

Radius Health, Inc.  
Form 10-Q  
August 07, 2012  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-Q**

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

**For the quarterly period ended June 30, 2012.**

**Or**

**o 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, \$0.001 par value per share, outstanding as of August 7, 2012: 857,301 shares

Table of Contents

**RADIUS HEALTH, INC.**  
**QUARTERLY REPORT FOR THE QUARTER ENDED June 30, 2012**  
**ON FORM 10-Q**

**INDEX**

**PART I FINANCIAL INFORMATION**

<u>Item 1.</u>	<u>Financial Statements (Unaudited)</u> <u>Condensed Balance Sheets as of June 30, 2012 and December 31, 2011</u> <u>Condensed Statements of Operations for the Three- and Six-Month Periods ended June 30, 2012 and 2011</u> <u>Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit for the Three- and Six-Month Period ended June 30, 2012</u> <u>Condensed Statements of Cash Flows for the Three- and Six-Month Periods ended June 30, 2012 and 2011</u> <u>Notes to Unaudited Financial Statements</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>

**PART II OTHER INFORMATION**

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

**SIGNATURES**

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 June 29, 2012, which was 1.00 = \$1.2668. 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)

<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$	18,832	\$ 25,128
Marketable securities		27,042	31,580
Prepaid expenses and other current assets		5,952	6,682
Total current assets		51,826	63,390
Property and equipment, net		98	167
Other assets		45	80
Total assets	\$	51,969	\$ 63,637
<b>Liabilities, convertible preferred stock, redeemable convertible preferred stock and stockholders deficit</b>			
Current liabilities:			
Accounts payable	\$	1,247	\$ 313
Accrued expenses		2,134	3,590
Current portion of note payable		5,836	2,880
Total current liabilities		9,217	6,783
Note payable, net of current portion and discount		17,083	8,886
Warrant liability		862	450
Other liabilities		17,456	10,470
Series A-1 Convertible Preferred Stock, \$.0001 par value; 1,000,000 shares authorized, 939,612 issued and outstanding at December 31, 2011 and June 30, 2012		68,755	65,675
Series A-2 Convertible Preferred Stock, \$.0001 par value; 983,213 shares authorized, 983,208 issued and outstanding at December 31, 2011 and June 30, 2012		83,238	79,979
Series A-3 Convertible Preferred Stock, \$.0001 par value; 142,230 shares authorized, 142,227 issued and outstanding at December 31, 2011 and June 30, 2012		10,679	10,208
Series A-4 Convertible Preferred Stock, \$.0001 par value; 4,000 shares authorized, 3,998 issued and outstanding at December 31, 2011 and June 30, 2012		271	271
Series A-5 Convertible Preferred Stock, \$.0001 par value; 7,000 shares authorized, 6,443 issued and outstanding at December 31, 2011 and June 30, 2012		525	525
Series A-6 Convertible Preferred Stock, \$.0001 par value; 800,000 shares authorized, no shares issued and outstanding at December 31, 2011 and June 30, 2012			

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

Stockholders' deficit:			
Common stock, \$.0001 par value; 34,859,964 shares authorized, 855,116 and 645,399 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively			
Additional paid-in-capital			2,744
Accumulated other comprehensive loss	10		5
Accumulated deficit	(156,127)		(122,359)
Total stockholders' deficit	(156,117)		(119,610)
Total liabilities, convertible preferred stock, redeemable convertible preferred stock and stockholders' deficit			
	\$	51,969	\$ 63,637

See accompanying notes.

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

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

	Three-Month Period Ended June 30,		Six-Month Period Ended June 30,	
	2012	2011	2012	2011
<b>Operating expenses:</b>				
Research and development	\$ 14,499	\$ 16,553	\$ 24,366	\$ 20,689
General and administrative	2,179	945	4,291	1,842
Loss from operations	(16,678)	(17,498)	(28,657)	(22,531)
Interest income	18	6	35	20
Other income (expense)	(717)	12	(1,184)	22
Interest expense	(584)	(108)	(1,027)	(108)
Net loss	\$ (17,961)	\$ (17,588)	\$ (30,833)	\$ (22,597)
Comprehensive loss	\$ (17,955)	\$ (17,588)	\$ (30,828)	\$ (22,594)
Earnings (loss) attributable to common stockholders - basic and diluted (Note 5)	\$ (21,417)	1,401	\$ (37,643)	\$ 1,013
<b>Earnings (loss) per share (Note 5):</b>				
Basic	\$ (25.06)	\$ 2.89	\$ (46.18)	\$ 2.51
Diluted	\$ (25.06)	\$ 0.44	\$ (46.18)	\$ 0.27
<b>Weighted average shares:</b>				
Basic	854,517	484,237	815,053	403,967
Diluted	854,517	3,175,348	815,053	3,790,913

See accompanying notes.

Table of Contents

**Radius Health, Inc.**

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

(Unaudited, in thousands except share amounts)

Balance at December 31, 2011	939,612	\$ 65,675	983,208	\$ 79,979	142,227	\$ 10,208	3,998	\$ 271	6,443	\$ 525	\$ 645,399	\$ 2,744	\$ 5	\$ (122,359)	\$ (119,610)
Net loss														(30,833)	(30,833)
Unrealized gain from available-for-sale securities													5		5
Total comprehensive loss															(30,828)
Accretion of dividends on preferred stock		3,080		3,259		471						(3,875)		(2,935)	(6,810)
Stock-based compensation expense												873			873
Stock options exercised											209,717	258			258
Balance at June 30, 2012	939,612	\$ 68,755	983,208	\$ 83,238	142,227	\$ 10,679	3,998	\$ 271	6,443	\$ 525	\$ 855,116	\$	\$ 10	\$ (156,127)	\$ (156,117)

See accompanying notes.



Table of Contents**Radius Health, Inc.****Statements of Cash Flows****(Unaudited, in thousands)**

<b>Operating activities</b>			
Net loss	\$	(30,833)	\$ (22,597)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation		24	15
Stock-based compensation expense		873	106
Research and development expense to be settled in stock		5,335	3,421
Amortization of premium (accretion of discount) on short-term investments, net		80	21
Non-cash interest		199	30
Change in fair value of warrant liability and other liability		1,184	
Milestone payment settled with stock			1,410
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets		1,219	(3,028)
Other long-term assets		35	31
Accounts payable		934	(541)
Accrued expenses		(1,456)	1,507
Net cash used in operating activities		(22,406)	(19,625)
<b>Investing activities</b>			
Purchases of property and equipment			(3)
Proceeds from sale of equipment		45	
Purchases of marketable securities		(17,722)	(899)
Sales and maturities of marketable securities		22,185	8,850
Net cash provided by investing activities		4,508	7,948
<b>Financing activities</b>			
Proceeds from the exercise of stock options		258	152
Net proceeds from the issuance of preferred stock			20,452
Proceeds on note payable, net		12,469	5,883
Deferred financing costs			(56)
Payments on note payable		(1,125)	
Net cash provided by financing activities		11,602	26,431
Net increase in cash and cash equivalents		(6,296)	14,754
Cash and cash equivalents at beginning of period		25,128	10,582
Cash and cash equivalents at end of period	\$	18,832	\$ 25,336
<b>Supplemental disclosures</b>			
Cash paid for interest	\$	721	\$
<b>Noncash financing activities</b>			
Fair value of preferred stock issued in the recapitalization, net of issuance costs	\$		\$ 85,879
Accretion of dividends on preferred stock	\$	6,810	\$ 5,595
Fair value of warrants issued	\$	379	\$ 217

See accompanying notes.



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 acquiring and 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 Injection, a daily subcutaneous injection of novel synthetic peptide analog of human parathyroid hormone-related protein (hPTHrP) for the treatment of osteoporosis. The BA058 Injection Phase 3 study began dosing patients in April 2011. The Company is also developing BA058 Microneedle Patch, a short wear time, transdermal form of BA058 delivered using a microneedle technology from 3M Drug Delivery Systems (3M), for which the Company expects to have a Phase 2 clinical study begin in the third quarter of 2012, with top-line data expected to be available in the second half of 2013. The Company also has two other product candidates, RAD1901, a selective estrogen receptor modulator, or SERM, in Phase 2 clinical development for the treatment of vasomotor symptoms (hot flashes) in women entering menopause, and RAD140, a selective androgen receptor modulator, or SARM, currently in preclinical development as a potential treatment for age-related muscle loss, frailty, weight loss associated with cancer cachexia and osteoporosis. As used throughout these financial statements, the terms Radius, Company, we, us and our refer to Radius Health, Inc. (f/k/a MPM Acquisition Corp.).

