value; 7,000 shares authorized, 6,443 shares issued and outstanding at September 30, 2013 and December 31, 2012	525	525
Series A-6 Convertible Preferred Stock, \$.0001 par value; 800,000 shares authorized, no shares issued and outstanding at September 30, 2013 and December 31, 2012		
Stockholders' deficit:		

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

Common stock, \$.0001 par value; 100,000,000 shares authorized, 879,370 and 867,204 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively			
Additional paid-in-capital			
Accumulated other comprehensive income			
Accumulated deficit		(260,258)	(200,661)
Total stockholders' deficit		(260,258)	(200,661)
Total liabilities, convertible preferred stock and stockholders' deficit	\$	30,121	\$ 25,300

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,	
	2013	2012	2013	2012
<b>OPERATING EXPENSES:</b>				
Research and development	\$ 15,543	\$ 14,173	\$ 49,070	\$ 38,539
General and administrative	1,621	1,918	4,643	6,209
Loss from operations	(17,164)	(16,091)	(53,713)	(44,748)
<b>OTHER (EXPENSE) INCOME:</b>				
Other (expense) income, net	(2,607)	(604)	7,465	(1,788)
Interest income	11	18	27	53
Interest expense	(582)	(853)	(1,938)	(1,880)
<b>NET LOSS</b>	<b>\$ (20,342)</b>	<b>\$ (17,530)</b>	<b>\$ (48,159)</b>	<b>\$ (48,363)</b>
<b>OTHER COMPREHENSIVE LOSS, NET OF TAX:</b>				
Unrealized gain from available-for-sale securities	(3)	(7)		(2)
<b>COMPREHENSIVE LOSS</b>	<b>\$ (20,345)</b>	<b>\$ (17,537)</b>	<b>\$ (48,159)</b>	<b>\$ (48,365)</b>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED (Note 10):</b>				
<b>LOSS PER SHARE:</b>				
Basic	\$ (28.53)	\$ (24.53)	\$ (69.77)	\$ (70.76)
Diluted	\$ (28.53)	\$ (24.53)	\$ (69.77)	\$ (70.76)
<b>WEIGHTED AVERAGE SHARES:</b>				
Basic	879,370	859,769	872,195	830,068
Diluted	879,370	859,769	872,195	830,068

See accompanying notes to unaudited condensed financial statements.

Table of Contents

**Radius Health, Inc.**

**Statements of Convertible Preferred Stock and Stockholders Deficit**

(Unaudited, in thousands except share amounts)

	Convertible Preferred Stock										Stockholders Deficit							
	Seris B Shares	Series A-1 Amount	Series A-1 Shares	Series A-2 Amount	Series A-2 Shares	Series A-3 Amount	Series A-3 Shares	Series A-4 Amount	Series A-4 Shares	Series A-5 Amount	Series A-5 Shares	Series A-Common Shares	Common Shares	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Total Deficit		
Balance at December 31, 2012			939,612	\$ 71,957	983,208	\$ 86,714	142,227	\$ 11,182	3,998	\$ 271	6,443	\$ 525	\$ 867,204	\$	\$	\$ (200,661)	\$ (200,661)	
Net loss																	(48,159)	(48,159)
Unrealized gain from available-for-sale securities																		
Issuance of common stock													12,166	13				
Issuance of preferred stock	701,235	41,514																
Accretion of dividends on preferred stock		1,510		5,030		5,380		778						(1,260)		(11,438)	(11,438)	
Stock-based compensation expense														1,247				
Balance at September 30, 2013	701,235	\$ 43,024	939,612	\$ 76,987	983,208	\$ 92,094	142,227	\$ 11,960	3,998	\$ 271	6,443	\$ 525	\$ 879,370	\$	\$	\$ (260,258)	\$ (260,258)	

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</b>	
	<b>September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>CASH FLOWS USED IN OPERATING ACTIVITIES:</b>		
Net loss	\$ (48,159)	\$ (48,363)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21	33
Amortization of premium (accretion of discount) on short-term investments, net	28	98
Stock-based compensation expense	1,247	1,311
Research and development expense settled in stock	10,568	6,872
Change in fair value of other current assets, warrant liability and other liability	(7,464)	1,766
Non-cash interest	307	339
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,813	4,437
Other long-term assets		35
Accounts payable	2,134	549
Accrued expenses and other current liabilities	9,646	891
Net cash used in operating activities	(29,859)	(32,032)
<b>CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES:</b>		
Proceeds from sale of equipment		45
Purchases of marketable securities	(17,070)	(18,989)
Sales and maturities of marketable securities	10,793	35,714
Net cash (used in) provided by investing activities	(6,277)	16,770
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	13	269
Payments on note payable	(5,907)	(2,155)
Proceeds from the issuance of preferred stock, net	42,870	
Proceeds from note payable, net		12,469
Net cash provided by financing activities	36,976	10,583
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>840</b>	<b>(4,679)</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR</b>	<b>18,653</b>	<b>25,128</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 19,493</b>	<b>\$ 20,449</b>
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	\$ 1,426	\$ 1,311
<b>NON-CASH FINANCING ACTIVITIES:</b>		
Accretion of dividends on preferred stock	\$ 12,698	\$ 10,370
Fair value of warrants issued	\$ 1,356	\$ 379

See accompanying notes to unaudited condensed financial statements.

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements**

**(Unaudited)**

**1. Organization**

Radius Health, Inc. ( Radius or the Company ), which was formerly known as MPM Acquisition Corp., is a biopharmaceutical company focused on developing new therapeutics for the treatment of osteoporosis and other women's health conditions. The Company's lead product candidate, currently in Phase 3 clinical development, is BA058-SC, a daily subcutaneous injection of novel synthetic peptide analog of human parathyroid hormone-related protein ( hPTHrP ) for the treatment of osteoporosis. The BA058-SC Phase 3 study began dosing patients in April 2011 and completed enrollment in March 2013. The Company is also developing BA058-TD, a short wear time, transdermal form of BA058 delivered using a microneedle patch technology from 3M Drug Delivery Systems ( 3M ). The Company commenced a Phase 2 clinical study of BA058-TD during the third quarter of 2012 and completed patient visits in August 2013. The Company received the top-line data from this study during the third quarter of 2013. The Company also has two other product candidates, RAD1901 and RAD140. RAD1901 is a selective estrogen receptor modulator which is in Phase 2 clinical development for the treatment of vasomotor symptoms (hot flashes) in women entering menopause. The Company is also exploring the use of RAD1901 as a potential treatment for breast cancer brain metastasis ( BCBM ). The Company has conducted a number of preclinical studies which have provided early proof of concept in application to BCBM and is currently reviewing strategic alternatives with respect to the future development of the product for this treatment. RAD140 is a selective androgen receptor modulator which is currently in preclinical development as a potential treatment for age-related muscle loss, frailty, and weight loss associated with cancer cachexia and osteoporosis.

Pursuant to an Agreement and Plan of Merger (the Merger Agreement or the Merger ) entered into in April 2011 by and among the Company (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 ), 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. This transaction is herein referred to as the Merger. The Merger was effective as of May 17, 2011, upon the filing of a certificate of merger with the Delaware Secretary of State. Following the Merger on May 17, 2011, the Company's Board of Directors approved a transaction pursuant to which the Former Operating Company merged with and into the Company, leaving the Company as the surviving corporation (the Short-Form Merger ). As part of the Short-Form Merger, the Company, then named MPM Acquisition Corp., changed its name to Radius Health, Inc. and assumed the operations of the Former Operating Company.

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, 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, 2013, the Company had an accumulated deficit of \$260.3 million and believes that its cash and cash equivalents and marketable securities at September 30, 2013 are sufficient to fund its operations into the first quarter of 2014. Accordingly, the Company expects to pursue financing opportunities to address its future capital needs, including the completion of an additional private placement or public offering and other strategic financing alternatives that could include, but are not limited to, partnering or other collaboration agreements. However, there is no guarantee that any of these financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company fails to obtain additional future capital, it may be unable to complete its planned preclinical and clinical trials and obtain approval of any product candidates from the Federal 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, 2013 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2013.

Table of Contents

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, 2012 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 15, 2013.

*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, 2012 relate to accrued clinical expenses, research and development expenses, stock-based compensation and fair value measures. There were no changes to significant accounting policies during the nine months ended September 30, 2013.

*Accounting Standards Updates* In July 2013, the 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 to ASU 2013-11 are effective for interim and annual fiscal periods beginning after December 15, 2013, with early adoption permitted. The Company does not expect adoption of ASU 2013-11 will have a material impact on its results of operations, financial position, or cash flows.

*Recently Adopted Accounting Standards* In February 2013, FASB issued Accounting Standards Update No. 2013-02, *Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income* (ASU 2013-02). Under ASU 2013-02, an entity is required to provide information about amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. ASU 2013-02 does not change the current requirements for reporting net income or other comprehensive income in the financial statements. The Company adopted ASU 2013-02 on January 1, 2013. Its adoption did not have a material impact on the Company's results of operations, financial position or cash flows.

**3. Marketable Securities**

Available-for-sale marketable securities consisted of the following (in thousands):

	Amortized Value	September 30, 2013		Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
Marketable securities:				
Domestic corporate debt securities	\$ 2,000	\$	\$	\$ 2,000
Domestic corporate commercial paper	8,250			8,250
Total	\$ 10,250	\$	\$	\$ 10,250

	Amortized	December 31, 2012	
		Gross Unrealized	Gross Unrealized

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

	Value	Gains	Losses	Fair Value
Marketable securities:				
Domestic corporate commercial paper	\$ 4,000			\$ 4,000
Total	\$ 4,000	\$	\$	\$ 4,000

The Company held one debt security at September 30, 2013 with a fair value of \$2.0 million that had been in an unrealized loss position for less than 12 months. The Company evaluated the security for other-than-temporary impairment based upon quantitative and qualitative factors and determined that the decline in the market value of the security was most likely due to current economic and market conditions. In addition, the Company believes that it is not more likely than not that it will be required to sell the security and it does not intend to sell it before the recovery of the amortized cost basis. Based upon the Company's analysis, it does not consider the investment to be other-than-temporarily impaired as of September 30, 2013.

The contractual term to maturity of all marketable securities held by the Company as of September 30, 2013 is less than one year.

Table of Contents**4. Accrued Expenses and Other Current Liabilities**

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

	September 30, 2013	December 31, 2012
Research costs	\$ 21,098	\$ 6,558
Payroll and employee benefits	647	962
Professional fees	245	399
Vacation	95	129
Interest on notes payable	799	595
Other	59	97
Total accrued expenses and other current liabilities	\$ 22,943	\$ 8,740

**5. Convertible Preferred Stock**

On April 23, 2013, the Company entered into a Series B Convertible Preferred Stock and Warrant Purchase Agreement (the "Purchase Agreement"), pursuant to which the Company could raise, at any time on or prior to May 10, 2013, up to approximately \$60.0 million through the issuance of (1) up to 980,000 shares of its Series B preferred stock (the "Series B Shares") and (2) warrants to acquire up to 2,450,000 shares of its common stock with an exercise price of \$6.142 per share. On April 23, 2013, the Company consummated a first closing under the Purchase Agreement, whereby in exchange for aggregate proceeds of approximately \$43.0 million, it issued 700,098 Series B Shares and warrants to purchase up to a total of 1,750,248 shares of its common stock. On May 10, 2013, the Company consummated a second closing under the Purchase Agreement, whereby in exchange for aggregate proceeds of approximately \$0.1 million, it issued 1,137 Series B Shares and warrants to purchase up to a total of 2,843 shares of its common stock.

