Radius Health, Inc.
Form 10-Q
May 06, 2015
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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 March 31, 2015.

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 001-35726

Radius Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**80-0145732**
(State or other jurisdiction of Incorporation or organization)	(IRS Employer Identification Number)
950 Winter Street Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	(Zip Code)

(617) 551-4000

(Registrant s telephone number, including area code)

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

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 x No o

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 o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company o

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

Number of shares of the registrant s Common Stock, $.0001 par value per share, outstanding as of May 1, 2015: 37,890,202 shares

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RADIUS HEALTH, INC.

QUARTERLY REPORT FOR THE QUARTER ENDED MARCH 31, 2015

ON FORM 10-Q

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CURRENCY AND CONVERSIONS

In this report, references to dollar or $ are to the legal currency of the United States, and references to euro or are to the single currency introduced on January 1, 1999 at the start of the third stage of European Economic and Monetary Union, pursuant to the Treaty establishing the European Communities, as amended by the Treaty on European Union and the Treaty of Amsterdam. Unless otherwise indicated, the financial information in this report has been expressed in U.S. dollars. Unless otherwise stated, the U.S. dollar equivalent information translating euros into U.S. dollars has been made, for convenience purposes, on the basis of the noon buying rate published by the Board of Governors of the Federal Reserve as of March 31, 2015, which was 1.00 = $1.0741. 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.

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Item 1. Financial Statements

Radius Health, Inc.

Condensed Balance Sheets

(In thousands, except share and per share amounts)

	March 31, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,810	$ 28,518
Marketable securities	199,364	76,758
Prepaid expenses and other current assets	2,489	2,057
Total current assets	236,663	107,333
Property and equipment, net	863	842
Marketable securities, long-term	8,904	
Other assets	261	242
Total assets	$ 246,691	$ 108,417
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,173	$ 2,292
Accrued expenses and other current liabilities	12,108	18,267
Current portion of note payable, net of discount	2,446	
Total current liabilities	17,727	20,559
Note payable, net of current portion and discount	22,016	24,394
Total liabilities	$ 39,743	$ 44,953
Commitments and contingencies		
Stockholders equity:		
Common stock, $.0001 par value; 200,000,000 shares authorized; 37,882,967 shares and 32,924,535 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	$ 4	$ 3
Additional paid-in-capital	568,198	407,720
Accumulated other comprehensive income (loss)	41	(21)
Accumulated deficit	(361,295)	(344,238)
Total stockholders equity	206,948	63,464
Total liabilities and stockholders equity	$ 246,691	$ 108,417

See accompanying notes to unaudited condensed financial statements.

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Radius Health, Inc.

Condensed Statements of Operations and Comprehensive Loss

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

	Three Months Ended March 31,	
	2015	**2014**
OPERATING EXPENSES:		
Research and development	$ 11,559	$ 9,717
General and administrative	4,756	2,139
Loss from operations	(16,315)	(11,856)
OTHER (EXPENSE) INCOME:		
Other income (expense), net	(50)	(2,233)
Interest income	105	2
Interest expense	(797)	(401)
NET LOSS	$ (17,057)	$ (14,488)
OTHER COMPREHENSIVE INCOME, NET OF TAX:		
Unrealized gain from marketable securities	62	
COMPREHENSIVE LOSS	$ (16,995)	$ (14,488)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED (Note 10):	$ (17,057)	$ (19,457)
LOSS PER SHARE:		
Basic	$ (0.47)	$ (50.45)
Diluted	$ (0.47)	$ (50.45)
WEIGHTED AVERAGE SHARES:		
Basic	36,268,975	385,664
Diluted	36,268,975	385,664

See accompanying notes to unaudited condensed financial statements.

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Radius Health, Inc.

Statement of Stockholders Equity

(Unaudited, in thousands except share amounts)

	Common Stock		Additional Paid-In-Capital	Stockholders Equity Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2014	32,924,535	$ 3	$ 407,720	$ (21)	$ (344,238)	$ 63,464
Net loss					(17,057)	(17,057)
Unrealized gain from available-for-sale securities				62		62
Exercise of warrants	357,029					
Exercise of options	1,403		4			4
Stock-based compensation expense			2,061			2,061
Issuance of common stock, net	4,600,000	1	158,413			158,414
Balance at March 31, 2015	37,882,967	$ 4	$ 568,198	$ 41	(361,295)	$ 206,948

See accompanying notes to unaudited condensed financial statements.

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Radius Health, Inc.