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 an accumulated deficit of \$156.1 million through June 30, 2012. The Company has incurred losses and expects to continue to incur additional losses for the foreseeable future. The Company intends to obtain additional equity and/or debt financing in order to meet working capital requirements and to further develop its product candidates. The Company believes that its existing cash and cash equivalents and marketable securities are sufficient to finance its operations, including its obligations under the Nordic agreement described in Note 12, into the first quarter of 2013.

**2. Basis of Presentation**

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

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 months ended June 30, 2012 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2012. For further information, refer to the financial statements and footnotes included in the Company s audited financial statements for the year ended December 31, 2011 included in the Company s Annual Report on Form 10-K as filed with the Securities and Exchange Commission ( SEC ) on February 6, 2012.

### **3. Summary of 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, 2011 related to accrued clinical expenses, research and development expenses, stock-based compensation, accrued expenses and income taxes. There were no changes to significant accounting policies in the three months ended June 30, 2012.

Table of Contents**Recently Adopted Accounting Standards**

In June 2011, the Financial Accounting Standards Board ( FASB ) issued Accounting Standard Update No. 2011-05, *Comprehensive Income* ( ASU No. 2011-05 ), which requires companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. ASU No. 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The update does not change the items which must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. The Company adopted ASU No. 2011-05 on January 1, 2012. Its adoption did not have a material impact on the Company's financial statements or results of operations.

In May 2011, FASB issued Accounting Standards Update No. 2011-04, *Fair Value Measurement (Topic 82) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* ( ASU No. 2011-04 ). The amendments in this update ensure that fair value has the same meaning in U.S. GAAP and in IFRS and that their respective fair value measurement and disclosure requirements are the same. This update is effective prospectively for interim and annual periods beginning after December 15, 2011. The Company adopted ASU No. 2011-04 on January 1, 2012. Its adoption did not have a material impact on the Company's results of operations, financial position or cash flows.

**4. Net Income (Loss) Per Share**

Basic and diluted net income (loss) per share is calculated as follows:

(In thousands, except share and per share numbers)	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
<b>Numerator:</b>				
Net loss	\$ (17,961)	\$ (17,588)	\$ (30,833)	\$ (22,597)
Extinguishment of preferred stock		60,937		60,937
Accretion of preferred stock	(3,456)	(2,719)	(6,810)	(5,595)
Earnings attributable to participating preferred stockholders		(39,229)		(31,732)
Earnings (loss) attributable to common stockholders - basic	(21,417)	1,401	(37,643)	1,013
Effect of dilutive convertible preferred stock				
Earnings (loss) attributable to common stockholders - diluted	\$ (21,417)	\$ 1,401	\$ (37,643)	\$ 1,013
<b>Denominator:</b>				
Weighted-average number of common shares used in earnings (loss) per share - basic	854,517	484,237	815,053	403,967
Effect of dilutive options to purchase common stock		409,113		261,193
Effect of dilutive convertible preferred stock		2,281,998		3,125,753
Weighted-average number of common shares used in earnings (loss) per share - diluted	854,517	3,175,348	815,053	3,790,913
Earnings (loss) per share - basic	\$ (25.06)	\$ 2.89	\$ (46.18)	\$ 2.51
Effect of dilutive options to purchase common stock		(1.32)		(0.99)

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

Effect of dilutive convertible preferred stock			(1.13)			(1.25)		
Earnings (loss) per share - diluted	\$	(25.06)	\$	0.44	\$	(46.18)	\$	0.27

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:

Table of Contents

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Convertible preferred stock	5,005,450	13,557,238	4,574,107	9,267,677
Options to purchase common stock	3,911,483		3,864,265	418,215
Warrants	15,000	4,154	15,000	4,154

**5. Marketable Securities**

Available-for-sale marketable securities consist of the following:

(In thousands)	June 30, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
Corporate debt securities	2,513		(1)	2,512
Corporate commercial paper	21,234	11		21,245
U.S Government Securities	3,285			3,285
Total	\$ 27,032	\$ 11	\$ (1)	\$ 27,042

(In thousands)	December 31, 2011			
	Carrying Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
Domestic corporate debt securities	10,260		(6)	10,254
Domestic corporate commercial paper	18,987	11		18,998
U.S. government securities	2,328			2,328
Total	\$ 31,575	\$ 11	\$ (6)	\$ 31,580

The Company held 6 debt securities at June 30, 2012 that had been in an unrealized loss position for less than 12 months. The fair value on these securities was \$5.8 million. The Company evaluated these securities for other-than-temporary impairments based on quantitative and qualitative factors. The Company considered the decline in market value for these 6 securities to be primarily attributable to current economic and market conditions. It is not more likely than not that the Company will be required to sell these securities, and it does not intend to sell these securities before the recovery of their amortized cost bases. Based on the Company's analysis, it does not consider these investments to be other-than-temporarily impaired as of June 30, 2012.

**6. Fair Value Measurements**

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

The Company has certain assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

- Level 1 Quoted market prices in active markets for identical assets or liabilities. Assets utilizing Level 1 inputs include money market funds and bank deposits;
- Level 2 Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves. Assets utilizing Level 2 inputs include U.S. government securities, including direct issuance bonds and corporate bonds; and
- Level 3 Unobservable inputs developed using estimates and assumptions developed by the Company, which reflect those that a market participant would use.

The following table summarizes the financial instruments measured at fair value on a recurring basis in the accompanying consolidated



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

Table of Contents

balance sheet as of June 30, 2012 and December 31, 2011:

(In thousands)	June 30, 2012			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Marketable Securities				
Domestic corporate debt securities	\$	\$ 2,512	\$	\$ 2,512
Domestic corporate commercial paper		21,245		21,245
U.S Government Securities		3,285		3,285
Stock dividend asset			3,706	3,706
	\$	\$ 27,042	\$ 3,706	\$ 30,748

(In thousands)	June 30, 2012			Total
	Level 1	Level 2	Level 3	
<b>Liabilities</b>				
Warrant liability	\$	\$	\$ 862	\$ 862
Other liability			17,456	17,456
	\$	\$	\$ 18,318	\$ 18,318

Fair value for Level 1 is based on quoted market prices. Fair value for Level 2 is based on 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. Fair value for Level 3 is based upon the fair values determined using the probability-weighted expected return method, or PWERM, as discussed below. Changes in fair value of the Level 3 assets and liabilities are recorded as other income (expense) in the statement of operations.

The stock dividend asset represents the prepaid balance of the accrued stock dividend ( other liability or stock liability ) to issue shares of Series A-6 preferred stock ( Series A-6 ) to Nordic Bioscience Clinical Development VII A/S ( Nordic ) (Note 12) and the amount of research and development expense related to stock dividend amounts being recognized ratably over the estimated per patient treatment period. The fair value of the stock liability is based upon the fair value of the Series A-6 shares as determined using PWERM, which considers the value of preferred and common stock based upon 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. PWERM is complex as it requires numerous assumptions relating to potential future outcomes of equity, hence, the use of this method can be applied: (i) when possible future outcomes can be predicted with reasonable certainty; and (ii) when there is a complex capital structure (i.e., several classes of preferred and common stock). The Company utilized the PWERM approach in its valuation based on the Company's expectations regarding the time to becoming a listed, publicly-traded entity as well as the Company's Series A-1 financing and the initiation of BA058 Injection Phase 3 study that resolved sufficient uncertainty regarding a discrete range of outcomes that could be identified and evaluated. As such, the valuation of the stock dividend asset was determined to be a Level 3 valuation.

The warrant liability represents the liability for the warrants issued to a placement agent and to the lenders in connection with the Company's credit facility in the year ended December 31, 2011 and three months ended June 30, 2012. 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 various classes of preferred stock, historical volatility, the term of the warrant and risk-free interest rates. The fair value of the Company's shares of common and

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

preferred stock was estimated using PWERM, as described above. As such, the valuation of the warrant liability was determined to be a Level 3 liability.

The other liability represents the liability to issue shares of Series A-6 to Nordic for services rendered in connection with the Company's Phase 3 clinical study of BA058 Injection (Note 12). 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. As such the valuation of the other

Table of Contents

liability was determined to be a Level 3 liability.

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

Instrument	Valuation Technique	Unobservable Input	Estimate
Preferred Stock	PWERM	• Time to becoming a listed, publicly-traded entity (years)	• 0.2 0.3
		• Probability of BA058 coming to market	• 70% 80%
		• Discount rate	• 20% 30%
		• Long-term revenue growth rate (1)	• 2% 117%
		• Long-term revenue growth rate (2)	• 8% 63%
		• Long-term pretax operating margin (3)	• 13% 79%
		• Long-term pretax operating margin (4)	• 28% 73%
		• Discount for lack of marketability	• 24% 53%
		Market Comparable Companies	• Revenue multiple (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 20% 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.