The rights, preferences, and privileges of the Series B convertible preferred stock ("Series B") and the 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") 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") as of September 30, 2013, are set forth below.

**Conversion** Each holder of Series B Shares has the right, at their option at any time, to convert any such shares of Series B into such number of fully paid shares of common stock as is 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 as of September 30, 2013 was \$6.142 per share (the "Series B Conversion Price"), which represents a conversion ratio of one share of Series B into ten shares of common stock.

Each holder of Series A-1, Series A-2 and Series A-3 has 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 is 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 \$8.142 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 ten shares of common stock. The issuance of the

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

Series B Shares and accompanying warrants under the Purchase Agreement 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 effective conversion price of each share of Series A-1, Series A-2 and Series A-3 was reduced to \$7.627, which represents a conversion ratio of one share of Series A-1, Series A-2 or Series A-3 into 10.675 shares of common stock.

Each holder of Series A-4, Series A-5 and Series A-6 has 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 is 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 September 30, 2013 was \$8.142 per share, which represents a conversion ratio of one share of Series A-4, Series A-5 or Series A-6 into ten shares of common stock.

Upon an optional conversion, the holders of the converted Series B and Series A Preferred Stock are 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.

Table of Contents

Each share of the Series B and Series A Preferred Stock is automatically convertible into fully paid and non-assessable shares of common stock at the applicable conversion price (as described above) in effect upon (1) a vote of the holders of at least 70% of the outstanding shares of Series B, Series A-1, Series A-2 and Series A-3 to convert all shares of Series B and Series A Preferred Stock or (2) 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 shall 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.

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

*Dividends* Holders of shares of Series B are 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. Dividends are payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series B are 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, holders of shares of Series A-1 are 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 A-1. Dividends are payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series A-1 are 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 A-1, holders of Series A-2 are 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 A-2. Dividends are payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series A-2 are 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 A-1 and Series A-2, holders of Series A-3 are 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 A-3. Dividends are payable, as accrued, upon liquidation, event of sale and conversion to common stock, as described above. The holders of shares of Series A-3 are 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 A-1, Series A-2 and Series A-3, holders of Series A-5 are 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 8. Dividends are payable, as accrued, upon liquidation, event of sale and conversion to common stock, as described above. The holders of shares of Series A-5 are 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 A-1, Series A-2, Series A-3 and Series A-5, holders of Series A-4 and Series A-6 are 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

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

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 are 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 are also entitled to dividends declared or paid on any shares of common stock.

Dividends on the Company's preferred stock are payable, at the sole discretion of the Board of Directors, in cash or in shares of the Company's common stock at the current market price of shares of common stock, when and if declared by the Board of Directors and upon liquidation or an event of sale. All accrued but unpaid dividends on Series B and Series A Preferred Stock will be paid in cash or shares of common stock, at the then effective Conversion Price of shares of Series B and Series A Preferred Stock, upon a Special Mandatory Conversion (as defined in the Company's certificate of incorporation). Upon Optional Conversion, dividends are payable in shares of the common stock at the then effective conversion price of shares of preferred stock.

As of September 30, 2013, the Company had accrued dividends of \$1.5 million, \$13.3 million, \$16.1 million and \$2.3 million on Series B, Series A-1, Series A-2 and Series A-3, respectively.

*Voting* The holders of Series B and Series A Preferred Stock are 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 are outstanding, the holders of Series A-1, voting as a separate class, have the right to elect two members of the Company's Board of Directors.

Table of Contents

*Liquidation* The shares of Series B rank senior to the Series A-1 and all other classes of Series A Preferred Stock. The shares of Series A-1 rank senior to all other classes of Series A Preferred Stock. Series A-2 ranks 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 rank equally but junior to Series A-1 and Series A-2 and senior to Series A-4. Series A-4 ranks 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 are 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 shall consist of two (2) times the original purchase price of \$61.42, plus all accrued but unpaid dividends. After such distribution to the holders of Series B, the holders of Series A-1 will be 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 shall 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 will be 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, will be 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 will be 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 are insufficient to pay the full preferential amounts to the holders of Series B, the assets will be distributed ratably among the holders of Series B in proportion to their aggregate liquidation preference amounts. If the assets of the Company are insufficient to pay the full preferential amounts to the holders of Series A-1, the assets will be distributed ratably among the holders of Series A-1 in proportion to their aggregate liquidation preference amounts. If the assets of the Company are insufficient to pay the full preferential amounts to the holders of Series A-2, the assets will be distributed ratably among the holders of Series A-2 in proportion to their aggregate liquidation preference amounts. If the assets of the Company are insufficient to pay the full preferential amounts to the holders of Series A-3, Series A-5 and Series A-6, the assets will be 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 are insufficient to pay the full preferential amounts to the holders of Series A-4, the assets will be 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 and Series A Preferred Stock, the holders of the Series B and Series A-1, Series A-2 and Series A-3 shall 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 shall redeem all of the shares of Series B and Series A Preferred Stock then outstanding at the Special Liquidation Price, as defined. If the event of sale involves consideration other than cash, the Special Liquidation Price may be paid with such consideration having a value equal to the Special Liquidation Price. The Special Liquidation Price shall 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. 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:

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

- 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.

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

Table of Contents

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, 2013 and December 31, 2012 (in thousands):

	September 30, 2013			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Marketable securities:				
Domestic corporate debt securities (1)	\$	\$ 2,000	\$	\$ 2,000
Domestic corporate commercial paper (1)		8,250		8,250
	\$	\$ 10,250	\$	\$ 10,250
<b>Liabilities</b>				
Warrant liability (2)	\$	\$	\$ 2,499	\$ 2,499
Other liability (2)			22,186	22,186
Stock liability (2)			4,830	4,830
	\$	\$	\$ 29,515	\$ 29,515

	December 31, 2012			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Marketable securities:				
Domestic corporate commercial paper (1)	\$	\$ 4,000	\$	\$ 4,000
Stock asset (2)			407	407
	\$	\$ 4,000	\$ 407	\$ 4,407
<b>Liabilities</b>				
Warrant liability (2)	\$	\$	\$ 830	\$ 830
Other liability (2)			24,387	24,387
Stock liability (2)			245	245
	\$	\$	\$ 25,462	\$ 25,462

(1) 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.

(2) 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 asset represents the prepaid balance of the research and development expense related to the stock dividends to be issued 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) 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 8). The stock liability represents the accrued balance of the research and development expense related to the stock dividends to be issued to Nordic in shares of Series A-6 (or in shares of common stock if the Company lists its common stock on a national exchange) which is being recognized ratably over the estimated per patient treatment period under the

Nordic Work Statements.

The fair values of the stock asset and stock liability are based upon the fair value of the Series A-6 as determined using PWERM, which considers the value of the Company's various classes of preferred stock. The fair value of the Company's various classes of preferred stock is determined through an analysis of the future values for equity assuming various future outcomes. Accordingly, share value is 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.

Table of Contents

PWERM is complex as it requires numerous assumptions relating to potential future outcomes of equity. Accordingly, the valuation of the Company's stock asset and stock liability is determined using Level 3 inputs.

The warrant liability 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 Finance LLC and General Electric Capital Corporation in May 2011. The warrant liability is 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. 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 is determined using Level 3 inputs.

The other liability represents the liability to issue shares of Series A-6 for services rendered in connection with the Nordic Work Statements. The liability is calculated based upon the number of shares earned by Nordic through the performance of clinical trial services multiplied by the estimated fair value of the Company's Series A-6 at each reporting date. The estimated fair value of the Series A-6 is determined using PWERM, as described above. Accordingly, the valuation of the other liability is determined using Level 3 inputs.

As noted above, the Company's Level 3 fair value measurements related to its stock asset, stock liability, warrant liability and other liability are based upon the fair value of the Company's common stock and preferred stock. The following table provides quantitative information about the fair value measurement of the Company's common stock and preferred stock, including significant unobservable inputs:

Instrument	Valuation Technique	Unobservable Input	Estimate	
Preferred Stock	PWERM	• Time until future exit event (years)	• 0.5 1.0	
		• Probability of BA058 coming to market	• 65% 75%	
		• Discount rate	• 20% 40%	
		• Long-term revenue growth rate (1)	• 2% 117%	
		• Long-term revenue growth rate (2)	• 8% 75%	
		• Long-term pre-tax operating margin (3)	• 13% 79%	
		• Long-term pre-tax operating margin (4)	• 27% 73%	
		• Discount for lack of marketability	• 14% 42%	
		Market Comparable Companies	• Revenue multiple (5)	• 2.9 7.5

(1) Estimated long-term revenue growth rate in one scenario has the above range and an average of approximately 24% over 16 revenue years.

(2) Estimated long-term revenue growth rate in a second scenario has the above range and an average of approximately 22% over 16 revenue years.

(3) Estimated long-term pretax operating margin in one scenario has the above range after achieving positive pretax operating margin and an average of approximately 69% for 17 years.

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

(4) Estimated long-term pretax operating margin in a second scenario has the above range after achieving positive pretax operating margin and an average of approximately 59% for 17 years.

(5) Represents amounts used when the Company has determined that market participants would use such multiples when valuing the Company's preferred stock.

As of September 30, 2013, the warrant liability, other liability and stock liability have fair values of \$2.5 million, \$22.2 million and \$4.8 million, respectively. Changes in the significant unobservable inputs used in the fair value measurements of the Company's common stock and preferred stock in isolation would result in a significantly different fair value measurement of the stock asset, stock liability, warrant liability and other liability. Generally, a change in the assumption used for the probability of successful development is accompanied by a directionally similar change in the assumption used for the long-term revenue growth rate and long-term pre-tax operating margin and estimated fair value measurement of the Company's common stock and preferred stock.

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, 2012	\$	407
Expense recognized		(313)
Additions		86
Change in fair value		(180)
Balance at September 30, 2013	\$	

Table of Contents

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, 2012	\$	25,462
Additions		11,697
Change in fair value		(7,644)
Balance at September 30, 2013	\$	29,515

Additions represent the value of the asset or liability for additional accrued shares of stock issuable to Nordic for services rendered in connection with the Company's Phase 3 clinical study of BA058-SC and Phase 2 clinical study of BA058-TD (see note 8), as well as the value of any new warrants issued during the period.

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, 2013, 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.

## 7. 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 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. BA058 (the Company's bone growth drug) 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 (\$13.5 million to \$48.7 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 connection with the Ipsen Agreement, the Company recorded less than

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

\$0.1 million and \$0.1 million in costs during the three months ended September 30, 2013 and 2012, respectively, and \$0.2 million and \$0.6 million during the nine months ended September 30, 2013 and 2012, respectively, which were incurred by Ipsen and charged to the Company for the manufacture of the clinical supply of the licensed compound.

### **8. Research Agreements**

*BA058-SC Phase 3 Clinical Study* 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 study (the "Phase 3 Clinical Study") of BA058-SC and is being compensated for such services in a combination of cash and shares of stock.

Table of Contents

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 study 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 (\$971,407) 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, 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 (\$16,162) per subject for any subjects enrolled in India or the United States. Such reductions shall be 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 (\$5.0 million) and \$205,540, respectively.