Statements of Cash Flows

(Unaudited, in thousands)

	Three Months Ended March 31,	
	2015	**2014**
CASH FLOWS USED IN OPERATING ACTIVITIES:		
Net loss	$ (17,057)	$ (14,488)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	36	16
Amortization of premium (accretion of discount) on marketable securities, net	290	
Stock-based compensation expense	2,061	511
Research and development expense settled in stock		2,717
Change in fair value of other current assets, warrant liability and other liability		2,233
Non-cash interest	78	63
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(428)	(690)
Other long-term assets	(31)	
Accounts payable	881	(21)
Accrued expenses and other current liabilities	(6,159)	2,453
Net cash used in operating activities	(20,329)	(7,206)
CASH FLOWS USED IN INVESTING ACTIVITIES:		
Purchases of property and equipment	(56)	
Purchases of marketable securities	(170,088)	
Sales and maturities of marketable securities	38,351	
Net cash used in investing activities	(131,793)	
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:		
Payments on note payable		(2,907)
Proceeds from the issuance of common stock, net	158,414	
Proceeds from the issuance of preferred stock, net		27,368
Net cash provided by financing activities	158,414	24,461
NET INCREASE IN CASH AND CASH EQUIVALENTS	6,292	17,255
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	28,518	12,303
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 34,810	$ 29,558
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$ 626	$ 310
NON-CASH FINANCING ACTIVITIES:		
Accretion of dividends on preferred stock	$	$ 4,969
Fair value of Series A-6 convertible preferred stock issued as settlement of liability	$	$ 10,109
Fair value of warrants issued	$	$ 1,216

See accompanying notes to unaudited condensed financial statements.

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Radius Health, Inc.

Notes to Financial Statements

(Unaudited)

1. Organization

Radius Health, Inc. (the Company) is a science-driven biopharmaceutical company focused on developing new therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases, including hormone responsive breast cancer. The Company s lead investigational product candidate is the investigational drug abaloparatide, a bone anabolic for potential use in the reduction of fracture risk in postmenopausal women with severe osteoporosis delivered via subcutaneous injection (abaloparatide-SC), which is currently in Phase 3 development. The Company is leveraging its investment in abaloparatide-SC to develop a potential future line extension that is designed to improve patient convenience by enabling administration of abaloparatide through an investigational short-wear-time patch (abaloparatide-TD).

The Company s current clinical product portfolio also includes the investigational drug RAD1901, a selective estrogen receptor down regulator/degrader and RAD140, a nonsteroidal selective androgen receptor modulator. The Company is developing RAD1901 at higher doses for potential use in the treatment of metastatic breast cancer and other estrogen receptor mediated oncology applications. The Company is currently enrolling a Phase 1, multicenter, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced estrogen receptor positive and HER2-negative breast cancer. Low-dose RAD1901 has shown potential to be effective for the treatment of vasomotor symptoms, such as hot flashes, in a successful Phase 2 proof of concept study. RAD140 resulted from an internal drug discovery program focused on the androgen receptor pathway, which is highly expressed in many breast cancers. Due to its receptor and tissue selectivity, potent oral activity, and long duration half-life, RAD140 could have clinical potential in the treatment of breast cancer.

The Company is subject to the risks associated with emerging companies with a limited operating history, including dependence on key individuals, a developing business model, the necessity of securing regulatory approval to market its investigational product candidates, market acceptance of the Company s investigational product candidates following receipt of regulatory approval, competition for its investigational product candidates following receipt of regulatory approval, and the continued ability to obtain adequate financing to fund the Company s future operations. The Company has incurred losses and expects to continue to incur additional losses for the foreseeable future. As of March 31, 2015, the Company had an accumulated deficit of $361.3 million, and total cash, cash equivalents and short and long-term marketable securities of $243.1 million.

The Company believes that its cash, cash equivalents and short and long-term marketable securities as of March 31, 2015, will be sufficient to fund its operations into the fourth quarter of 2016. The Company expects to finance the future development costs of abaloparatide-SC, abaloparatide-TD and RAD1901 with its existing cash and cash equivalents and marketable securities, or through strategic financing opportunities, future offerings of its equity, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company fails to obtain additional future capital, it may be unable to complete its planned preclinical and clinical trials and obtain approval of certain investigational product candidates from the U.S. Food and Drug Administration or other foreign regulatory authorities.