(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 June 30, 2012, the stock dividend asset, warrant liability and other liability have fair values of \$3.7 million, \$0.9 million and \$17.5 million, respectively. Significant changes in the significant unobservable inputs used in the fair value measurement of the Company's preferred stock in isolation would result in a significantly different fair value measurement of the stock dividend asset, 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 pretax operating margin and estimated fair value measurement of the Company's preferred stock.

Significant increases (decreases) in the significant unobservable inputs used in the fair value measurement of the warrant liability and other liability in isolation would result in a significantly higher (lower) fair value measurement. 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 pretax operating margin.

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

The following table provides a rollforward of the fair value of the assets, where fair value is determined by Level 3 inputs:

**(In thousands)**

Balance at January 1, 2012	\$	3,379
Reductions		(173)
Change in fair value		500
Balance at June 30, 2012	\$	3,706

The following table provides a rollforward of the fair value of the liabilities, where fair value is determined by Level 3 inputs:

**(In thousands)**

Balance at January 1, 2012	\$	10,920
Additions		5,714
Change in fair value		1,684
Balance at June 30, 2012	\$	18,318

Table of Contents

Additions represents i) the value of the liability for additional accrued shares of Series A-6 issuable to Nordic for services rendered in connection with the Company's Phase 3 clinical study of BA058 Injection (Note 12) and ii) warrants issued the lenders in connection with the Company's credit facility in the three months ended June 30, 2012.

The fair value of the Company's notes payable is determined using current applicable rates for similar instruments as of the balance sheet date. The carrying value of the Company's notes payable approximates fair value because the Company's interest rate is near current market rates. The Company's notes payable are Level 3 liabilities within the fair value hierarchy.

**7. Accrued Expenses**

Accrued expenses consist of the following:

(In thousands)	June 30, 2012	December 31, 2011
Research costs	\$ 805	\$ 2,276
Payroll and employee benefits	515	586
Professional fees	304	472
Vacation	118	79
Accrued interest on notes payable	392	177
<b>Total accrued expenses</b>	<b>\$ 2,134</b>	<b>\$ 3,590</b>

**8. Loan and Security Agreement**

On May 29, 2012, the Company borrowed \$12.5 million ( Term Loan C ) from Oxford Finance Corporation and General Electric Capital Corporation (collectively, the Lender ) pursuant to the terms of the loan and security agreement (the Loan and Security Agreement ) entered into between the Company and the Lender on May 23, 2011.

The Company is required to pay interest on Term Loan C on a monthly basis through and including November 1, 2012. Beginning December 1, 2012 through the maturity of Term Loan C on November 24, 2014, the Company will be required to make payments of outstanding principal and interest on Term Loan C in 25 payments of principal and interest, which are payable monthly in arrears with a final balloon payment of \$1,250,000. Interest is payable on Term Loan C at an annual interest rate of 10%.

Upon the last payment date of Term Loan C, whether on the maturity date of one of the term loans, on the date of any prepayment or on the date of acceleration in the event of a default, the Company will be required to pay the Lender a final payment fee equal to 3.5% of Term Loan C. In addition, if the Company repays all or a portion of Term Loan C prior to maturity, it will pay the Lender a prepayment fee of 3% of the total amount prepaid if the prepayment occurs prior to the first anniversary of the funding of Term Loan C, 2% of the total amount prepaid if the

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

prepayment occurs between the first and second anniversary of the funding of Term Loan C, and 1% of the total amount prepaid if the prepayment occurs on or after the second anniversary of the funding of Term Loan C.

In connection with the borrowings under Term Loan C, the Company issued to the Lender warrants to purchase 6,140 shares of the Company's Series A-1 Preferred Stock (the Warrants). The Warrants are exercisable, in whole or in part, immediately, and have a per share exercise price of \$81.42 and may be exercised on a cashless basis. The Warrants will expire on May 29, 2022. The exercise price may be adjusted in the event the Company issues shares of Series A-1 preferred stock (Series A-1) at a price lower than \$81.42 per Warrants issued in connection with Term Loan C was \$379,684 and was recorded as a discount to Term Loan C and is reflected in note payable in the balance sheet. The discount is being amortized to interest expense over the 30 month period that Term Loan C is outstanding. The Warrants are classified as a liability in the Company's balance sheet and will be remeasured at their estimated fair value at each reporting period. The changes in fair value are recorded as other income (expense) in the Statement of Operations.

Future principal payments under the Loan and Security Agreement at June 30, 2012, are as follows:

Table of Contents

(In thousands)		Principal Payments
2012	\$	2,375
2013		8,188
2014		13,156
Total	\$	23,719
Current portion of note payable		6,313
Discount on current portion of note payable		(477)
Current portion of note payable, net of discount	\$	5,836
Discount on noncurrent portion of note payable		(323)
Note payable, net of current portion and discount	\$	17,083

**9. Convertible Preferred Stock**

The rights, preferences, and privileges of the Series A-1, Series A-2 preferred stock ( Series A-2 ), Series A-3 preferred stock ( Series A-3 ), Series A-4 preferred stock ( Series A-4 ), Series A-5 preferred stock ( Series A-5 ) and Series A-6 are as follows:

**Conversion**

Each preferred stockholder 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 conversion price of the Preferred Stock as of June 30, 2012 was \$8.142 per share (the Conversion Price ), which represents a conversion ratio of one share of Preferred Stock into ten shares of Common Stock. Upon the Optional Conversion, the holder of the converted Preferred Stock is entitled to payment of all accrued, whether or not declared, but unpaid dividend in shares of the Common Stock of the Company at the then effective conversion price of shares of Preferred Stock.

Each share of Preferred Stock is automatically convertible into fully paid and non-assessable shares of Common Stock at the applicable Conversion Price then in effect upon (i) a vote of the holders of at least 70% of the outstanding shares of Series A-1, Series A-2 and Series A-3 to convert all shares of Preferred Stock or (ii) 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 of the Series A-1) at the discretion of the Company's Board of Directors.

**Redemption**

The shares of Preferred Stock are not currently redeemable.

**Dividends**

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

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 quarterly 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 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 quarterly 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. 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 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 quarterly 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.



Table of Contents

Without regard to the payment of required dividends to the holders of Series A-1, Series A-2 and Series A-3, holders of Series A-5 are entitled to receive the Series A-5 Accruing Dividend paid in shares of Series A-6 as described in Note 12. Holders of shares of Series A-6 are entitled to receive dividends on shares of Series A-6, when and if declared by the Board of Directors at a rate to be determined by the Board of Directors.

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 and Series A-6 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 A-1, Series A-2, Series A-3 and Series A-5, holders of Series A-4 are entitled to receive dividends on shares of Series A-4, when and if declared by the Board of Directors at a rate to be determined by the Board of Directors. 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 are also entitled to dividends declared or paid on any shares of Common Stock.

Dividends on the Preferred Stock are payable, at the sole discretion of the Board of Directors, in cash or in shares of the Company's Common Stock, when and if declared by the Board of Directors, upon liquidation or upon an event of sale at the current market price of shares of Common Stock. Upon Optional Conversion, dividends are payable in shares of the Common Stock at the then effective conversion price of shares of Preferred Stock.

The Company has accrued dividends of \$5.0 million, \$7.3 million and \$1.1 million on Series A-1, Series A-2 and Series A-3, respectively, as of June 30, 2012.

**Voting**

The preferred stockholders 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.

**Liquidation**

The shares of Series A-1 rank senior to all other classes of 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 the Series A-1 are entitled to be paid first out of the 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

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

the holders of Series A-1 shall consist of the original issuance price of \$81.42, plus all accrued but unpaid dividends. After the distribution to the holders 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 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 Preferred Stock, the holders of the Preferred Stock 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 Articles of Incorporation), the Company shall redeem all of the shares of Series A-1, Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6 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 Preferred Stockholder 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

Table of Contents

by the Company, and the Company was immediately liquidated thereafter and its assets distributed pursuant to the liquidation terms above.

**10. Stock-based Compensation**

A summary of stock option activity is as follows:

(In thousands, except for per share amounts)	Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Life (In Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2011	3,950	\$ 2.94		
Granted	198	4.21		
Exercised	(210)	1.23		
Cancelled	(1)	1.20		
Options outstanding at June 30, 2012	3,937	\$ 3.10	8.57	\$ 4,617
Options exercisable at June 30, 2012	1,030	\$ 1.53	6.21	\$ 2,826
Options vested or expected to vest at June 30, 2012	3,827	\$ 3.10	8.57	\$ 4,257

The total grant-date fair value of stock options that vested during the three- and six-month periods ended June 30, 2012 was approximately \$130,000 and \$270,000, respectively. The aggregate intrinsic value of options that vested during the three- and six-month periods ended June 30, 2012 was approximately \$155,000 and \$286,000 respectively.