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 Study 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 Study schedule may alter the timing, but not the aggregate amounts of the payments.

The Work Statement NB-1, as amended on December 9, 2011 and June 18, 2012, provides for a total of up to approximately 41.2 million (\$55.7 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 Study. 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 Preferred Stock of the Former Operating Company at \$8.142 per share, and the Former Operating Company sold 64,430 shares of its Series A-5 Preferred Stock to Nordic on May 17, 2011 for proceeds of \$525,154. These shares were exchanged in the Merger for an aggregate of 6,443 shares of the Company's Series A-5.

The Stock Issuance Agreement provides that Nordic is entitled to receive quarterly stock dividends, payable in shares of Series A-6 or shares of common stock if the Company's preferred stock has been converted in accordance with its amended certificate of incorporation, having an aggregate value of up to 36.8 million (\$49.8 million) (the Nordic Accruing Dividend). In the event Nordic sells the shares of Series A-5 or in the event the shares of Series A-5 are converted into common stock in accordance with the Company's 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 or common stock, as applicable, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

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

The Nordic Accruing Dividend is determined based upon the estimated period that will be required to complete the Phase 3 Clinical Study. On the last business day of each calendar quarter (each, an Accrual Date), beginning with the quarter ended June 30, 2011, the Company has a liability to issue shares of Series A-6 (or common stock, after the conversion of the Company's preferred stock into common stock) to Nordic that is referred to as the Applicable Quarterly Amount and is equal to 36.8 million (\$49.8 million) (subject to adjustment in accordance with the provisions of the Second Amendment for patients enrolled in India and the U.S.) minus the aggregate value of any prior Nordic Accruing Dividend accrued divided by the number of calendar quarters it will take to complete the Phase 3 Clinical Study. To calculate the aggregate number of shares due to Nordic in each calendar quarter, the Company converts the portion of 36.8 million (\$49.8 million) to accrue in such calendar quarter into U.S. dollars using the simple average of the exchange rate for buying U.S. dollars with euros for all Mondays in such calendar quarter. The Company then calculates the aggregate number of shares to accrue in such calendar quarter by dividing the U.S. dollar equivalent of the Applicable Quarterly Amount, by the greater of (1) the fair market value as of the applicable Accrual Date or (2) \$8.142 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic will be issued when declared or paid by the Company's Board of Directors, who are required to do so upon Nordic's request, or upon an event of sale. As of September 30, 2013, 405,909 shares of Series A-6 were due to Nordic, or, after the automatic conversion into common stock of the Company's preferred stock, 4,059,090 shares of common stock.

Table of Contents

Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock is being accounted for as a liability in the Company's condensed balance sheet. As of September 30, 2013, the fair value of the liability is \$19.7 million based upon the fair value of the Series A-6 as determined using PWERM (see note 6). Changes in the fair value from the date of accrual to the date of issuance of the shares are recorded as a gain or loss in other (expense) income in the condensed statement of operations.

The Company recognizes research and development expense for the amounts due to Nordic under the Work Statement NB-1 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 3 Clinical Study, or a twenty-month period. The Company recorded \$7.6 million and \$8.5 million of research and development expense during the three months ended September 30, 2013 and 2012, respectively and \$25.5 million and \$20.3 million during the nine months ended September 30, 2013 and 2012, respectively, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Study.

As of September 30, 2013, in addition to the \$19.7 million liability that is reflected in other liabilities on the condensed balance sheet for the Nordic Accruing Dividend, as noted above, the Company has (1) a liability of \$4.5 million reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in the form of a stock dividend and (2) a liability of \$13.1 million that is reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in cash.

*BA058-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 BA058-SC Phase 3 Clinical Study (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 (\$1.1 million).

Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to 4.5 million (\$6.1 million) and \$579,495, respectively. In addition, the Company will issue to Nordic, shares of the Company's Series A-6 having a value of up to 4.5 million (\$6.1 million) and \$0.3 million, as additional payment for services to be provided under the Work Statement NB-3 and the Services Agreement.

The Stock Issuance Agreement provides 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 has been automatically converted into common stock in accordance with its amended certificate of incorporation, having an aggregate value of up to 4.5 million (\$6.1 million) and \$0.3 million. In the event Nordic sells the shares of Series A-5 or in the event the shares of Series A-5 are converted into common stock in accordance with the Company's 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 or common stock, as applicable, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

The Nordic Accruing Dividend related to the Extension Study is determined based upon the estimated period that will be required to complete the Extension Study. On each Accrual Date, beginning with the quarter ended March 31, 2013, the Company will recognize a liability to issue shares of Series A-6 to Nordic that is referred to as the Applicable Quarterly Amount and is equal to 4.5 million (\$6.1 million) and \$0.3 million minus the aggregate value of any prior Nordic Accruing Dividend related to the Extension Study divided by the number of calendar quarters it will take to complete the Extension Study. The Company calculates the aggregate number of shares of Series A-6 to accrue in such calendar

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

quarter by dividing the Applicable Quarterly Amount, by the greater of (1) the fair value as of the applicable Accrual Date or (2) \$8.142 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic will be issued when declared or paid by the Company's board of directors, who are required to do so upon Nordic's request, or upon an event of sale. As of September 30, 2013, 19,329 shares of Series A-6 are due to Nordic in connection with the Extension Study, or after the automatic conversion into common stock of the Company's preferred stock, 193,290 shares of common stock.

Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock is being accounted for as a liability in the Company's condensed balance sheet. As of September 30, 2013, the fair value of the liability is \$0.9 million 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 shares are recorded as a gain or loss in other (expense) income in the condensed statement of operations.

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

Table of Contents

As of September 30, 2013, in addition to the \$0.9 million liability that is reflected in other liabilities on the condensed balance sheet that will be settled in shares of stock, as noted above, the Company has (1) a liability of \$0.2 million reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in the form of a stock dividend and (2) a liability of \$0.7 million that is reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in cash.

*BA058-TD Phase 2 Clinical Study* On July 26, 2012, the Company entered into a Letter of Intent (the Letter of Intent ) with Nordic, which provides that the Company and Nordic will, 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 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 will provide clinical trial services relating to the Phase 2 Clinical Study and will 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 are denominated in both euros and U.S. dollars and total up to 3.6 million (\$4.9 million) and \$257,853, respectively. In addition, the Company will 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 Services Agreement.

The Stock Issuance Agreement provides that Nordic is entitled to receive quarterly stock dividends in connection with services performed under Work Statement NB-2, payable in shares of Series A-6, or shares of common stock if the Company's preferred stock has been automatically converted in accordance with its amended certificate of incorporation. In the event Nordic sells the shares of Series A-5 or in the event the shares of Series A-5 are converted into common stock in accordance with the Company's 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 or common stock, as applicable, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

The Nordic Accruing Dividend related to the Phase 2 Clinical Study is determined based upon the estimated period that will be required to complete the Phase 2 Clinical Study. On each Accrual Date, beginning with the quarter ended December 31, 2012, the Company will recognize a liability to issue shares of Series A-6 to Nordic that is referred to as the Applicable Quarterly Amount and is equal to up to \$2.9 million minus the aggregate value of any prior Nordic Accruing Dividend related to the Phase 2 Clinical Study divided by the number of calendar quarters it will take to complete the Phase 2 Clinical Study. The Company calculates the aggregate number of shares of Series A-6 to accrue in such calendar quarter by dividing the Applicable Quarterly Amount, by the greater of (1) the fair value as of the applicable Accrual Date or (2) \$8.142 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic will be issued when declared or paid by the Company's board of directors, who are required to do so upon Nordic's request, or upon an event of sale. As of September 30, 2013, 32,215 shares of Series A-6 are due to Nordic in connection with the Phase 2 Clinical Study, or after the automatic conversion into common stock of the Company's preferred stock, 322,150 shares of common stock.

Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock is being accounted for as a liability in the Company's condensed balance sheet. As of September 30, 2013, the fair value of the liability is \$1.6 million 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 shares are recorded as a gain or loss in other (expense) income in the condensed statement of operations.

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

The Company recognizes 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 Study, or a nine-month period. The Company recorded \$0.6 million and \$0.1 million of research and development expense during the three months ended September 30, 2013 and 2012, respectively, and \$4.1 million and \$0.1 million during the nine months ended September 30, 2013 and 2012, respectively, for per patient costs incurred for patients that had enrolled in the Phase 2 Clinical Study. Additionally, the Company recorded approximately \$0.9 million of research and development expense associated with the costs incurred for preparatory and other start-up costs to initiate the Phase 2 Clinical Study during the three months ended September 30, 2012.

As of September 30, 2013, in addition to the \$1.6 million liability that is reflected in other liabilities on the condensed balance sheet that will be settled in shares of stock, as noted above, the Company has a liability of \$0.5 million that is reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in cash.

The Company is also responsible for certain pass-through costs in connection with the Phase 3 Clinical Study, Extension Study and Phase 2 Clinical Study. Pass through costs are expensed as incurred or upon delivery. The Company recognized research and

Table of Contents

development expense of \$1.3 million and \$0.5 million for pass-through costs during the three months ended September 30, 2013 and 2012, and \$3.3 million and \$5.4 million for the nine months ended September 30, 2013 and 2012, respectively.

**9. Stock-Based Compensation**

A summary of stock option activity during the nine months ended September 30, 2013 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, 2012	3,899	\$ 3.10		
Granted				
Exercised	(12)	1.10		
Cancelled	(13)	3.22		
Options outstanding at September 30, 2013	3,874	\$ 3.11	7.32	\$ 2,355
Options exercisable at September 30, 2013	2,281	\$ 2.65	6.71	\$ 2,239
Options vested or expected to vest at September 30, 2013	3,732	\$ 3.08	7.29	\$ 2,350

The total grant-date fair value of stock options that vested during the three and nine months ended September 30, 2013 was approximately \$0.7 million and \$2.3 million, respectively.

As of September 30, 2013, there was approximately \$2.7 million of total unrecognized compensation expense related to unvested employee stock options, which is expected to be recognized over a weighted-average period of approximately two years.

**10. Net Loss Per Share**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Numerator:				
Net loss	\$ (20,342)	\$ (17,530)	\$ (48,159)	\$ (48,363)
Accretion of Preferred Stock	(4,748)	(3,560)	(12,698)	(10,370)

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

Loss attributable to common stockholders - basic and diluted	\$	(25,090)	\$	(21,090)	\$	(60,857)	\$	(58,733)
Denominator:								
Weighted-average number of common shares used in (loss) earnings per share - basic and diluted		879,370		859,769		872,195		830,068
(Loss) earnings per share - basic and diluted	\$	(28.53)	\$	(24.53)	\$	(69.77)	\$	(70.76)

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, 2013 and 2012, 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		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Convertible preferred stock	12,128,879	4,758,216	10,495,608	4,161,270
Options to purchase common stock	3,875,614	3,934,488	3,888,660	3,887,672
Warrants	1,768,091	15,000	1,042,276	15,000

Table of Contents

**11. Commitments and Contingencies**

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

**12. Subsequent Events**

On November 11, 2013 (the Resignation Date ), Michael S. Wyzga resigned as the President and Chief Executive Officer and as a member of the Board of Directors (the Board ) of the Company and entered into a Separation and Release Agreement (the Separation Agreement ) with the Company. In connection with such resignation, Mr. Wyzga also entered into a letter agreement (the Advisory Letter ) with the Company pursuant to which Mr. Wyzga will provide transition advisory services for the Company during a period commencing on the Resignation Date and ending up to 6 months thereafter (the Advisory Period ).