2. Basis of Presentation and Significant Accounting Policies

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

When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2015. Subsequent events have been evaluated up to the date of issuance of these financials. For further information, refer to the financial statements and footnotes included in the Company s audited financial statements for the year ended December 31, 2014 included in the Company s Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 10, 2015.

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, 2014 which require the Company to make estimates and assumptions include:

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research and development costs, stock-based compensation and fair value measures. There were no changes to significant accounting policies during the three months ended March 31, 2015.

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

In January 2015, the FASB issued Accounting Standards Update No. 2015-01, *Income Statement Extraordinary and Unusual Items (Subtopics 225-20)*(ASU 2015-01). ASU 2015-01 eliminates the concept of extraordinary items from GAAP. The amendments under ASU 2015-01 are effective for interim and annual fiscal periods beginning after December 15, 2015, with early adoption permitted. The Company does not expect the adoption of ASU 2015-01 to have a material impact on its results of operations, financial position or cash flows.

3. Accrued Expenses and Other Current Liabilities

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

	March 31, 2015	December 31, 2014
Research costs - Nordic (1)	$ 6,024	$ 11,536
Research costs - other	2,666	3,336
Payroll and employee benefits	652	1,659
Professional fees	2,439	1,304
Accrued interest on notes payable	327	234
Other		198
Total accrued expenses and other current liabilities	$ 12,108	$ 18,267

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

4. Loan and Security Agreement

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

aggregate principal amount equal to $21.0 million (the Initial Term Loan).

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

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On July 10, 2014, the Company entered into a first amendment to the Credit Facility (the First Amendment). The terms of the First Amendment, among other things, provide the Company with, subject to certain customary funding conditions, additional term loans in an aggregate principal amount of $4.0 million upon the closing of the First Amendment (the Modified Term B Loan). All other terms applicable to the Original Term B Loan remain applicable to the Modified Term B Loan and the Modified Term B Loan replaced the Original Term B Loan. The Company borrowed the full amount of the Modified Term B Loan on July 10, 2014.

The Company is required to make interest-only payments through December 1, 2015, and beginning on January 1, 2016, it is required to make payments of principal and accrued interest in equal monthly installments over a term of 30 months.

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

The future principal payments under the Credit Facility, as amended, are as follows, as of March 31, 2015 (in thousands):

Years ending December 31,	Principal Payments
2015	$
2016	10,000
2017	10,000
2018	5,000
Total	$ 25,000

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

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

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

5. Marketable Securities

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

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	March 31, 2015			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 2,284	$	$	$ 2,284
Money market funds	32,526			32,526
Total	$ 34,810	$	$	$ 34,810
Marketable securities:				
Domestic corporate debt securities	150,058	11	(44)	150,025
Domestic corporate commercial paper	55,668	72		55,740
U.S. Agency bonds	2,501	2		2,503
Total	$ 208,227	$ 85	$ (44)	$ 208,268

	December 31, 2014			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 1,519	$	$	$ 1,519
Money market funds	23,994			23,994
Domestic corporate debt securities	3,005			3,005
Total	$ 28,518	$	$	$ 28,518
Marketable securities:				
Domestic corporate debt securities	69,542		(33)	69,509
Domestic corporate commercial paper	7,237	12		7,249
Total	$ 76,779	$ 12	$ (33)	$ 76,758

There were no debt securities that had been in an unrealized loss position for more than 12 months as of March 31, 2015 or December 31, 2014. There were 38 debt securities in an unrealized loss position for less than 12 months at March 31, 2015 and there were 34 debt securities that had been in an unrealized loss position for less than 12 months at December 31, 2014. The aggregate unrealized loss on these securities as of March 31, 2015 was less than $44 thousand and the fair value was $117.6 million. The Company considered the decline in market value for these securities to be primarily attributable to current economic conditions. As it was not more likely than not that the Company would be required to sell these securities before the recovery of their amortized cost basis, which may be maturity, the Company did not consider these investments to be other-than-temporarily impaired as of March 31, 2015.

As of March 31, 2015, marketable securities consisted of investments that mature within one year, with the exception of certain corporate bonds and U.S. Agency bonds, which have maturities within two years and an aggregate fair value of $8.9 million.