As of June 30, 2012, there was approximately \$4.8 million of total unrecognized compensation expense related to unvested employee share-based compensation arrangements, which is expected to be recognized over a weighted-average period of approximately 3.5 years.

**11. 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

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

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 pro-promotion rights retained by Ipsen) France. In consideration for these licenses, the Company made a nonrefundable, non-creditable payment of \$250,000 to Ipsen, which was expensed during 2005. The Ipsen Agreement provides for further payments in the range of 10.0 million to 36.0 million (\$12.7 million to \$45.6 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 sublicensees 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 sublicensees commercialize a product that includes a compound discovered by it based on or derived from confidential Ipsen know-how, it will be obligated to pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the last to expire of its patents that cover such product or for

Table of Contents

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 approximately \$0.4 million, \$0.2 million, \$0.6 million, and \$0.3 million in research and costs in the three- and six-month periods ended June 30, 2012 and 2011, respectively. The costs were incurred by Ipsen and charged to the Company for the manufacture of the clinical supply of the licensed compound.

**12. Research Agreements**

On March 29, 2011, the Company and Nordic entered into a Clinical Trial Services Agreement, a Work Statement NB-1 (the Work Statement ) under such Clinical Trial Services Agreement and a related Stock Issuance Agreement. Pursuant to the Work Statement, Nordic is managing the Phase 3 clinical study (the Clinical Study ) of BA058 Injection and Nordic will be compensated for such services in a combination of cash and shares of Series A-6.

In December 2011, the Company entered into an amendment to the Work Statement, or the First Amendment. Pursuant to the original terms of the Work Statement, the study was to be conducted in 10 countries at a specified number of sites within each country. The terms of the First Amendment provide for two additional countries (the United States and India) in which the study will be conducted, specify a certain number of sites within each such additional country for the conduct of the study, and amend various terms and provisions of the Work Statement 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 in connection with the conduct of the study in such additional countries are denominated in both euros and U.S. dollars and total up to both 717,700 (\$909,182) and \$289,663, respectively, for the 15 additional study sites in India contemplated by the First Amendment and up to both 1.2 million (\$1.5 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, or the Second Amendment. Pursuant to the original terms of the Work Statement, 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 (i) increase the overall number of sites by adding sites in Europe, Brazil and Argentina and removing other sites, (ii) specify a certain number of sites within each country for the conduct of the study, and (iii) amend various terms and provisions of the Work Statement to reflect additional services 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 Series A-6 under the related Stock Issuance Agreement shall each be reduced by an amount of 11,941 (\$15,127) 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 extra 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 3.7 million (\$4.7 million) and \$205,540, respectively.

Pursuant to the Work Statement, the Company is required to make certain per patient payments denominated in both euros and U.S. dollars for each patient enrolled in the 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, as amended on December 9, 2011 and June 18, 2012, provides for a total of up to approximately 41.2 million (\$52.1 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 Clinical Study.

Pursuant to the Stock Issuance Agreement, as amended, Nordic agreed to purchase the equivalent of 371,864 of Series A-5 Preferred Stock at \$8.142 per share, and the Company sold 64,430 shares of Series A-5 to Nordic on May 17, 2011 for proceeds of \$525,154 to the Former

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

Operating Company. These shares were exchanged in the Merger for an aggregate of 6,443 shares of 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 automatically converted in accordance with its amended certificate of incorporation, having an aggregate value of up to 36.8 million (\$46.6 million), or the Series A-5 Accruing Dividend. This right to receive the Series A-5 Accruing Dividend is non-transferrable and will remain with Nordic in the event it 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.

The Series A-5 Accruing Dividend is determined based upon the estimated period that will be required to complete the 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 to Nordic that is referred to as the Applicable Quarterly Amount and is equal to (A) 36.8 million (\$46.6 million) minus the aggregate value of any prior Series A-5 Accruing Dividend accrued divided by (B) the number of calendar quarters it will take to complete the Clinical Study. To calculate the aggregate number of shares of Series A-6 due to Nordic in each calendar quarter, the Company converts the portion of 36.8 million (\$46.6 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

Table of Contents

Company then calculates the aggregate number of shares of Series A-6 to accrue in such calendar quarter by dividing the U.S. dollar equivalent of the Applicable Quarterly Amount, by the greater of (i) the fair market value as of the applicable Accrual Date and (ii) \$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. During the three months ended March 31, 2012, additional information became available that required the Company to update the estimated period it will take to complete the Clinical Study, which is part of the calculation of the Applicable Quarterly Amount, as described above. The estimated period that it will take to complete the Clinical Study was updated from a total of 11 calendar quarters as of December 31, 2011 to a total of 13 calendar quarters as of March 31, 2012. Such change in the number of calendar quarters it will take to complete the Clinical Study resulted in a lower number of shares due to Nordic at the end of the quarter ended March 31, 2012 and June 30, 2012 and will result in a lower number of shares due to Nordic at the end of future quarters through the end of the Clinical Study and does not impact the Statement of Operations. As of June 30, 2012, 244,834 shares of Series A-6 are due to Nordic, or after the automatic conversion into common stock of the Company's convertible preferred stock, 2,448,340 shares of common stock.

Prior to the issuance of shares of Series A-6 to Nordic, the liability to issue shares of Series A-6 will be accounted for as a liability in the Company's Balance Sheet. As of June 30, 2012, the fair value of the liability was \$17.5 million based upon the fair value of the Series A-6 as determined using PWERM (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 income (expense) in the Statement of Operations.

The Company recognizes research and development expense for the amounts due to Nordic under the Work Statement ratably over the estimated per patient treatment period beginning upon enrollment in the Clinical Study, or a twenty-month period. The Company recorded \$6.9 million and \$11.8 million of research and development expense in the three- and six-month periods ended June 30, 2012 for per patient costs incurred for patients that had enrolled in the Clinical Study as of June 30, 2012. As of June 30, 2012, in addition to the \$17.5 million liability that is reflected in other liabilities on the Balance Sheet that will be settled in shares of Series A-6 Preferred Stock or common stock, as noted above, the Company has an asset resulting from payments to Nordic of approximately \$4.6 million that is included in prepaid expenses on the Balance Sheet.

The Company is also responsible for certain pass through costs in connection with the Clinical Study. Pass through costs are expensed as incurred or upon delivery. The Company recognized research and development expense of \$3.6 million and \$4.9 million for pass through costs in the three- and six-month periods ended June 30, 2012.

### **13. Commitments and Contingencies**

The Company may be exposed 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.

### **14. Subsequent Event**

*Letter of Intent regarding Clinical Trial Services*

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 that certain Amended and Restated Stock Issuance Agreement entered into by the Company and Nordic as of May 16, 2011 (the "Stock Issuance Agreement Amendment"). The Work Statement NB-2 is contemplated by the terms of that certain Clinical Trial Services Agreement, entered into as of March 29, 2011, between the Company and Nordic (the "Services Agreement").

The Letter of Intent further provides that Nordic will begin providing clinical trial services relating to the Phase 2 clinical study of the Company's BA058 Transdermal product, as contemplated by the Services Agreement and the draft Work Statement NB-2. Payments in cash to be made by the Company to Nordic under the Letter of Intent in connection with the services to be provided are denominated in both euros and U.S. dollars and total up to 3.5 million (\$4.4 million) and \$257,856, respectively. In addition, the Company will issue to Nordic, subject to the execution of the Work Statement NB-2 and the Stock Issuance Agreement Amendment, shares of its Series A-6 Convertible Preferred Stock having a value of at least \$2.9 million, as additional payment for services to be provided under the Work Statement NB-2 and the Services Agreement.

The Letter of Intent will terminate on the earlier of (1) the date on which the Company and Nordic enter into the Work Statement NB-2 and the Stock Issuance Agreement Amendment and (2) September 30, 2012.

*Amendment to Side Letter Agreement*

On July 26, 2012, the Company entered into an Amendment (the "Side Letter Amendment") to that certain Side Letter Agreement, dated March 29, 2011, between the Company and Nordic (the "Side Letter"). The Side Letter had provided that, upon entry into the Work Statement NB-2, a portion of the price for the services to be performed by Nordic thereunder would be paid in cash, and a portion would be paid in shares of the Company's Series A-6 Convertible Preferred Stock worth at least \$4.0 million. The Side Letter Amendment



Table of Contents

amends the Side Letter to provide that the value of the Series A-6 Convertible Preferred Stock issued as part of the payment made under the Work Statement NB-2 will be at least \$2.9 million.