Pursuant to the Separation Agreement, Mr. Wyzga agreed to a general release of claims and the Company agreed to provide the severance payments contemplated by the terms of the employment letter agreement entered into between the Company and Mr. Wyzga on December 1, 2011, which include payments totaling \$500,000 (an amount equal to Mr. Wyzga s annual base salary as of the Resignation Date) to be made over the 12 month period following the Resignation Date in accordance with the Company s normal payroll procedures, and payment of continued medical care premiums necessary for Mr. Wyzga to continue to participate in the Company s group medical plan during such 12 month period. In addition, Mr. Wyzga is entitled, as part of such severance payments, to his prorated calendar year 2013 discretionary cash performance bonus under the Company s bonus plan or program applicable to senior executives based on a target bonus amount equal to 50% of Mr. Wyzga s annualized base salary, but with the actual amount of any such bonus being determined on the basis of the attainment of Company performance metrics and/or individual performance objectives, in each case, as established and approved by the Board in its sole discretion. Pursuant to the Advisory Letter, the stock options held by Mr. Wyzga to purchase shares of the Company s common stock will continue to vest while Mr. Wyzga provides services to the Company during the Advisory Period and will remain exercisable for three months following the Advisory Period.

The Board appointed Andrew J. Fromkin to the Board and as the Company s President and Chief Executive Officer, effective as of November 12, 2013.

Table of Contents

**Item 2. Management's Discussion and Analysis of Financial Condition and results of Operation**

***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 BA058, RAD1901, and RAD140 for commercialization activities with target characteristics;*
- *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;*
- *our ability to attract and motivate key personnel; and*
- *other factors discussed elsewhere in this Quarterly Report on Form 10-Q.*

*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*

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

*important factors include our financial performance, our ability to attract and retain customers, our development activities and those factors we discuss in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 15, 2013 under the caption Risk Factors. You should read these factors and the other cautionary statements made in this Quarterly Report on Form 10-Q as being applicable to all related forward-looking statements wherever they appear in this Quarterly Report on Form 10-Q. These 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 Operation section refer to Radius Health, Inc., a Delaware corporation, or Radius.

Table of Contents

**Overview**

We are a biopharmaceutical company focused on developing new therapeutics for the treatment of osteoporosis and other women's health conditions. We have three product candidates in development, the most advanced of which is BA058. We began dosing subjects in a pivotal Phase 3 clinical study of BA058-SC, a daily subcutaneous injection of novel synthetic peptide analog of human parathyroid hormone, or hPTHrP, used for the prevention of fractures in women suffering from osteoporosis in April 2011 and completed enrollment in March 2013. We are also developing BA058-TD, a short wear time, transdermal form of BA058 that is based on a microneedle patch technology from 3M. We believe that BA058-TD may eliminate the need for injections and lead to better treatment compliance for patients. We commenced a Phase 2 clinical study of BA058-TD during the third quarter of 2012 and completed patient visits in August 2013. Our second clinical-stage product candidate is RAD1901, which is in Phase 2 clinical development for the treatment of vasomotor symptoms, commonly known as hot flashes, in women entering menopause. We are also exploring the use of RAD1901 as a potential treatment for breast cancer brain metastasis, or BCBM. We have conducted a number of preclinical studies which have provided early proof of concept in application to BCBM and are currently reviewing strategic alternatives with respect to the future development of the product for this treatment. Our third product candidate, RAD140, is in preclinical development and is a potential treatment for age-related muscle loss, frailty, and weight loss associated with cancer cachexia and osteoporosis.

BA058 is a novel synthetic peptide analog of hPTHrP that we are developing as a bone anabolic treatment for osteoporosis. Unlike PTH, hPTHrP is a critical cytokine for the regulation of bone formation, able to rebuild bone with low associated risk of inducing hypercalcemia as a side effect. In August 2009, we announced positive Phase 2 data that showed BA058-SC produced faster and greater bone mineral density, or BMD, increases at the spine and the hip after six months and 12 months of treatment than did Forteo, which was a comparator in our study. Key findings were that the highest dose of BA058 tested of 80 µg increased mean lumbar spine BMD at six months and 12 months by 6.7% and 12.9% compared to the increases seen with Forteo trial arms of 5.5% and 8.6%, respectively. BA058 also produced increases in mean femoral neck BMD at the hip at six months and 12 months of 3.1% and 4.1% compared to increases for Forteo of 1.1% and 2.2%, respectively. We believe there is a strong correlation between an increased level of BMD and a reduction in the risk of fracture for patients with osteoporosis. BA058 was generally safe and well tolerated in this study, with adverse events similar between BA058, placebo and Forteo groups. In addition, the occurrence of hypercalcemia as a side effect for the 80 µg dose of BA058 was half that seen with Forteo.

In April 2011, we began the dosing of subjects in a pivotal Phase 3 clinical study 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 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 (µg) of BA058, a matching placebo, or the approved dose of 20 µg of Forteo for 18 months. The study will also include a 6-month extension period in order to obtain 24-months of fracture data, as requested by the FDA. We plan to file the New Drug Application, or NDA, with the 18-month fracture data and supplementally provide the 24-month fracture data, when available. We believe the study is powered to show that BA058 is superior to placebo for prevention of vertebral fracture. We believe the study is also powered to show that BA058 is superior to Forteo for greater BMD improvement at major skeletal sites and for a lower occurrence of hypercalcemia, a condition in which the calcium level in a patient's blood is above normal. We expect to report top-line 18-month fracture data from this study in the fourth quarter of 2014.

In September 2013, we received the top-line data for the BA058 Phase 2 clinical trial, which tested BA058-SC and BA058-TD. The BA058 Phase 2 clinical trial was a 6-month randomized, placebo-controlled study of 250 healthy postmenopausal women with osteoporosis, designed to assess changes in lumbar spine BMD for BA058-TD and BA058-SC. In addition, hip and forearm BMD, pharmacokinetic parameters and serum markers of bone metabolism, as well as safety and tolerability were measured. Subjects were randomized to receive one of the following: (1) 50 µg of BA058-TD, (2) 100 µg of BA058-TD, (3) 150 µg of BA058-TD, (4) 80 µg of BA058-SC, or (5) placebo-TD, once daily for six months. The transdermal patches were applied to the skin and removed after five minutes. All doses of BA058-TD and BA058-SC were well tolerated and there were no treatment-related serious adverse events reported in the study.



## Table of Contents

As in our prior Phase 2 study of BA058-SC, the preliminary data for patients who received the 80 µg dose of BA058-SC in the current BA058 Phase 2 study demonstrated consistent increases in BMD from baseline in the lumbar spine (5.8% increase from baseline) and total hip (2.7% increase from baseline). In addition to the BMD results, these study results add to the safety data from the prior Phase 2 study with BA058-SC, which demonstrated that BA058 was generally safe and well tolerated.

The top-line results demonstrated that, for each BA058-TD dose, there was a statistically significant mean percent increase from baseline in BMD, as compared to placebo at the lumbar spine. For the 100 µg and 150 µg BA058-TD doses, there was also a statistically significant mean percent increase from baseline in BMD at the hip, as compared to placebo. The highest BA058-TD dose of 150 µg produced increases in BMD from baseline in the lumbar spine and total hip of +2.9% and +1.5%, respectively, compared to increases in placebo of +0.04% and -0.02%, respectively. In addition, there was a consistent dose effect seen with increasing doses of BA058-TD, with a statistically significant dosing trend seen for changes in both spine and total hip BMD, and patient ratings of patch adhesion and local skin response to the transdermal patch technology showed acceptable evidence of patient tolerability. In an initial analysis, detectable antibodies against BA058 were noted in a subset of patients. However, these antibodies were of low titer, and there was no evidence of an effect on safety or attenuation of treatment efficacy.

We believe that the top-line results of the BA058 Phase 2 clinical trial are clinically relevant and support the continued development of an injection-free delivery system. Accordingly, we are evaluating the next steps in the development of BA058-TD. Based upon the current expected path of development within Radius, we have updated our expectations with respect to the filing of an NDA submission for BA058-TD to mid-2019.

Our efforts and resources are focused primarily on developing BA058 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 approval for BA058-SC from the FDA, or equivalent foreign regulatory bodies. However, developing pharmaceutical products is a lengthy and very expensive process. Assuming we do not encounter any unforeseen delays during the course of developing BA058, we expect to complete development and file the NDA submission for BA058-SC by mid-2015. Accordingly, our success depends not only on the safety and efficacy of BA058, but also on our ability to finance the development of these products, which will require substantial additional funding to complete development and file for marketing approval. Our ability to raise this additional financing will depend on our ability to execute on the BA058 development plan, manage and coordinate, on a cost-effective basis, all the required components of the NDA submission for BA058-SC and scale-up BA058-SC and BA058-TD manufacturing capacity. In addition, we currently have no sales, marketing or distribution capabilities and thus our ability to market BA058 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.

## **Financial Overview**

### *Research and Development Expenses*

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

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

None of the research and development expenses in relation to our product candidates are currently borne by third parties. Our lead product candidate is BA058 and it represents the largest portion of our research and development expenses for our product candidates. We began tracking program expenses for BA058-SC in 2005, and program expenses from inception to September 30, 2013 were approximately \$133.8 million. We began tracking program expenses for BA058-TD in 2007, and program expenses from inception to September 30, 2013 were approximately \$29.0 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to September 30, 2013 were approximately \$15.5 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to September 30, 2013 were approximately \$5.2 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs. Costs related to facilities, depreciation, share-based compensation and research and development support services are not directly charged to programs as they benefit multiple research programs that share resources.

Table of Contents

We expect that future development costs related to the BA058-SC and BA058-TD programs will increase through possible marketing approval in the United States for BA058-SC in mid-2016 and for BA058-TD in mid-2020. For BA058-SC, we estimate that future development costs may exceed \$72.0 million, including \$42.0 million for clinical costs, \$23.0 million for license and milestone payments and NDA filing fees, \$2.0 million for preclinical costs and \$5.0 million for manufacturing costs. For BA058-TD, we estimate that future development costs may exceed \$46.0 million, including \$35.0 million for clinical costs, \$9.0 million for manufacturing costs, \$2.0 million for preclinical costs and NDA filing fees. As a portion of the development costs for BA058-SC and BA058-TD are to be settled in shares of our series A-6 convertible preferred stock, the amount of future development costs will be affected by changes in the fair value of the series A-6 convertible preferred stock (see notes 6 and 8 to the condensed quarterly financial statements for the three and nine months ended September 30, 2013).

We expect to finance the future development costs of BA058 with our existing cash and cash equivalents and marketable securities, future offerings of our common stock or preferred stock, or through other strategic financing opportunities. In addition, our current strategy is to collaborate with third parties for the further development and commercialization of RAD1901 and RAD140. Therefore, we do not expect that we will incur substantial future costs for these programs because we expect these costs to be borne by third parties. Our ability to further develop these product candidates will be dependent upon our ability to secure third-party collaborators. Therefore, it is not possible to project the future development costs for RAD1901 and RAD140 or possible marketing approval timeline at this time.

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 such product development. If we are unable to continue to fund the development of RAD1901 and/or RAD140 and are unable to secure third-party collaborators for these product candidates, our business will be adversely affected and we will depend solely on the successful development, regulatory approval and commercialization of BA058-SC and BA058-TD.