6. Fair Value Measurements

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

- Level 1 Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

- Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table summarizes the financial instruments measured at fair value on a recurring basis in the accompanying condensed balance sheets as of March 31, 2015 and December 31, 2014 (in thousands):

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	March 31, 2015			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents:				
Cash	$ 2,284	$	$	$ 2,284
Money market funds (1)	32,526			32,526
Total	$ 34,810	$	$	$ 34,810
Marketable securities:				
Domestic corporate debt securities (2)		150,025		150,025
Domestic corporate commercial paper (2)		55,740		55,740
U.S. Agency bonds (2)		2,503		2,503
Total	$	$ 208,268	$	$ 208,268

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents:				
Cash	$ 1,519	$	$	$ 1,519
Money market funds (1)	23,994			23,994
Domestic corporate debt securities (2)		3,005		3,005
Total	$ 25,513	$ 3,005	$	$ 28,518
Marketable securities:				
Domestic corporate debt securities (2)	$	$ 69,509	$	$ 69,509
Domestic corporate commercial paper (2)		7,249		7,249
Total	$	$ 76,758	$	$ 76,758

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

(2) Fair value is based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Inputs are obtained from various sources, including market participants, dealers and brokers.

The fair value of the Company s note payable is determined using current applicable rates for similar instruments as of the balance sheet date. The carrying value of the Company s note payable approximated its fair value as of March 31, 2015, as the Company s interest rate is near current market rates. The fair value of the Company s notes payable was determined using Level 3 inputs.

7. License Agreements

On September 27, 2005, the Company entered into a license agreement (the Ipsen Agreement), as amended, with SCRAS S.A.S, a French corporation on behalf of itself and its affiliates (collectively, Ipsen). Under the Ipsen Agreement, Ipsen granted to the Company an exclusive right and license under certain Ipsen compound technology and related patents to research, develop, manufacture and commercialize certain compounds and related products in all countries, except Japan (where the Company does not hold commercialization rights) and France (where the Company s commercialization rights are subject to certain co-marketing and co-promotion rights retained by Ipsen). 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 the Company a mid-single digit royalty on Ipsen s allocable portion of aggregate revenue from the sale of products by both parties in France. Abaloparatide is subject to the Ipsen Agreement. Ipsen also granted the Company an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen also granted the Company an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling the Company to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan (where the Company does not hold commercialization rights) and France (where the Company s commercialization rights are subject to certain co-marketing and co-promotion rights retained by Ipsen).

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In consideration for these licenses, the Company made a nonrefundable, non-creditable payment of $250.0 thousand 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 ($10.7 million to $38.7 million) to Ipsen upon the achievement of certain development and commercialization milestones specified in the Ipsen Agreement, and for the payment of fixed 5% royalties on net sales of any product by the Company or its sublicensees on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country of any product that includes the compound licensed from Ipsen or any analog thereof.

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

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

On March 9, 2015, the Company entered into an amendment to the Eisai Agreement (the Eisai Amendment) in which Eisai granted to the Company the exclusive right and license to research, develop, manufacture and commercialize RAD1901 in Japan. In consideration for the rights to RAD1901 in Japan, the Company paid Eisai an initial license fee of $0.4 million upon execution of the contract, which was recognized as research and development expense during the three months ended March 31, 2015.

Under the Eisai Agreement, as amended, should a product covered by the licensed technology be commercialized, the Company will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the product on a country-by-country basis until the later of the last to expire of the licensed patents or the expiration of data protection clauses covering such product in such country. 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. The latest valid claim to expire, barring any extension thereof, is expected on August 18, 2026.

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

8. Research Agreements

Abaloparatide-SC Phase 3 Clinical Trial On March 29, 2011, the Company and Nordic entered into a Clinical Trial Services Agreement (the Clinical Trial Services Agreement), a Work Statement NB-1, as amended on December 9, 2011, June 18, 2012, March 28, 2014, May 19, 2014 and July 22, 2014 (the Work Statement NB-1) and a Stock Issuance Agreement, as amended and restated on May 16, 2011, and as further amended on February 21, 2013, March 28, 2014, and May 19, 2014 (the Stock Issuance Agreement). Pursuant to the Work Statement NB-1, Nordic is managing the Phase 3 clinical trial of abaloparatide-SC (the Phase 3 Clinical Trial).

Pursuant to the Work Statement NB-1, the Company was required to make certain per patient payments denominated in both euros and U.S. dollars for each patient enrolled in the Phase 3 Clinical Trial followed by monthly payments for the duration of the study and final payments in two equal euro-denominated installments and two equal U.S. dollar-denominated installments. In addition, the Company agreed to pay to Nordic an additional performance incentive (each a Performance Incentive Payment) of $500,000 for every 50 patients that, subsequent to March 28, 2014, completed all end-of-study procedures, up to a maximum aggregate amount of additional payments equal to $5.0 million. The Work Statement NB-1, provided for a total of up to approximately 41.2 million ($44.2 million) of euro-denominated payments and a total of up to approximately $3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus Performance Incentive Payments.