**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 important factors include our financial performance, our ability to attract and retain customers, our development activities and those factors we discuss in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on February 6, 2012 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 ( 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 have begun dosing subjects in a pivotal Phase 3 clinical study of BA058 Injection for the prevention of fractures in women suffering from osteoporosis. We are also developing BA058 Microneedle Patch, a short wear time, transdermal form of BA058 that is based on a microneedle technology from 3M Drug Delivery Systems, or 3M. We expect to have a Phase 2 clinical study of BA058 Microneedle Patch begin in the third quarter of 2012, and expect top-line data from this study to be available in the second half of 2013. We believe that BA058 Microneedle Patch may eliminate the need for injections and lead to better treatment compliance for patients. Our second clinical-stage product candidate is RAD1901, which has completed an initial Phase 2a clinical study for the treatment of vasomotor symptoms, commonly known as hot flashes, in women entering menopause. Our third product candidate, RAD140, is in preclinical development and is a potential treatment for age-related muscle loss, frailty, weight loss associated with cancer cachexia and osteoporosis.

BA058 is a novel synthetic peptide analog of hPTHrP we are developing as a bone anabolic treatment for osteoporosis. 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 Injection 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, and expect to report top-line 18 month fracture data from this study in the second half of 2014. 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 is powered to show that BA058 is superior to placebo for prevention of vertebral fracture. 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.

In early 2012, we received a letter from the U.S. Food and Drug Administration, or the FDA, stating that, after internal consideration, the agency believes that a minimum of 24-month fracture data are necessary for approval of new products for the treatment of postmenopausal osteoporosis. Our ongoing BA058 Injection pivotal Phase 3 clinical study is designed to produce fracture data based on an 18-month primary endpoint. The FDA's letter solicited a meeting to review the status of our Phase 3 clinical study and discuss options for fulfilling the FDA's new request for 24-month fracture data in the context of the ongoing Phase 3 study. We subsequently met with the FDA and exchanged correspondence to discuss satisfying the 24-month data request while preserving the current 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 New Drug Application, or 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 daily oral doses of alendronate (generic Fosamax®) or other standard of care for osteoporosis management. We intend to include the 24-month fracture data in our NDA submission, as requested by the FDA.

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 until we receive approval for BA058 Injection 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 do not expect to complete development and file the NDA submission for BA058 Injection until approximately mid-2015 and/or BA058 Microneedle Patch until approximately mid-2017. Accordingly, our success depends not only on the safety and efficacy of BA058, but also on our ability to finance the

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

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, complete patient enrollment in clinical studies in a timely fashion, manage and coordinate on a cost-effective basis all the required components of the NDA submission for BA058 Injection and scale-up BA058 Injection and BA058 Microneedle Patch manufacturing capacity, as well as overall capital market conditions for companies with limited operating histories.

In addition, we currently have no sales, marketing or distribution capabilities and thus our ability to market BA058 will depend 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. Our ability to secure collaborators for BA058 will depend on the strength of our clinical data. However, we believe that there are certain favorable trends that will interest third parties to collaborate on BA058, including increasing prevalence of osteoporosis due to an increase in the elderly

Table of Contents

population in most developed countries, increased availability and reimbursement of diagnostic facilities, growing physician and patient awareness regarding the importance of treating osteoporosis, and concerns regarding the long-term safety profiles of the bisphosphonates prompting physicians to be interested in new therapies for osteoporosis. We are also evaluating strategic alternatives with respect to collaborating with third parties for the future development of RAD1901 and RAD140. Our ability to further develop these product candidates will be dependent upon the outcome of our collaboration strategy.

**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.

Our lead product candidate is BA058 and it represents the largest portion of our research and development expenses for our product candidates. BA058 is a novel synthetic peptide analog of hPTHrP being developed by us as a treatment for osteoporosis in both injection and transdermal methods of administration. BA058 Injection is currently in a Phase 3 study and BA058 Microneedle Patch is expected to be in a Phase 2 clinical study commencing in the third quarter of 2012, with top-line data expected to be available in the second half of 2013. Our other clinical-stage program is RAD1901, a SERM, which has completed an initial Phase 2a clinical study for the treatment of vasomotor symptoms, commonly known as hot flashes, in women entering menopause. A Phase 2 study is designed to test the efficacy of a novel treatment and confirm the safety profile established in a Phase 1 trial. Our third product candidate is RAD140, a SARM, which is in preclinical development.

The following table sets forth our research and development expenses related to BA058 Injection, BA058 Microneedle Patch, RAD1901 and RAD140 for the three-month periods ended June 30, 2012 and 2011. No research and development expenses in relation to our product candidates are currently borne by third parties. We began tracking program expenses for BA058 Injection in 2005, and program expenses from inception to June 30, 2012 were approximately \$73.6 million. We began tracking program expenses for BA058 Microneedle Patch in 2007, and program expenses from inception to June 30, 2012 were approximately \$14.1 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to June 30, 2012 were approximately \$15.4 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to June 30, 2012 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.

(In thousands)	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
BA058 Injection	\$ 12,492	\$ 13,797	\$ 20,166	\$ 16,774

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

BA058 Microneedle Patch	1,063	2,184	2,209	2,758
RAD1901				
RAD140		3	18	23

The majority of our external costs are spent on BA058, as costs associated with later stage clinical trials are, in most cases, more significant than those incurred in earlier stages of our pipeline. In April 2011, we began the dosing of patients in a pivotal Phase 3 clinical study of BA058 Injection for the treatment of osteoporosis. In addition, we expect to begin a Phase 2 clinical study of BA058 Microneedle Patch in the third quarter of 2012, and expect top-line data from this study to be available in the second half of 2013. We expect that future development costs related to BA058 Injection and BA058 Microneedle Patch programs will increase significantly through possible marketing approval in the United States for BA058 Injection in mid-2016 and for BA058 Microneedle Patch in mid-2018. For BA058 Injection, we estimate that future development costs may exceed \$118.0 million including \$88.0 million for clinical costs, \$17.0 million for license and milestone payments and NDA filing fees, \$7.0 million for preclinical costs and \$6.0 million for manufacturing costs. For BA058 Microneedle Patch, we estimate that future development costs may exceed \$43.0 million, including \$28.0 million for clinical costs, \$11.0 million for manufacturing costs, \$4.0 million for preclinical costs and NDA filing fees. We expect to finance these future development costs of BA058 with our existing cash and cash equivalents and marketable securities and future offerings of our common stock or preferred stock. In addition, our current strategy is to collaborate with third parties for the further development and

Table of Contents

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, and it is not possible to project the future development costs for RAD1901 and RAD140 or possible marketing approval timeline at this time.

The successful development of BA058 Injection and BA058 Microneedle Patch 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 costs and timing associated with the development of that product candidate.

BA058 Injection 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 no drug products for sale currently and may never be able to develop marketable drug products. 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 Injection may be delayed, limited or denied for many reasons, including:

- we may experience delays in the enrollment of patients in our ongoing Phase 3 clinical trial;
  
- 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;

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

- the FDA may not accept data generated at our clinical study sites;
- 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;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval; 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 Injection 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 daily oral doses of alendronate (generic Fosamax®) or other standard of care for osteoporosis management. We cannot be certain that the FDA will not change this approval policy again, or adopt other approval policies or regulations that adversely affect an NDA that we may submit.

We are unable to determine the duration and costs to be incurred by us to continue development of RAD1901 and RAD140 until such time as we are able to secure a third party to collaborate on the further development and commercialization of these product candidates. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to



Table of Contents

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 Injection and BA058 Microneedle Patch.

*General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related expense for executive, finance and other administrative personnel, professional fees, business insurance, rent, general legal activities, including costs of maintaining our intellectual property portfolio and other corporate expenses. We expect our general and administrative expenses to increase as a result of higher costs associated with being a public company and any listing of our securities on a national securities exchange.

Our results include non-cash compensation expense as a result of the issuance of stock and stock option grants. Compensation expense for options granted to employees and directors represent the difference between the fair value of our common stock and the exercise price of the options at the date of grant. Compensation for options granted to consultants has been determined based upon the fair value of the equity instruments issued and the unvested portion of such option grants is remeasured at each reporting period. The stock-based compensation expense is included in the respective categories of expense in the statement of operations (research and development and general and administrative expenses). We expect to record additional non-cash 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 current credit facility, which we entered into on May 23, 2011 and pursuant to which we borrowed an aggregate of \$12.5 million during the year ended December 31, 2011 and \$12.5 million during the three months ended June 30, 2012.