The successful development of BA058-SC and BA058-TD is subject to numerous risks and uncertainties associated with developing drugs, including 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.

BA058-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 other regulatory authorities. Obtaining approval of an NDA is an extensive, lengthy, expensive and uncertain process, and any approval of BA058-SC may be delayed, limited or denied for many reasons, including:

- we may not be able to demonstrate that BA058 is safe and effective as a treatment for osteoporosis to the satisfaction of the FDA;
- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the clinical research organization, or CRO, that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;

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

- the FDA may not find the data from preclinical studies and clinical studies sufficient to demonstrate that BA058's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;
- the FDA 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 may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

In addition, the FDA 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-months of fracture data is necessary for approval of new products for the treatment of postmenopausal osteoporosis, and our ongoing BA058-SC pivotal Phase 3 clinical study is designed to produce fracture data based on an 18-month primary endpoint. Based on our discussions with the agency, 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 BA058 80 µg and placebo groups in our Phase 3 clinical study that will receive

Table of Contents

an approved alendronate (generic Fosamax®) therapy for osteoporosis management. We plan to file the NDA with the 18-month fracture data and supplementally provide the 24-month fracture data, when available. We cannot be certain that the FDA will be supportive of this plan, will not change this approval policy again or adopt approval policies or regulations that adversely affect any NDA that we may submit.

The following table sets forth our research and development expenses related to BA058-SC, BA058-TD, RAD1901 and RAD140 for the three and nine months ended September 30, 2013 and 2012 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
BA058-SC	\$ 11,815	\$ 11,435	\$ 35,753	\$ 31,601
BA058-TD	2,942	1,562	10,867	3,771
RAD1901		8		8
RAD140				18

*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 general and administrative expenses may increase as a result of any listing of our securities on a national securities exchange due to the higher costs of being a publically traded company.

Our results also include stock-based compensation expense as a result of the issuance of stock and stock option grants to employees, directors and consultants. The stock-based compensation expense is included in the respective categories of expense in the condensed statement of operations (research and development and general and administrative expenses). We expect to record additional non-cash 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, or the Credit Facility, entered into on May 23, 2011 with General Electric Capital Corporation, or GECC, as agent and lender, and Oxford Finance, as a lender. 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. In connection with the funding of the term loans, we issued warrants to purchase up to 12,280 shares of our series A-1 convertible preferred stock at an exercise price of \$81.42 per share, which exercise price, as a result of an anti-dilution adjustment effected in connection with our issuance of the Series B Shares and warrants pursuant to the Purchase Agreement, has been reduced to \$76.27.

*Other (Expense) Income*

For the three and nine months ended September 30, 2013 and 2012, other (expense) income primarily reflects changes in the fair value of the series A-6 convertible preferred stock liability from the date of the initial accrual to the reporting date as discussed in note 6 to our condensed quarterly financial statements for the three and nine months ended September 30, 2013.

**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, 2012. 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.

Table of Contents

We have reviewed our policies and estimates to determine our critical accounting policies for the three and nine months ended September 30, 2013. 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, 2012.

**Results of Operations**

The following discussion summarizes the key factors our management believes are necessary for an understanding of our financial statements.

*Three Months Ended September 30, 2013 and September 30, 2012 (in thousands, except percentages)*

	Three Months Ended September 30,		Change	
	2013	2012	\$	%
<b>Operating expenses:</b>				
Research and development	\$ 15,543	\$ 14,173	\$ 1,370	10%
General and administrative	1,621	1,918	(297)	-15%
Loss from operations	(17,164)	(16,091)	1,073	7%
<b>Other (expense) income:</b>				
Other (expense) income, net	(2,607)	(604)	2,003	332%
Interest (expense) income, net	(571)	(835)	(264)	-32%
Net Loss	\$ (20,342)	\$ (17,530)	\$ 2,812	16%

*Research and development expenses* For the three months ended September 30, 2013, research and development expense was \$15.5 million compared to \$14.2 million for the three months ended September 30, 2012, an increase of \$1.4 million, or 10%. During the three months ended September 30, 2013, we incurred professional contract services associated with the development of BA058-SC and BA058-TD of \$14.8 million, compared to \$13.0 million for the three months ended September 30, 2012. This increase was primarily the result of our Phase 2 clinical study of BA058-TD, which began dosing patients in September 2012 and completed patient visits in August 2013, as well as our Phase 3 clinical study of BA058-SC. We expect that BA058-SC expenses will be maintained or increase over the course of the clinical study. However, there will be variability from quarter to quarter in the costs for BA058-SC, driven primarily by the euro/dollar exchange rate and fluctuations in the value of the convertible preferred stock issuable to Nordic under a Stock Issuance Agreement between us and Nordic, or the Stock Issuance Agreement, which is more fully described below under Research and Development Agreements .

*General and administrative expenses* For the three months ended September 30, 2013, general and administrative expense was \$1.6 million compared to \$1.9 million for the three months ended September 30, 2012, a decrease of \$0.3 million, or 15%. The decrease was primarily the result of lower legal expenses incurred during the three months ended September 30, 2013, as compared to the three months end September 30, 2012.

*Other (expense) income, net* For the three months ended September 30, 2013, other expense, net of other income, was \$2.6 million. Other expense, net of other income, primarily reflects changes in the fair value of the stock liability and other liability as discussed in notes 6 and 8 to

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

our condensed quarterly financial statements for the three and nine months ended September 30, 2013. 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, 2013, interest expense, net of interest income, was \$0.6 million compared to \$0.8 million for the three months ended September 30, 2012, a decrease of \$0.3 million, or 32%. This decrease was

Table of Contents

primarily a result of lower average debt outstanding during the three months ended September 30, 2013 as compared to the three months ended September 30, 2012.

*Nine Months Ended September 30, 2013 and September 30, 2012 (in thousands, except percentages)*

	Nine Months Ended September 30,		Change	
	2013	2012	\$	%
<b>Operating expenses:</b>				
Research and development	\$ 49,070	\$ 38,539	\$ 10,531	27%
General and administrative	4,643	6,209	(1,566)	-25%
Loss from operations	(53,713)	(44,748)	8,965	20%
<b>Other (expense) income:</b>				
Other income (expense), net	7,465	(1,788)	(9,253)	-518%
Interest (expense) income, net	(1,911)	(1,827)	84	5%
Net Loss	\$ (48,159)	\$ (48,363)	\$ (204)	0%

*Research and development expenses* For the nine months ended September 30, 2013, research and development expense was \$49.1 million compared to \$38.5 million for the nine months ended September 30, 2012, an increase of \$10.5 million, or 27%. During the nine months ended September 30, 2013, we incurred professional contract services associated with the development of BA058-SC and BA058-TD of \$46.6 million, compared to \$35.4 million for the nine months ended September 30, 2012. This increase was primarily the result of additional expenses incurred for the enrollment of patients in our Phase 3 clinical study of BA058-SC, which began with the dosing of patients in April 2011 and completed enrollment in March 2013, and for the enrollment of patients in our Phase 2 clinical study of BA058-TD, which began dosing patients in September 2012 and completed patient visits in August 2013. We expect that BA058-SC expenses will be maintained or increase over the course of the clinical study. However, there will be variability from quarter to quarter in the costs for BA058-SC, driven primarily by the euro/dollar exchange rate and fluctuations in the value of the convertible preferred stock issuable to Nordic under the Stock Issuance Agreement, which is more fully described below under Research and Development Agreements .

*General and administrative expenses* For the nine months ended September 30, 2013, general and administrative expense was \$4.6 million compared to \$6.2 million for the nine months ended September 30, 2012, a decrease of \$1.6 million, or 25%. This decrease was primarily the result of significant fees incurred during the nine months ended September 30, 2012 for consulting and legal costs associated with the filing of our first Form 10-K as a public company with the Securities and Exchange Commission and a one-time non-recurring consultation fee of approximately \$0.3 million, as well as a decrease in the amount of excise tax expense recognized during the nine months ended September 30, 2013, as compared to the nine months ended September 30, 2012.

*Other income (expense)* For the nine months ended September 30, 2013, other income, net of other expense, was \$7.5 million. Other income, net of other expense, primarily reflects changes in the fair value of the stock liability and other liability as discussed in notes 6 and 8 to our condensed quarterly financial statements for the three and nine months ended September 30, 2013. The \$7.5 million of other income, net of 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 an overall decline in the fair value of the underlying convertible preferred stock from December 31, 2012 to September 30, 2013.



Table of Contents

*Interest (expense) income* For the nine months ended September 30, 2013, interest expense, net of interest income, was \$1.9 million, which was consistent with the interest expense, net of interest income, incurred during the nine months ended September 30, 2012

***Liquidity and Capital Resources***

From inception to September 30, 2013, we have incurred an accumulated deficit of \$260.3 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. We believe that our existing cash and cash equivalents and marketable securities will be sufficient to fund our operations into the first quarter of 2014. Accordingly, we plan to pursue financing opportunities to address our future capital needs, including the completion of an additional private placement or public offering and other strategic financing alternatives that could include, but are not limited to, partnering or other collaboration agreements. However, there is no guarantee that any of these financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If 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 regulatory authorities.

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. We have also borrowed \$25.0 million under our Credit Facility in three term loans. Our total cash, cash equivalents and marketable securities balance as of September 30, 2013 is \$29.7 million.

The following table sets forth the major sources and uses of cash for the nine months ended September 30, 2013 and 2012 (in thousands):

	Nine Months Ended		Change	
	September 30, 2013	2012	\$	%
Net cash (used in) provided by:				
Operating activities	\$ (29,859)	\$ (32,032)	\$ (2,173)	-7%
Investing activities	(6,277)	16,770	(23,047)	-137%
Financing activities	36,976	10,583	26,393	249%
Net increase (decrease) in cash and cash equivalents	\$ 840	\$ (4,679)		

***Cash Flows from Operating Activities***

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 BA058-SC and our Phase 2 clinical study of BA058-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, and was 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.

Net cash used in operating activities for the nine months ended September 30, 2012 was \$32.0 million, which was primarily the result of a net loss of \$48.4 million, partially offset by \$10.4 million of non-cash adjustments to reconcile net loss to net cash used in operations, including \$6.9 million of research and development expenses settled in stock, and \$5.9 million of changes in working capital. The \$48.4 million net loss and \$6.9 million of research and development expenses settled in stock were primarily due to expenses incurred in connection with our ongoing Phase 3 clinical study of BA058-SC which commenced in April 2011.

*Cash Flows from Investing Activities*

Net cash used in investing activities for the nine months ended September 30, 2013 was \$6.3 million, as compared to net cash provided by investing activities of \$16.8 million for the nine months ended September 30, 2012.

The net cash used in investing activities during the nine months ended September 30, 2013 was primarily a result of \$17.1 million in purchases of marketable securities, partially offset by \$10.8 million net proceeds received from the sale or maturity of marketable

Table of Contents

securities. The net cash provided by investing activities during the nine months ended September 30, 2012 was primarily a result of \$35.7 million in proceeds from the sale or maturity of marketable securities, partially offset by \$19.0 million in purchases 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.

*Cash Flows from Financing Activities*

Net cash provided by financing activities for the nine months ended September 30, 2013 was \$37.0 million, as compared to \$10.6 million net cash provided by financing activities for the nine months ended September 30, 2012.