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The Company recognized research and development expense for the amounts due to Nordic under the Work Statement NB-1 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 3 Clinical Trial, or a twenty-month period. The Company recognized research and development expense for the amounts due to Nordic under the fourth amendment to the Work Statement NB-1, which is recognized on a per patient basis when the end-of-study visit and all other required procedures are completed. The Company recorded $4.5 million of research and development expense during the three months ended March 31, 2014, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Trial. As of March 31, 2015, all obligations due to Nordic under Work Statement NB-1 had been paid.

Abaloparatide-SC Phase 3 Clinical Extension Study On February 21, 2013, the Company entered into a Work Statement NB-3, as amended on March 4, 2014 (the Work Statement NB-3). Pursuant to the Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial (the Extension Study), and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management (the Second Extension).

Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to 7.5 million ($8.0 million) and $1.1 million, respectively. In addition, payments are due to Nordic in connection with the Work Statement NB-3 pursuant to the Stock Issuance Agreement, as discussed below.

The Company recognizes research and development expense for the amounts due to Nordic under the Extension Study and the Second Extension ratably over the estimated per patient treatment periods beginning upon enrollment, or over a nine-month and nineteen-month period, respectively. The Company recorded $1.4 million and $2.5 million of research and development expense during the three months ended March 31, 2015 and 2014, respectively, for per patient costs incurred for patients that had enrolled in the Extension Study and the Second Extension.

As of March 31, 2015, the Company had a liability of $6.0 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

Stock Issuance Agreement Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase 6,443 shares of the Company s Series A-5 convertible preferred stock (Series A-5) and to receive quarterly stock dividends, payable in shares of the Company s Series A-6 convertible preferred stock (Series A-6). In connection with the Work Statement NB-1, the Stock Issuance Agreement provided that Nordic was entitled to receive stock dividends, having an aggregate value of up to 36.8 million ($39.5 million) (the NB-1 Accruing Dividend). In connection with Work Statement NB-3, the Stock Issuance Agreement provided that, beginning with the quarter ended March 31, 2013, Nordic was entitled to receive stock dividends having an aggregate value of up to 7.5 million ($8.0 million) and $0.8 million (the NB-3 Accruing Dividend and together with the NB-1 Accruing Dividend, the Nordic Accruing Dividend). On March 28, 2014, the Company entered into the second amendment to the Stock Issuance Agreement (the Second Stock Issuance Agreement Amendment). The Second Stock Issuance Agreement Amendment required that the Company s Board of Directors declare, as soon as reasonably practical, a stock dividend of twenty-nine (29) shares of its Series A-6 for each share of the Company s then-outstanding Series A-5, all of which were held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in connection with Work Statement NB-1 and Work Statement NB-3. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, the Company s Board of Directors declared and issued a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment further provided that in the event an initial public offering of the Company s common stock occurred prior to May 31, 2014, any payments owed by the Company to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, excluding Performance Incentive Payments, for all periods of time after 2014, would be changed from the right to receive stock to the right to receive a total cash payment from the Company of $4.3 million payable in ten equal monthly installments of $430,000 beginning on March 31, 2015. On May 19, 2014, the Company entered into the third amendment to the Stock Issuance Agreement, which amended the date prior to which an initial public offering must occur to June 30, 2014. The Second Stock Issuance Agreement Amendment also stipulated that all consideration to be paid to

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

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

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9. Stock-Based Compensation

A summary of stock option activity during the three months ended March 31, 2015 is as follows (in thousands, except for per share amounts):

	Shares	Weighted-Average Exercise Price (in dollars per share)	Weighted-Average Contractual Life (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2014	3,220	$ 13.58		
Granted	432	46.29		
Exercised	(1)	2.74		
Cancelled	(26)	13.54		
Expired				
Options outstanding at March 31, 2015	3,625	$ 17.48	8.51	$ 88,050
Options exercisable at March 31, 2015	1,460	$ 9.78	7.19	$ 45,795
Options vested or expected to vest at March 31, 2015	3,523	$ 17.32	8.48	$ 86,075

The weighted-average grant-date fair value per share of options granted during the three months ended March 31, 2015 was $24.97. As of March 31, 2015, there was approximately $24.4 million of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 4 years.