*Other Income and Other Expense*

Other expense primarily reflects changes in the fair value of the Series A-6 preferred stock liability from the date of the initial accrual to the reporting date as discussed in Note 12 to our condensed quarterly financial statements for the period ended June 30, 2012.

*Accretion of Preferred Stock*

Accretion of preferred stock reflects the periodic accretions of issuance costs, dividends and the investor rights/obligations on the Series B and C redeemable convertible preferred stock of MPM Acquisition Corp., or the Former Operating Company, and accretion of dividends on the Former Operating Company's Series A-1, A-2 and A-3 convertible preferred stock.

### **Critical Accounting Policies and Estimates**

The preparation of our financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and expenses during the reported periods. We believe the following accounting policies are critical because they require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates, which would have been reasonable could have been used, which would have resulted in different financial results.

The critical accounting policies we identified in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2011 related to accrued clinical expenses, research and development expenses, stock-based compensation, fair value measurements, accrued expenses and income taxes. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in our Annual Report on Form 10-K, as filed with the SEC on February 6, 2012.

### **Results of Operations**

The following discussion summarizes the key factors our management believes are necessary for an understanding of our financial statements. The discussion under Results of Operations discusses results for the three and six months ended June 30, 2012 in comparison with the three and six months ended June 30, 2011. The results for the three and six months ended June 30, 2011 include the results of the Former Operating Company. The results for the three and six months ended June 30, 2012 are post-Merger results.

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

Table of Contents

	Three months Ended June 30,		Six months Ended June 30,	
	2012	2011	2012	2011
	(In thousands)			
<b>Operating expenses:</b>				
Research and development	\$ 14,499	\$ 16,553	\$ 24,366	\$ 20,689
General and administrative	2,179	945	4,291	1,842
Loss from operations	(16,678)	(17,498)	(28,657)	(22,531)
Interest income	18	6	35	20
Other income (expense)	(717)	12	(1,184)	22
Interest expense	(584)	(108)	(1,027)	(108)
Net loss	\$ (17,961)	\$ (17,588)	\$ (30,833)	\$ (22,597)

Three months ended June 30, 2012 and 2011

	Three months Ended June 30,		Change	
	2012	2011	\$	%
	(In thousands)			
<b>Operating expenses:</b>				
Research and development	\$ 14,499	\$ 16,553	(2,054)	-12%
General and administrative	2,179	945	1,234	131%
Loss from operations	(16,678)	(17,498)	820	-5%
Interest income	18	6	12	200%
Other income (expense)	(717)	12	(729)	-6075%
Interest expense	(584)	(108)	(476)	441%
Net loss	\$ (17,961)	\$ (17,588)	(373)	2%

*Research and development expenses:* For the three months ended June 30, 2012, research and development expense was \$14.5 million compared to \$16.6 million for the three months ended June 30, 2011, a decrease of \$2.1 million and 12%. For the three months ended June 30, 2012, we incurred professional contract services associated with the development of BA058 Injection of \$12.5 million compared to \$13.8 million for the three months ended June 30, 2011. The decrease was primarily the result of both higher startup expenses incurred in 2011 for the initiation of the Phase 3 study of BA058 Injection, which began with the dosing of patients in April 2011, as well as lower contract services costs associated with the development of the BA058 Microneedle Patch in 2012. We expect that BA058 Injection expenses will be maintained or increase over the course of the Phase 3 study. However, there will be variability from quarter to quarter driven primarily by the rate of patient enrollment, the euro/dollar exchange rate, and fluctuations in the value of Radius stock issued to Nordic under the Stock Issuance Agreement.

*General and administrative expenses:* For the three months ended June 30, 2012, general and administrative expense was \$2.2 million compared to \$0.9 million for the three months ended June 30, 2011, an increase of \$1.2 million and 131%. The increase is primarily the result of increased legal fees, including costs associated with maintaining our intellectual property portfolio and costs associated with being a public company, and additional personnel.

*Other income (expense):* For the three months ended June 30, 2012, other expense, net of other income, was \$717,000. Other expense primarily reflects changes in the fair value of the Series A-6 liability from the date of the initial accrual to the reporting date as discussed in Note 12 to our condensed quarterly financial statements for the period ended June 30, 2012.

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

*Interest expense:* For the three months ended June 30, 2012, interest expense was \$584,000. Interest expense reflects interest due on our loan and security agreement with Oxford Finance and GECC, which was effective on May 23, 2011.

Table of ContentsSix months ended June 30, 2012 and 2011

	Six months Ended June 30,		Change	
	2012	2011	\$	%
	(In thousands)			
<b>Operating expenses:</b>				
Research and development	\$ 24,366	\$ 20,689	3,677	18%
General and administrative	4,291	1,842	2,449	133%
Loss from operations	(28,657)	(22,531)	(6,126)	27%
Interest income	35	20	15	75%
Other income (expense)	(1,184)	22	(1,206)	-5482%
Interest expense	(1,027)	(108)	(919)	851%
Net loss	\$ (30,833)	\$ (22,597)	(8,236)	36%

*Research and development expenses:* For the six months ended June 30, 2012, research and development expense was \$24.4 million compared to \$20.7 million for the six months ended June 30, 2011, an increase of \$3.7 million and 18%. For the six months ended June 30, 2012, we incurred professional contract services associated with the development of BA058 Injection of \$20.2 million compared to \$16.8 million for the six months ended June 30, 2011. The increase was primarily the result of expenses incurred for continuing enrollment of patients in our Phase 3 study of BA058 Injection, which began with the dosing of patients in April 2011. We expect this higher level of BA058 Injection expenses to be maintained or increase over the course of the Phase 3 study. However, there will be variability from quarter to quarter driven primarily by the rate of patient enrollment, the euro/dollar exchange rate, and fluctuations in the value of Radius stock issued to Nordic under the Stock Issuance Agreement. Offsetting these increases, we incurred \$550,000 less in contract services associated with the development of BA058 Microneedle Patch in relation to the manufacture of Phase 2 clinical supplies.

*General and administrative expenses:* For the six months ended June 30, 2012, general and administrative expense was \$4.3 million compared to \$1.8 million for the six months ended June 30, 2011, an increase of \$2.4 million and 133%. The increase is primarily the result of increased legal fees, including costs associated with maintaining our intellectual property portfolio and costs associated with being a public company, and additional personnel.

*Other income (expense):* For the six months ended June 30, 2012, other expense, net of other income, was \$1.2 million. Other expense primarily reflects changes in the fair value of the Series A-6 liability from the date of the initial accrual to the reporting date as discussed in Note 12 to our condensed quarterly financial statements for the period ended June 30, 2012.

*Interest expense:* For the six months ended June 30, 2012, interest expense was \$1.0 million. Interest expense reflects interest due on our loan and security agreement with Oxford Finance and GECC, which was effective on May 23, 2011.

*Liquidity and Capital Resources*

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

From inception to June 30, 2012, we have incurred an accumulated deficit of \$156.1 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 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 June 30, 2012 was \$45.9 million.

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

Table of Contents

	Six months ended June 30,		Change	
	2012 (In thousands)	2011	\$	%
Net cash provided by (used in):				
Operating activities	\$ (22,406)	\$ (19,625)	\$ (2,781)	-14%
Investing activities	4,508	7,948	(3,440)	-43%
Financing activities	\$ 11,602	\$ 26,431	\$ (14,829)	-56%
Net increase in cash and cash equivalents	\$ (6,296)	\$ 14,754	\$ (21,050)	-143%

*Cash Flows From Operating Activities*

Our operating activities used cash of \$22.4 million and \$19.6 million for the six months ended June 30, 2012 and 2011, respectively. The increase in the net cash used in operating activities was primarily attributed to a \$3.7 million increase in research and development expense, which is primarily the result of expenses incurred for continuing enrollment of patients in our Phase 3 study of BA058 Injection, which began with the dosing of patients in April 2011. We expect this higher level of BA058 Injection expenses to be maintained or increase over the course of the Phase 3 study.

*Cash Flows From Investing Activities*

Our investing activities provided cash of \$4.5 million and \$7.9 million for the six months ended June 30, 2012 and 2011, respectively. The cash provided by investing activities for both the six months ended June 30, 2012 and 2011 was primarily due to the sales and maturities of our short-term investments.

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 due to the short-term duration of our investments.

*Cash Flows From Financing Activities*

Our financing activities provided cash of \$11.6 million and \$26.4 million for the six months ended June 30, 2012 and 2011, respectively. The cash provided by financing activities for the six months ended June 30, 2012 consists of \$12.5 million of net proceeds from our note payable and \$258,000 of net proceeds from stock option exercises, offset by \$1.1 million of payments on our notes payable. The cash provided by financing activities for the six months ended June 30, 2011 consists of \$20.5 million of net proceeds from the issuance of common stock, \$5.9 million of net proceeds from our note payable and \$152,000 of net proceeds from stock option exercises.