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 Credit Facility of \$5.9 million.

Net cash provided by financing activities for the nine months ended September 30, 2012 included \$12.5 million of net proceeds from our Credit Facility and \$0.3 million of net proceeds from stock option exercises, partially offset by \$2.2 million of payments under our Credit Facility.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing and potential collaboration agreements. Through September 30, 2013, almost all of our financing has been through private placements of preferred stock and borrowings under our Credit Facility. 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.

*Financings*

On April 23, 2013, we entered into a Series B Convertible Preferred Stock and Warrant Purchase Agreement, or the Purchase Agreement, pursuant to which we could raise, at any time on or prior to May 10, 2013, up to approximately \$60.0 million through the issuance of (1) up to 980,000 shares of series B convertible preferred stock, or the Series B Shares and (2) warrants to acquire up to 2,450,000 shares of our common stock with an exercise price of \$6.142 per share. On April 23, 2013, we consummated a first closing under the Purchase Agreement, whereby in exchange for aggregate proceeds of approximately \$43.0 million, we issued 700,098 Series B Shares and warrants to purchase up to a total of 1,750,248 shares of our common stock. On May 10, 2013, we consummated a second closing under the Purchase Agreement, whereby in

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

exchange for aggregate proceeds of approximately \$0.1 million, we issued 1,137 Series B Shares and warrants to purchase up to a total of 2,843 shares of our common stock.

Shares of the Company's Series B convertible preferred stock, or the Series B, are convertible, in whole or in part, at the option of the holder at any time into shares of common stock, on a ten-for-one basis at an initial effective conversion price of \$6.142 per share. Holders of shares of Series B are 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. Dividends are payable, as accrued, upon liquidation, event of sale, and conversion to common stock, including upon mandatory conversion of the Series B upon the Company's common stock becoming listed for trading on a national stock exchange. The holders of shares of Series B are also entitled to dividends declared or paid on any shares of common stock.

The Series B Shares rank senior in payment to any other dividends payable on any and all series of our preferred stock and upon liquidation, or an event of sale, each share of Series B shall rank equally with each other share of Series B, senior to all shares of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock, Series A-3 convertible preferred stock, Series A-4 convertible preferred stock, Series A-5 convertible preferred stock and Series A-6 convertible preferred stock, or collectively, our Series A Preferred Stock, 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 are entitled to be paid first out of the assets available for distribution, before any payment is made to our Series A Preferred Stock. Payment to the holders of Series B shall consist of two (2) times the original issuance price of \$61.42, plus all accrued but unpaid dividends.

Each share of Series B has 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 is then convertible.

Table of Contents

The warrants issuable pursuant to the Purchase Agreement are exercisable at any time prior to April 23, 2018 and May 10, 2018.

The issuance of the Series B Shares and accompanying warrants under the Purchase Agreement resulted in an adjustment to the Conversion Price of the Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series A-3 convertible preferred stock, or the Anti-Dilution Adjustment. As a result of the Anti-Dilution Adjustment, the effective conversion price of each share of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series A-3 convertible preferred stock was reduced from \$8.142 to \$7.627. Accordingly, each share of Series A-1, Series A-2 and Series A-3 is currently convertible into 10.675 shares of our common stock.

***Research and Development Agreements***

***BA058-SC Phase 3 Clinical Study*** On March 29, 2011, we and Nordic entered into a Clinical Trial Services Agreement, a Work Statement NB-1, or the Work Statement NB-1, under such 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 study, or the Phase 3 Clinical Study, of BA058-SC and will be compensated for such services in a combination of cash and shares of stock.

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 study 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 (\$971,407) 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 (\$16,162) per subject for any subjects enrolled in India or the United States. Such reductions shall be 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 (\$5.0 million) and \$205,540, respectively.

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 Study 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 Study schedule may alter the timing, but not the aggregate amounts of the payments.

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

The Work Statement NB-1, as amended on December 9, 2011 and June 18, 2012, provides for a total of up to approximately 41.2 million (\$55.7 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 Study. 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 of our former operating company at \$8.142 per share, and our former operating company sold 64,430 shares of series A-5 convertible preferred stock 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 1 to the condensed quarterly financial statements for the three and nine months ended September 30, 2013) for an aggregate of 6,443 shares of our series A-5 convertible preferred stock.

The Stock Issuance Agreement provides that Nordic is 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 has been converted in accordance with its amended certificate of incorporation, having an aggregate value of up to 36.8 million (\$49.8 million), or the Nordic Accruing Dividend. In the event Nordic sells the shares of series A-5 convertible preferred stock or in the event the shares of series A-5 convertible preferred stock are converted into common stock in accordance with our amended certificate of incorporation, this right to receive the Nordic

Table of Contents

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

The Nordic Accruing Dividend is determined based upon the estimated period that will be required to complete the Phase 3 Clinical Study. On the last business day of each calendar quarter, each, an Accrual Date, beginning with the quarter ended June 30, 2011, we have a liability to issue shares of series A-6 convertible preferred stock (or common stock, after the conversion of our preferred stock into common stock) to Nordic that is referred to as the Applicable Quarterly Amount and is equal to up to 36.8 million (\$49.8 million) (subject to adjustment in accordance with the provisions of the Second Amendment for patients enrolled in India and the U.S.) minus the aggregate value of any prior Nordic Accruing Dividend accrued divided by the number of calendar quarters it will take to complete the Phase 3 Clinical Study. To calculate the aggregate number of shares due to Nordic in each calendar quarter, we convert the portion of 36.8 million (\$49.8 million) to accrue in such calendar quarter into U.S. dollars using the simple average of the exchange rate for buying U.S. dollars with euros for all Mondays in such calendar quarter. We then calculate the aggregate number of shares to accrue in such calendar quarter by dividing the U.S. dollar equivalent of the Applicable Quarterly Amount, by the greater of (1) the fair value as of the applicable Accrual Date or (2) \$8.142 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic will be issued when declared or paid by our board of directors, who are required to do so upon Nordic's request, or upon an event of sale. As of September 30, 2013, 405,090 shares of our series A-6 convertible preferred stock were due to Nordic, or, after the automatic conversion into common stock of our preferred stock, 4,059,090 shares of our common stock.

Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock is being accounted for as a liability in our condensed balance sheet. As of September 30, 2013, the fair value of the liability is \$19.7 million based upon the fair value of the series A-6 convertible preferred stock as determined using a probability-weighted expected return model, or PWERM (see note 6 to our quarterly condensed financial statements). Changes in the fair value from the date of accrual to the date of issuance of the shares are recorded as a gain or loss in other (expense) income in the condensed statement of operations.

We recognize research and development expense for the amounts due to Nordic under the Work Statement NB-1 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 3 Clinical Study, or a twenty-month period. We recorded \$7.6 million and \$8.5 million of research and development expense during the three months ended September 30, 2013 and 2012, respectively, and \$25.5 million and \$20.3 million during the nine months ended September 30, 2013 and 2012, respectively, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Study.

As of September 30, 2013, in addition to the \$19.7 million liability that is reflected in other liabilities on the condensed balance sheet for the Nordic Accruing Dividend, as noted above, we have (1) a liability of \$4.5 million reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in the form of a stock dividend and (2) a liability of \$13.1 million that is reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in cash.

*BA058-SC Phase 3 Clinical Extension Study* In February 2013, we entered into 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 BA058-SC Phase 3 Clinical Study, 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 (\$1.1 million).

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

Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to 4.5 million (\$6.1 million) and \$579,495, respectively. In addition, we will issue to Nordic shares of our series A-6 convertible preferred stock having a value of up to 4.5 million (\$6.1 million) and \$0.3 million, as additional payment for services to be provided under the Work Statement NB-3 and the Services Agreement.

The Stock Issuance Agreement provides 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 has been automatically converted into common stock in accordance with our amended certificate of incorporation. In the event Nordic sells the shares of series A-5 convertible preferred stock or in the event the shares of series A-5 convertible preferred stock are 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, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

Table of Contents

The Nordic Accruing Dividend related to the Extension Study is determined based upon the estimated period that will be required to complete the Extension Study. On each Accrual Date, beginning with the quarter ended March 31, 2013, we will recognize a liability to issue shares of series A-6 convertible preferred stock to Nordic that is referred to as the Applicable Quarterly Amount and is equal to 4.5 million (\$6.1 million) and \$0.3 million minus the aggregate value of any prior Nordic Accruing Dividend related to the Extension Study divided by the number of calendar quarters it will take to complete the Extension Study. We calculate the aggregate number of shares of series A-6 convertible preferred stock to accrue in such calendar quarter by dividing the Applicable Quarterly Amount, by the greater of (1) the fair value as of the applicable Accrual Date or (2) \$8.142 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic will be issued when declared or paid by our board of directors, who are required to do so upon Nordic's request, or upon an event of sale. As of September 30, 2013, 19,329 shares of series A-6 convertible preferred stock are due to Nordic in connection with the Extension Study, or after the automatic conversion into common stock of our preferred stock, 193,290 shares of common stock.

Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock is being accounted for as a liability in our condensed balance sheet. As of September 30, 2013, the fair value of the liability is \$0.9 million based upon the fair value of the series A-6 convertible preferred stock as determined using PWERM. Changes in the fair value from the date of accrual to the date of issuance of the shares are recorded as a gain or loss in other (expense) income in the condensed statement of operations.

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

As of September 30, 2013, in addition to the \$0.9 million liability that is reflected in other liabilities on the condensed balance sheet that will be settled in shares of stock, as noted above, we have (1) a liability of \$0.2 million reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in the form of a stock dividend and (2) a liability of \$0.7 million that is reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in cash.

*BA058-TD Phase 2 Clinical Study* On July 26, 2012, we entered into a Letter of Intent, or the Letter of Intent, with Nordic, which provides that we and Nordic will, subject to compliance by us 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, or the Work Statement NB-2, a draft of which is attached to the 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 will provide clinical trial services relating to the Phase 2 Clinical Study and will 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 are denominated in both euros and U.S. dollars and total up to 3.6 million (\$4.9 million) and \$257,853, respectively. In addition, we will 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 Services Agreement.

The Stock Issuance Agreement provides that Nordic is entitled to receive quarterly stock dividends in connection with services performed under Work Statement NB-2, payable in shares of series A-6 convertible preferred stock, or shares of common stock if our preferred stock has been automatically converted in accordance with its amended certificate of incorporation. In the event Nordic sells the shares of series A-5

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

convertible preferred stock or in the event the shares of series A-5 convertible preferred stock are 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, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

The Nordic Accruing Dividend related to the Phase 2 Clinical Study is determined based upon the estimated period that will be required to complete the Phase 2 Clinical Study. On each Accrual Date, beginning with the quarter ended December 31, 2012, we will recognize a liability to issue shares of series A-6 convertible preferred stock to Nordic that is referred to as the Applicable Quarterly Amount and is equal to up to \$2.9 million minus the aggregate value of any prior Nordic Accruing Dividend related to the Phase 2 Clinical Study divided by the number of calendar quarters it will take to complete the Phase 2 Clinical Study. We calculate the aggregate number of shares of series A-6 convertible preferred stock to accrue in such calendar quarter by dividing the Applicable Quarterly Amount, by the greater of (1) the fair value as of the applicable Accrual Date or (2) \$8.142 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic will be issued when declared or paid by our board of directors, who are required to do so upon Nordic's request, or upon an event of sale. As of September 30, 2013, 32,215 shares of series A-6

Table of Contents

convertible preferred stock are due to Nordic in connection with the Phase 2 Clinical Study, or after the automatic conversion into common stock of our preferred stock, 322,150 shares of common stock.

Prior to the issuance of shares of stock to Nordic in satisfaction of the Nordic Accruing Dividend, the liability to issue shares of stock is being accounted for as a liability in our condensed balance sheet. As of September 30, 2013, the fair value of the liability is \$1.6 million based upon the fair value of the series A-6 convertible preferred stock as determined using PWERM. Changes in the fair value from the date of accrual to the date of issuance of the shares are recorded as a gain or loss in other (expense) income in the condensed statement of operations.

We recognize 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 Study, or a nine-month period. We recorded \$0.6 million and \$0.1 million of research and development expense during the three months ended September 30, 2013 and 2012, respectively, and \$4.1 million and \$0.1 million during the nine months ended September 30, 2013 and 2012, respectively, for per patient costs incurred for patients that had enrolled in the Phase 2 Clinical Study. Additionally, we recorded approximately \$0.9 million of research and development expense associated with the costs incurred for preparatory and other start-up costs to initiate the Phase 2 Clinical Study during the three months ended September 30, 2012.

As of September 30, 2013, in addition to the \$1.6 million liability that is reflected in other liabilities on the condensed balance sheet that will be settled in shares of stock, as noted above, we have a liability of \$0.5 million that is reflected in accrued expenses and other current liabilities on the condensed balance sheet resulting from services provided by Nordic, which are payable in cash.

We are also responsible for certain pass-through costs in connection with the Phase 3 Clinical Study, Extension Study and Phase 2 Clinical Study. Pass-through costs are expensed as incurred or upon delivery. We recognized research and development expense of \$1.3 million and \$0.5 million for pass through costs during the three months ended September 30, 2013 and 2012, and \$3.3 million and \$5.4 million for the nine months ended September 30, 2013 and 2012, respectively.

*License Agreement Obligations*

*BA058*

In September 2005, we exclusively licensed the worldwide rights (except Japan) to BA058 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 *Analog of Parathyroid Hormone* that claims BA058 and US Patent No. 6,544,949, (effective filing date March 26, 1996, statutory term expires March 29, 2016) entitled *Analog of Parathyroid Hormone* that claims methods of treating osteoporosis using BA058 and pharmaceutical compositions comprising BA058, and the corresponding foreign patents and continuing patent applications. In addition, we have rights to joint intellectual property related to BA058, 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 study

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

dosage strength and form. In consideration for the rights to BA058 and in recognition of certain milestones having been met as of December 31, 2011, 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 (\$13.5 million to \$48.7 million). Should BA058 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 BA058 patents, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense BA058 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 date of the last to expire of the BA058 patents, barring any extension thereof, is expected to be March 26, 2028. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

### *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

Table of Contents

days of patent 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 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 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, 2012, we had federal and state net operating loss carryforwards of approximately \$194.4 million and \$161.6 million, respectively. If not utilized, the net operating loss carryforwards will expire at various dates through 2032.

Under Section 382 of the Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be utilized 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 addition, we have not, as yet, conducted a study of research and development credit carryforwards. These studies may result in adjustments to our research and development credit carryforwards and net operating loss carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. 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 condensed statement of operations.

***Internal Control over Financial Reporting***

We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and are therefore not required to make an assessment of the effectiveness of our internal control over financial reporting. Further, our independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting. As a public company that may become listed on a national securities exchange, we intend to hire additional accounting personnel with

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

public company and SEC reporting experience and to focus on implementing appropriate internal controls and other procedures.

### **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.

Table of Contents

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

Our primary exposure to market risk is foreign currency exposure. A substantial portion of our BA058 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, 2013 and December 31, 2012, we had cash, cash equivalents and short-term investments of \$29.7 million and \$22.7 million, respectively, consisting of money market funds, U.S. Treasuries, Certificates of Deposit 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. Our short-term investments are subject to interest rate risk and will fall in value if market interest rates increase. 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, 2013, we do not have any hard to value investment securities or securities for which a market is not readily available or active.

We are also exposed to market risk related to changes in the fair value of our common stock and convertible preferred stock. Fluctuations in the fair value of our common stock and convertible preferred stock affect the value of our warrant liability, stock liability and other liability, which as of September 30, 2013 were valued at approximately \$2.5 million, \$4.8 million and \$22.2 million, respectively.

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

Table of Contents

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Company's management, including the Chief Executive Officer and the Chief Financial Officer, the Company's principal executive officer and principal financial officer, respectively, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective at the reasonable assurance level in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Table of Contents

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are not currently a party to any material litigation, and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our financial position, results of operations or cash flows.

**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 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 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 Food and Drug Administration, or FDA and other 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 BA058, RAD1901 and RAD140, and none of these products candidates is approved by the FDA for sale. Therefore, for the foreseeable future, we will have to fund our operations and capital expenditures from cash on hand, borrowings, licensing fees and grants and, potentially, future offerings of our securities. We believe that our existing resources as of September 30, 2013 will be sufficient to fund our planned operations into the first quarter of 2014. We have based this estimate on assumptions that may prove to be wrong, and we could use 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 regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, 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 \$48.2 million for the nine months ended September 30, 2013 and \$69.1 million and \$42.5 million during the years ended December 31, 2012 and 2011, respectively. As of September 30, 2013, we had an accumulated deficit of \$260.3 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.

Table of Contents

***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 2011, we entered into our \$25.0 million credit facility with General Electric Capital Corporation, or GECC, as agent and lender, and Oxford Finance LLC, as lender. We drew \$12.5 million under our credit facility during 2011 and we drew the remaining \$12.5 million on May 29, 2012. Our credit facility contains a number of covenants that impose significant operating and financial restrictions on us. These covenants 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 for consideration in excess of an allowable amount;
- 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.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, 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

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

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 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.

*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

Table of Contents

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 section could adversely affect our financial results and cause the value of our stock to fall.

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

*We are heavily dependent on the success of BA058-SC, and BA058-TD as a follow on product, both of which are under clinical development. We cannot be certain that BA058-SC or BA058-TD will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.*

BA058-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 regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market BA058-SC in the United States unless and until we receive approval of a New Drug Application, or NDA, from the Food and Drug Administration, or FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in such countries. In addition, the approval of BA058-TD as a follow-on product is dependent on the earlier approval of BA058-SC. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. Obtaining approval of an NDA is an extensive, lengthy, expensive and uncertain process, and any approval of BA058-SC may be delayed, limited or denied for many reasons, including:

- we may not be able to demonstrate that BA058 is safe and effective as a treatment for osteoporosis to the satisfaction of the FDA;
- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the clinical research organization, or CRO, that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA may not find the data from preclinical studies and clinical studies sufficient to demonstrate that BA058's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;
- the FDA 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 may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

In addition, the FDA 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, and our ongoing BA058-SC pivotal Phase 3 clinical study 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 BA058 80 µg and placebo groups in our Phase 3 study that will receive an approved alendronate (generic Fosamax®) therapy for osteoporosis management. We plan to file the NDA with the 18-month fracture data and supplementally provide the 24-month fracture data, when available. We cannot be certain that the FDA 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.

Before we submit an NDA to the FDA for BA058 as a treatment for osteoporosis, we must complete several additional studies, including, but not limited to, our pivotal Phase 3 study based upon 18-month fracture data, a thorough QT Phase 1 study, a Phase 1 pharmacokinetic, or PK, study in renal patients, a Phase 1 absolute bioavailability PK study, several drug interaction studies, a carcinogenicity study in rats, and bone quality studies in rats and monkeys. Not all of these required studies have commenced and the results of these studies will have an important bearing on the approval of BA058. 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-BA058 antibodies, which may have an important bearing on the approval of BA058. At an interim preliminary analysis of histopathology of pre-terminal rats in our rat carcinogenicity study, which includes BA058 and hPTH(1-34), a daily subcutaneous injection of human parathyroid hormone as a positive control, we have observed osteosarcomas in both the BA058 and hPTH(1-34) treated groups. The final results from the rat carcinogenicity study may

Table of Contents

show that BA058 dosing results in more osteosarcomas than PTH, at similar exposure multiples to the human therapeutic dose, which may have a material adverse bearing on approval of BA058.

***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 BA058 development costs are denominated in euro 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 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;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we, the FDA, or other 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 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.

***The results of our 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 our product candidate claims. 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 study of BA058-SC for fracture prevention may not replicate the positive efficacy results with respect to BMD obtained in our Phase 2 study.

The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated 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 filing of our NDAs with the FDA 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.

*If serious adverse or inappropriate 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.

*If we do not obtain the necessary United States or foreign regulatory approvals to commercialize any product candidate, we will not be able to sell our product candidates.*

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including BA058, RAD1901 and RAD140, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from 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 intended 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 indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or

Table of Contents

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 BA058. 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.

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

Except for BA058, each of our other product candidates, which are 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 for regulatory approval for any of our product candidates or whether any such NDA will be accepted.

***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 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, 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

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

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;
- 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.

Table of Contents

***Physicians and patients may not accept and use our drugs.***

Even if the FDA 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 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 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, such as Nordic, 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 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 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 BA058-SC by any of the entities managing our Phase 3 study affected the reliability of the data from the Phase 3 study, 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 study of BA058-SC is 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

Table of Contents

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 study, we 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 41.2 million (\$55.7 million) and a total of up to approximately \$3.2 million. 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 preferred stock for proceeds of approximately \$0.5 million. These shares of our Series A-5 preferred stock will automatically convert into 64,430 shares of our common stock upon the listing of our common stock on a national securities exchange. Pursuant to the terms of our agreements with Nordic, we will also issue to Nordic shares of stock with an aggregate value of up to 36.8 million (\$49.8 million) for consideration of Nordic's management of the Phase 3 study. These shares of stock accrue at a quarterly rate based on the progress of the Phase 3 clinical study and are issuable at a price per share equal to the greater of \$8.142 or the 20-day average of the closing price of our common stock at any time after our common stock is publicly traded. 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 will issue to Nordic in consideration of Nordic's management of the Phase 3 study may be less than the full value contemplated under our agreements with Nordic. 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 issuable 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 study. However, if the FDA, the European Medicines Agency, 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 study, we could be subject to additional regulatory scrutiny and the utility of the Phase 3 data 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 BA058 for use in clinical trial activities. These contract manufacturers are currently our only source for the production and formulation of BA058. We may not have sufficient clinical supplies of BA058 to complete the Phase 3 study for BA058-SC but believe that our contract manufacturers will be able to produce sufficient supply of BA058 to complete all of the planned BA058 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 BA058. Any modification of our finished product or modification or termination of our Phase 3 clinical study could adversely affect our ability to obtain necessary regulatory approvals and significantly delay or prevent the commercial launch of the product, 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 BA058. For example, we depend on Lonza Group Ltd., or Lonza, which produces supplies of bulk drug product of BA058 to support the BA058-SC and BA058-TD clinical studies and potential commercial launch. We also depend on Ipsen and its subcontractor Vetter Pharma Fertigung GmbH & Co, or Vetter, for the production of finished supplies of BA058-SC and we depend on 3M for the production of BA058-TD. Because of our dependence on Vetter for the fill and finish part of the manufacturing process for BA058-SC, we are subject to the risk that Vetter may not have the capacity from time to time to produce sufficient quantities of BA058 to meet the needs of our clinical studies or be able to scale to commercial production of BA058. Because

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

the manufacturing process for BA058-TD requires the use of 3M's proprietary technology, 3M is our sole source for finished supplies of BA058-TD.