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

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 June 30, 2012, almost all of our financing has been through private placements of preferred stock and borrowings under our credit facility. We will seek to continue to fund operations from cash on hand and through additional equity and/or debt financing and potential collaboration agreements. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. We believe that our existing resources will be sufficient to fund our planned operations into the first quarter of 2013. 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. After such date, we will need additional financing until we can achieve profitability, if ever, including funds to conduct clinical and non-clinical studies, achieve regulatory approvals and, subject to such approvals, commercially launch our product candidates. 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. If additional funds are required, we may raise such funds from time to time through public or private sales of equity or from borrowings. 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.



Table of Contents

*Financings*

On May 23, 2011, we entered into our credit facility with GECC, as agent and a lender, and Oxford Finance, as a lender, consisting of three term loans, pursuant to which we may draw an aggregate of \$25.0 million. We drew \$12.5 million under the initial and second term loans in the year ended December 31, 2011 and \$12.5 million under the third term loan in the three months ended June 30, 2012. In connection with the funding of the third term loan, we issued warrants to purchase an additional 6,140 shares of Series A-1 at a purchase price of \$81.42 per share. The exercise period of each warrant is 10 years from the date of issuance.

*Research and Development Agreements:*

On March 29, 2011, we and Nordic entered into a Clinical Trial Services Agreement, a Work Statement NB-1, or the Work Statement, under such Clinical Trial Services Agreement and a related Stock Issuance Agreement. Pursuant to the Work Statement, Nordic is managing the Phase 3 clinical study, or the Clinical Study, of BA058 Injection and Nordic will be compensated for such services in a combination of cash and shares of Series A-6 or after the automatic conversion into common stock of our convertible preferred stock, in shares of common stock.

In December 2011, we entered into an amendment to the Work Statement, or the First Amendment. Pursuant to the original terms of the Work Statement, the study was to be conducted in 10 countries at a specified number of sites within each country. The terms of the First Amendment provide for two additional countries (the United States and India) in which the study will be conducted, specify a certain number of sites within each such additional country for the conduct of the study, and amend various terms and provisions of the Work Statement 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 in connection with the conduct of the study in such additional countries are denominated in both euros and U.S. dollars and total up to both 717,700 (\$909,182) and \$289,663, respectively, for the 15 additional study sites in India contemplated by the First Amendment and up to both 1.2 million (\$1.5 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, or the Second Amendment. Pursuant to the original terms of the Work Statement, 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 (i) increase the overall number of sites by adding sites in Europe, Brazil and Argentina and removing other sites, (ii) specify a certain number of sites within each country for the conduct of the study, and (iii) amend various terms and provisions of the Work Statement to reflect additional services 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 Series A-6 under the related Stock Issuance Agreement shall each be reduced by an amount of 11,941 (\$15,127) 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 extra 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 3.7 million (\$4.7 million) and \$205,540, respectively.

Pursuant to the Work Statement, we are required to make certain per patient payments denominated in both euros and U.S. dollars for each patient enrolled in the 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, as amended on December 9, 2011 and June 18, 2012, provides for a total of up to approximately 41.2 million (\$52.1 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 Clinical Study.

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

Pursuant to the Stock Issuance Agreement, as amended, Nordic agreed to purchase the equivalent of 371,864 of series A-5 preferred stock at \$8.142 per share, and we sold 64,430 shares of series A-5 preferred stock to Nordic on May 17, 2011, for proceeds of \$525,154 to the Former Operating Company. These shares were exchanged in the Merger for an aggregate of 6,443 shares of our 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 our preferred stock has been automatically converted into common stock in accordance with our certificate of incorporation, having an aggregate value of up to 36.8 million (\$46.6 million), or the Series A-5 Accruing Dividend. This right to receive the Series A-5 Accruing Dividend is non-transferrable and will remain with Nordic in the event it sells the shares of series A-5 preferred stock or in the event the shares of Series A-5 are converted into common stock in accordance with our amended certificate of incorporation. As of June 30, 2012, 244,834 shares of Series A-6 preferred stock are due to Nordic, or after the automatic conversion into common stock of our convertible preferred stock, 2,448,340 shares of common stock.

Table of Contents

We recorded \$6.9 million and \$11.8 million of research and development expense in the three- and six month periods ended June 30, 2012 for per-patient costs incurred for patients that had enrolled in the Clinical Study as of June 30, 2012. As of June 30, 2012, in addition to the \$17.5 million liability that is reflected in other liabilities on the Balance Sheet that will be settled in shares of Series A-6 or common stock, as noted above, we have an asset resulting from payments to Nordic of approximately \$4.6 million that is included in prepaid expenses on the Balance Sheet.

We are also responsible for certain pass through costs in connection with the Clinical Study. We recognized research and development expense of \$3.6 million and \$4.9 million for pass through costs in the three- and six-month periods ended June 30, 2012.

*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 expires October 3, 2027, plus 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 expires October 3, 2027 plus 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 (excluding Japan) that cover the method of treating osteoporosis using the Phase 3 clinical study 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 (\$12.7 million to \$45.6 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 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 days of patent term adjustment due to delays by the USPTO). In consideration for the rights to RAD1901 and in recognition of certain milestones having been

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

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 (i) 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 (ii) 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.

Table of Contents

*Net Operating Loss Carryforwards*

As of December 31, 2011, we had federal and state net operating loss carryforwards of approximately \$128.3 million and \$109.7 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2023 and 2012 for federal and state purposes, respectively.

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 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 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 3, *Summary of Significant Accounting Policies - Recently Adopted Accounting Standards*, in Notes to Condensed Financial Statements, for a discussion of new accounting standards.

**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 impact 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 June 30, 2012 and December 31, 2011, we had cash, cash equivalents and short-term investments of \$45.9 million and \$56.7 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 have the ability to hold our short-investments until maturity, and therefore we would not expect our operations 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. We do not currently have any hard to value investment securities or securities for which a market is not readily available or active.

Table of Contents

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.

**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.

**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 consolidated 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 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 a net loss of \$18.0 million for the three months ended June 30, 2012, \$42.5 million for the year ended December 31, 2011 and \$14.6 million for the year ended December 31, 2010. As of June 30, 2012, we had an accumulated deficit of \$156.1 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. We may not be able to generate these revenues or achieve profitability in the future. Accordingly, unless and until we generate revenues and become profitable, we will need to raise additional capital to continue to operate our business, including after the consummation of this offering. Our failure to achieve or maintain profitability or to raise additional capital could negatively impact the value of our securities.



Table of Contents

***We currently have no product revenues and will need to raise additional capital to operate our business.***

To date, we have generated no product revenues. Until, and unless, we receive approval from the 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 will be sufficient to fund our planned operations into the first quarter of 2013. 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. 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.

***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 GECC, as agent and lender, and Oxford Finance, as lender. We drew \$12.5 million and \$12.5 million under our credit facility during 2011 and 2012, respectively. 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.

*We will need to seek additional sources of financing, which may not be available on favorable terms, if at all.*

If we do not succeed in the timely raising of additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or 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 and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders.

*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

Table of Contents

that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or 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 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 our stock price to fall.

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

*We are heavily dependent on the success of BA058 Injection, which is under clinical development. We cannot be certain that BA058 Injection will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.*

BA058 Injection 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 Injection in the United States unless and until we receive approval of an NDA from the 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 Microneedle Patch as a follow-on product is dependent on the earlier approval of BA058 Injection. 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 Injection may be delayed, limited or denied for many reasons, including:

- we may experience delays in the enrollment of patients in our ongoing Phase 3 clinical trial;
- 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;

Table of Contents

- the CRO that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA 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;
- 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;
- the FDA may require development of a REMS as a condition of approval; 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 Injection 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 daily oral doses of alendronate (generic Fosamax®) or other standard of care for osteoporosis management. We cannot be certain that the FDA 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 our pivotal Phase 3 study, a thorough QT Phase 1 study, a Phase 1 PK study in renal patients, a Phase 1 PK study in hepatic patients, a Phase 1 absolute bioavailability PK study, a carcinogenicity study in rats, and bone quality studies in rats and monkeys. We have not commenced all of these required studies and the results of these studies will have an important bearing on the approval of BA058. In addition to fracture and BMD, our pivotal Phase 3 study will measure a number of other potential safety indicators, including anti-BA058 antibodies which will have an important bearing on the approval of BA058. We have observed osteosarcomas in the rats in our carcinogenicity study. The final results from the rat carcinogenicity study, which includes hPTH(1-34), a daily subcutaneous injection of human parathyroid hormone as a comparator, may show that BA058 dosing results in more osteosarcomas than PTH, which may have a material adverse bearing on approval of BA058.