While we are currently in discussions, to date, neither we nor our collaborators have entered into a long-term agreement with Lonza or Vetter, each of whom currently produce BA058 or related components on a purchase order basis for us. Accordingly, Lonza and Vetter 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 BA058 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 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:

Table of Contents

- 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. 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 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 Relating to Marketing and Sale of Our Products**

*We have no experience selling, marketing or distributing products and no internal capability to do so.*

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products. 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 pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. 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 there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

***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 approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. If we fail to develop BA058-TD, our commercial opportunity for BA058 will be limited. Existing or future competing products may provide greater therapeutic convenience, 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.

Table of Contents

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 regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling 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 BA058, RAD1901 and RAD140 will have to compete with existing therapies. 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 pursuing 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.

***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 part on the extent to which coverage and reimbursement will be available from:

- 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, insurance coverage may not be available, and reimbursement levels may be inadequate to cover such drug. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our product candidates, once approved, market acceptance of such product 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. 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.

Table of Contents

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 BA058, RAD1901 and/or RAD140 fail to adequately protect these assets, we may suffer the loss of the ability to license or successfully commercialize one or more of these candidates.***

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 BA058, RAD1901 and RAD140.

Patents covering BA058 as a composition of matter have been issued in the United States (US Patent No. 5,969,095), Europe and several additional countries. Because the BA058 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 USPTO) and additional countries where it has issued.

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 extensions) for the method of treating osteoporosis with the intended therapeutic dose for BA058-SC. We and 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 extensions) for the intended therapeutic formulation for BA058-SC.

We and 3M are co-assignees to an international patent application and corresponding U.S. patent applications with a priority date of April 20, 2012 which cover various aspects of BA058 for microneedle application. Any issued claims resulting from these applications 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 BA058-TD technology exists in the form of proprietary information contained by 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 marketing advantage of BA058-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 BA058, 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 available on the market and/or one or more generic competitor products on the market with a corresponding decrease in market share and/or price for BA058-TD.

Patents covering RAD1901 as a composition of matter have been issued in the United States, Canada and Australia and are pending in Europe and India. The RAD1901 composition of matter patent in the United States expires in 2026 (not including any Hatch-Waxman 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 that 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.

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

Patent applications covering RAD140 and other SARM compounds that are part of the SARM portfolio have been granted in the United States, 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 (this does not include the possibility of any Hatch-Waxman extension) and additional countries if and when it issues. Since patents are both highly technical and legal documents that are frequently subject to intense litigation pressure, there is risk that even if one or more RAD140 patents 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

Table of Contents

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.

***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 such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

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 which protect our technology or products or which 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. 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. 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. 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. Such 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 patent portfolio 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 the 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. 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. Such an occurrence could compromise the intellectual property protection around a preclinical or clinical candidate and possibly weaken or eliminate our ability to protect our eventual market share for that product.

Table of Contents

***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 them, such as our employees, 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 such 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.

***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 and 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 such 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. 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. Such litigation or 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 such litigation or proceedings. Some of our competitors may be able to sustain the costs of such 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.

Table of Contents

**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 certain 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 new Patient-Centered Outcomes Research Institute to oversee, identify priorities in 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 certain 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.

*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 governments 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 certain 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 payors 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 payor, 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.

Table of Contents

**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 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.

*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;
- potential 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.*

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

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

*There is not now and never has been any market for our securities and an active market may never develop. You may therefore be unable to re-sell shares of our securities at times and prices that you believe are appropriate.*

There is no market active or otherwise for our common stock or our preferred stock and neither is eligible for listing or quotation on any securities exchange, automated quotation system or any other over-the-counter market, such as the OTC Bulletin Board, or the OTCBB, or the Pink Sheets. Even if we are successful in obtaining approval to have our common stock quoted on the OTCBB, it is unlikely that an active market for our common stock will develop any time soon thereafter. Accordingly, our common stock is highly illiquid. Because of this illiquidity, you will likely experience difficulty in re-selling such shares at times and prices that you may desire.

*There is no assurance that our common stock will be listed on a national securities exchange or quoted on an automated quotation system.*

We may seek listing of our common stock on a national securities exchange or quotation of our common stock on the OTCBB. However, there is no assurance we will be able to meet the initial listing standards of either of those or any other stock exchange or automated quotation systems, or that we will be able to maintain a listing of our common stock on either of those or any other stock exchange or automated quotation system. An investor may find it more difficult to dispose of shares or obtain accurate quotations as to the market value of our common stock while our common stock is listed on the OTCBB. If our common stock is listed on the OTCBB, we would be subject to an SEC rule that, if it failed to meet the criteria set forth in such rule, imposes various practice requirements on broker-dealers who sell securities governed by the rule to persons other than established customers and accredited investors.

Table of Contents

Consequently, such rule may deter broker-dealers from recommending or selling our common stock, which may further limit its liquidity. This would also make it more difficult for us to raise additional capital.

***Shares of our capital stock issued in the Merger are subject to a lock-up provision, which limits our stockholders' ability to sell such shares of our capital stock.***

Shares of our preferred stock and our common stock issued as consideration in the Merger pursuant to the Merger Agreement are deemed Restricted Securities under the federal securities laws, and consequently such shares may not be resold without registration under the Securities Act of 1933, as amended, or the Securities Act, or without an exemption from the Securities Act, such as resales effected in compliance with Rule 144 promulgated under the Securities Act. Notwithstanding any such exemption, all shares of our stock issued in the Merger are subject to a lock-up provision set forth in the applicable stockholders' agreement and may not be resold prior to the expiration of the specified lock-up period. Subject to the transfer restrictions contained in the stockholders' agreement, shares of our preferred stock and our common stock issued as consideration in the Merger will be eligible for sale under Rule 144, subject to volume limitations for shares held by affiliates. We cannot estimate the number of shares of our common stock that our existing stockholders may elect to sell under Rule 144.

***Because we became an operating company by means of a reverse merger, we may not be able to attract the attention of major brokerage firms.***

Additional risks may exist as a result of our becoming a public reporting operating company through a reverse merger. Security analysts of major brokerage firms may not provide coverage of our capital stock or business. Because we became a public reporting operating company through a reverse merger, there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to provide analyst coverage of our capital stock or business in the future.

***The resale of shares covered by a resale registration statement could adversely affect the market price of our common stock in the public market, should one develop, which result would in turn negatively affect our ability to raise additional equity capital.***

The sale, or availability for sale, of our common stock in the public market pursuant to a resale registration statement may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional capital by selling equity or equity-linked securities. In the past, we have maintained a resale registration statement to register the resale of a significant number of shares of our common stock and may be required to do so in the future. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there would be a large number of shares registered pursuant to the registration statement, selling stockholders will continue to offer shares covered by such registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to such a registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

***We are subject to Sarbanes-Oxley and the reporting requirements of federal securities laws, which can be expensive.***

As a public reporting company, we are subject to the Sarbanes-Oxley Act, as well as the information and reporting requirements of the Exchange Act and other federal securities laws. The costs of compliance with the Sarbanes-Oxley Act and of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC, and furnishing audited reports to stockholders, cause our expenses to be higher than they would be if we were privately held. We are not currently subject to Section 404 of the Sarbanes-Oxley Act, but may be subject to Section 404 in the future. Section 404 may require us, on an annual basis, to review and evaluate our internal controls, and may require our independent auditors to attest to the effectiveness of our internal controls. Any failure by us to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

***For so long as shares of our preferred stock remain outstanding, if we are sold in a transaction yielding less than the liquidation preference payable in the aggregate to holders of outstanding preferred stock, holders of our common stock may not receive any proceeds from such transaction and may lose their investment entirely.***

As of October 31, 2013, we had outstanding 879,370 shares of common stock; 701,235 shares of series B preferred stock; 939,612 shares of series A-1 preferred stock; 983,208 shares of series A-2 preferred stock; 142,227 shares of series A-3 preferred stock; 3,998 shares of series A-4 preferred stock; 6,443 shares of series A-5 preferred stock; warrants to acquire 14,734 shares of series A-1 preferred stock; and warrants to acquire 1,753,357 shares of common stock. As more fully described herein and in our Certificate of

Table of Contents

Incorporation, holders of shares of our preferred stock outstanding at the time of a sale or liquidation will have a right to receive proceeds, if any, from any such transactions, before any payments are made to holders of our common stock. In the event that there are not enough proceeds to satisfy the entire liquidation preference of our preferred stock, holders of our common stock will receive nothing in respect of their equity holdings.

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

As a public company that may become listed on a national securities exchange, we will incur significant legal, accounting and other expenses that we did not incur as a private company and prior to any listing of our common stock. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and the national securities exchanges 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 will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act we may be required to furnish a report by our management on our internal control over financial reporting, including 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. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

As of September 30, 2013, our directors, executive officers and holders of more than five percent of our common stock, together with their affiliates, owned, in the aggregate, substantially all of our outstanding voting stock. As a result, these stockholders, acting together, 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 substantially all of our assets. In addition, these stockholders, acting together, 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.

*Certain provisions in our charter documents and Delaware law could discourage takeover attempts and lead to management entrenchment.*

Our certificate of incorporation and bylaws contain provisions that could have the effect of delaying or preventing changes in control or changes in our management without the consent of our board of directors. These provisions include:

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to determine to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; and
- the requirement that a special meeting of stockholders may be called only by the directors or any officer instructed by the directors to call the meeting, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors.

We are also subject to certain anti-takeover provisions under Delaware law. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction by which such holder acquired the stock.

Table of Contents

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

As of December 31, 2012, we had \$194.4 million of federal and \$161.6 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.

Table of Contents

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

None.

**Item 5. Other Information**

None.

Table of Contents

**Item 6. Exhibits.**

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

<b>Exhibit No.</b>	<b>Description</b>
10.1	(1) Consulting Agreement, dated July 1, 2013, by and between the Company and Morana Jovan-Embiricos.
10.2	(2) Clinical Trial Services Agreement Amendment No. 1 to Work Statement NB-2, dated November 6, 2013, by and between the Company and Nordic Bioscience Clinical Development VII A/S.
10.3	(2) Clinical Trial Services Agreement Amendment NO. 3 to Work Statement NB-1, dated November 6, 2013, by and between the Company and Nordic Bioscience Clinical Development VII A/S.
31.1	(2) Certification of the Company's Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013.
31.2	(2) Certification of the Company's Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013.
32.1	(2) Certification of the Company's Principal Executive Officer and Principal 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	(2) XBRL Instance Document
101.SCH	(2) XBRL Taxonomy Extension Schema Document
101.CAL	(2) XBRL Extension Calculation Linkbase Document
101.LAB	(2) XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	(2) XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	(2) XBRL Taxonomy Extension Definition Linkbase Document

---

(1) Incorporated by reference to our Current Report on Form 8-K filed on July 30, 2013.

(2) Filed herewith.

Table of Contents

**SIGNATURES**

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

**RADIUS HEALTH, INC.**

By:

*/s/ Andrew J. Fromkin*  
Andrew J. Fromkin  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: November 14, 2013

**RADIUS HEALTH, INC.**

By:

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

Date: November 14, 2013