*If we experience delays in the enrollment of patients in our Phase 3 clinical trial of BA058 Injection or any other clinical trial, 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. If we do not enroll patients in our Phase 3 clinical trial of BA058 Injection at the rate that we expect, we will not be able to complete the trial in a timely manner and may be required to incur additional expenses in order to seek to accelerate the rate of patient enrollment. 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.

Table of Contents

*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 the FDA-equivalent 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 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 for a minimum of 24-month fracture data for approval of new products for the treatment of postmenopausal osteoporosis. 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 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.

*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. We estimate that clinical trials of BA058 Injection will take several additional years to complete. 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:

- 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



Table of Contents

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 Injection for fracture prevention may not replicate the positive efficacy results for BMD from 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.

***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, 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 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;
- recall of products;
- 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

Table of Contents

- injunctions or the imposition of civil or criminal penalties.

***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 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.

#### **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 Injection 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 Injection is being managed by Nordic at certain clinical sites operated by the Center for Clinical and Basic Research, or CCBR. Nordic controls, and holds an ownership interest in, the local CCBR clinical sites. The clinical trial investigators are employees of CCBR and may also hold an equity interest in the local CCBR clinical trials.

Table of Contents

In consideration of Nordic's management of this Phase 3 study, we agreed to make various cash payments to Nordic over the course of the Phase 3 study equal to a total of up to approximately \$41.2 million (\$52.1 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 \$525,000. 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 Series A-6 with an aggregate value of up to \$36.8 million (\$46.6 million). These shares of Series A-6 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 Injection for use in clinical trial activities. These contract manufacturers are currently our only source for the production and formulation of BA058. We currently do not have sufficient clinical supplies of BA058 to complete the Phase 3 study for BA058 Injection but believe that our contract manufacturers will be able to produce sufficient supply of BA058 to complete all of the planned BA058 clinical studies. However, 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 BA058 Injection and BA058 Microneedle Patch 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 Injection and we depend on 3M for the production of BA058 Microneedle Patch. Because of our dependence on Vetter for the "fill and finish" part of the manufacturing process for BA058 Injection, we are subject to the risk that Vetter may not have the capacity from time to time to produce sufficient quantities of

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

BA058 to meet the needs of our clinical studies or be able to scale to commercial production of BA058. Because the manufacturing process for BA058 Microneedle Patch requires the use of 3M's proprietary technology, 3M is our sole source for finished supplies of BA058 Microneedle Patch.

While we are currently in discussions, to date, neither we nor our collaborators have entered into a long-term agreement with Lonza, Vetter or 3M, each of whom currently produce BA058 or related components on a purchase order basis for us. Accordingly, Lonza, Vetter and 3M 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 good manufacturing practice 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.



Table of Contents

***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 Microneedle Patch, our commercial opportunity for BA058 will be limited. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

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

- developing drugs;
  
- undertaking preclinical testing and human clinical trials;
  
- obtaining FDA and other 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

Table of Contents

could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators.

**Risks Related to Our Intellectual Property**

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

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

*If our efforts to protect our intellectual property related to 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 expiry of approximately 2016 in the United States (this date does not include the possibility of Hatch-Waxman patent term extension of up to five years which could extend the expiration in the United States until at least the fourth quarter of 2020) and additional countries where it has issued.

We and Ipsen are also coassignees 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 Injection.

We and Ipsen are also coassignees 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 Injection.

Currently, additional intellectual property covering BA058 Microneedle Patch is the subject of an international patent application and a corresponding U.S. patent application filed in 2012 with priority dates of 2011; 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

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

requirements of patentability in view of claimed inventions are not always predictable. Additional intellectual property covering BA058 Microneedle Patch 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 Microneedle Patch. In addition, trade secrets may in some instances become publicly available 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 Microneedle Patch.

Patents covering RAD1901 as a composition of matter have been issued in the United States, Canada and Australia and are pending in Europe and several additional countries. 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, clinical dosage strengths and combination treatment modalities all covering 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.

We have yet to conduct comprehensive freedom-to-operate searches to determine whether our use of the patents licensed or issued to us that are believed to cover BA058 and RAD1901 would infringe patents owned by third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to these issued or licensed

Table of Contents

patents, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Patent applications covering RAD140 and other SARM compounds that are part of the SARM portfolio have been granted in the United States 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.

***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, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. We may become involved in opposition or interference 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.

Table of Contents

***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.

***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. In addition, 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.



Table of Contents

*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.

**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.*

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

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

Table of Contents

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.

***Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.***

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, we could be required to report those actions as recalls. A recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

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

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

*We may not successfully manage our growth.*

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on 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;

Table of Contents

- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

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

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

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

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

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

**Risks Relating to Our Securities**

***We have a history of operating losses, expect to incur significant and increasing operating losses in the future, and may never be consistently profitable.***

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

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue from sales. We have primarily incurred operating losses. As of June 30, 2012, we had an accumulated deficit of \$156.1 million. We have spent, and expect to continue to spend, significant resources to fund the research and development of BA058 Injection and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

Our drug candidates are in varying stages of preclinical and clinical development and may never be approved for sale or generate any revenue. We will not be able to generate product revenue unless and until one of our drug candidates successfully completes clinical trials and receives regulatory approval. Since even our most advanced drug candidate requires substantial additional clinical development, we do not expect to receive revenue from our drug candidates for several years, if at all. Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

***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.

Table of Contents

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

We plan to seek listing of our common stock on a national securities exchange or quotation of our common stock on the OTCBB, as soon as practicable. 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. 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 not freely tradable under federal securities laws, which will limit 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. Further, Rule 144 covering resales of unregistered securities and promulgated under the Securities Act will not be available for resale of our capital stock unless or until one year following the date on which we filed the information required by Form 10 as to the performance of our business. In addition, all shares of our stock issued in the Merger is subject to a lock-up provision set forth in the applicable stockholders' agreement.

***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 our existing 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 our existing 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. Our existing resale registration statement registered the resale of a significant number of shares of our common stock. 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 are a large number of shares registered pursuant to the registration statement, selling stockholders will continue to offer shares

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

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 the 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, will cause our expenses to be higher than they would be if we were privately held. We were 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.



Table of Contents

***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 June 30, 2012, we had outstanding 855,116 shares of common stock; 939,612 shares of Series A-1; 983,208 shares of Series A-2; 142,227 shares of Series A-3; 3,998 shares of Series A-4; 6,443 shares of Series A-5; warrants to acquire 14,734 shares of Series A-1; and warrants to acquire 266 shares of Common Stock. As more fully described herein and in our Certificate of 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 June 30, 2012, our directors, executive officers and holders of more than five percent of our common stock, together with their affiliates, own, 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

Table of Contents

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.

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

As of December 31, 2011, we had \$128.3 million of federal and \$109.7 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.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits.**

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

<b>Exhibit No.</b>	<b>Description</b>
10.1	Third Amendment to Loan and Security Agreement, dated as of May 29, 2012, by and among the Company, General Electric Capital Corporation and Oxford Finance LLC(1)
10.2	Warrant to Purchase Shares of Series A-1 Convertible Preferred Stock, dated May 29, 2012, issued by the Company to GE Capital Equity Investments(1)
10.3	Warrant to Purchase Shares of Series A-1 Convertible Preferred Stock, dated May 29, 2012, issued by the Company to Oxford Finance LLC(1)
10.4	Clinical Trial Services Agreement Amendment No. 2 to Work Statement NB-1, effective as of June 18, 2012, by and between the Company and Nordic Bioscience Clinical Development VII A/S*(2)

Table of Contents

- 31.1 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 June 30, 2012
- 31.2 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 June 30, 2012
- 32.1 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 The following materials from Radius Health, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Balance Sheets, (ii) the Condensed Statement of Operations, (iii) the Condensed Statements of Cash Flows and (iv) the Notes to Unaudited Financial Statements

- 
- (1) Incorporated by reference to the Company's Current Report on Form 8-K filed on June 4, 2012.
- (2) Incorporated by reference to the Company's Current Report on Form 8-K filed on June 22, 2012.

\* Confidential treatment has been granted with respect to portions of this exhibit. Redacted portions of this exhibit have been filed separately with the Securities and Exchange Commission.

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/ Michael S. Wyzga*  
Michael S. Wyzga  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: August 7, 2012

**RADIUS HEALTH, INC.**

By:

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

Date: August 7, 2012