10. Net Loss Per Share

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

	Three Months Ended March 31,	
	2015	2014
Numerator:		
Net loss	$ (17,057)	$ (14,488)
Accretion of Preferred Stock		(4,969)
Loss attributable to common stockholders - basic and diluted	$ (17,057)	$ (19,457)
Denominator:		
Weighted-average number of common shares used in loss per share - basic and diluted	36,268,975	385,664
Loss per share - basic and diluted	(0.47)	$ (50.45)

The following potentially dilutive securities, prior to the use of the treasury stock method, have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive. For the three months ended March 31, 2015 and 2014, all of the Company s classes of preferred stock, options to purchase common stock and warrants outstanding were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Three Months Ended March 31,	
	2015	**2014**
Convertible preferred stock		7,628,051
Options to purchase common stock	3,376,071	2,121,606
Warrants	1,113,622	1,010,257

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11. Commitments and Contingencies

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

12. Stockholders Equity and Convertible Preferred Stock

Common Stock On June 11, 2014, the Company completed its initial public offering whereby the Company sold 6,500,000 shares of common stock at a price of $8.00 per share. In connection with the offering, all outstanding shares of its convertible preferred stock converted into 19,465,132 shares of common stock and 2,862,654 shares of common stock were issued in satisfaction of accumulated dividends accrued on the preferred stock.

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

On October 7, 2014, the Company completed an additional public offering whereby it sold 2,750,000 shares of common stock at a price of $18.25 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately $46.9 million. On October 7, 2014, the underwriters purchased an additional 378,524 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the over-allotment option, the Company received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately $53.4 million.

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

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

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

Cautionary Statement

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

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

- *our expectations as to future financial performance, expense levels and liquidity sources;*

- *our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;*

- *anticipated trends and challenges in our potential markets; and*

- *our ability to attract and motivate key personnel.*

The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements. These important factors include our financial performance, our ability to attract and retain customers, our development activities and those factors we discuss in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 10, 2015 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 Operations section refer to Radius Health, Inc., a Delaware corporation, or Radius.

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Executive Overview

We are a science-driven biopharmaceutical company focused on developing new therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases, including hormone responsive breast cancer. Our lead product candidate is the investigational drug abaloparatide, a bone anabolic for potential use in the reduction of fracture risk in postmenopausal women with severe osteoporosis. We are developing two formulations of abaloparatide: abaloparatide-SC, an injectable subcutaneous formulation of abaloparatide, and abaloparatide-TD, a line extension of abaloparatide-SC in the form of a convenient, short-wear-time transdermal patch.

Our current clinical product portfolio also includes the investigational drug RAD1901, a selective estrogen receptor down regulator/degrader, or SERD, and the investigational drug RAD140, a nonsteroidal selective androgen receptor modulator, or SARM. We are developing RAD1901 at higher doses for potential use in the treatment of metastatic breast cancer and other estrogen receptor mediated applications. We are currently enrolling a Phase 1, multicenter, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced estrogen receptor positive and HER2-negative breast cancer. Low-dose RAD1901 has shown potential to be effective for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study. RAD140 resulted from an internal drug discovery program focused on the androgen receptor pathway which is highly expressed in many breast cancers. Due to its receptor and tissue selectivity, potent oral activity and long duration half-life, RAD140 could have clinical potential in the treatment of breast cancer or possibly other conditions where androgen modulation may offer therapeutic benefit.

Abaloparatide

Abaloparatide is a novel synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a bone anabolic treatment for potential use in the reduction of fracture risk in postmenopausal women with severe osteoporosis. We also believe that, subject to further research and development, abaloparatide may have potential applications across a variety of skeletal or bone related diseases or medical conditions. We are developing two formulations of abaloparatide:

- *Abaloparatide-SC* - In December 2014, we announced the 18-month top-line data from our Phase 3 ACTIVE clinical trial of abaloparatide-SC. The study was designed to evaluate whether abaloparatide-SC is superior to placebo for prevention of vertebral fracture. The study was also designed to evaluate whether abaloparatide-SC is superior to open-label teriparatide for greater bone mineral density, or 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. The top-line results of the 18-month ACTIVE clinical trial showed that abaloparatide-SC met the primary endpoint with a statistically significant 86% reduction in new vertebral fractures versus placebo, and teriperatide met the same endpoint with a statistically significant 80% reduction. On the secondary endpoints, as compared to placebo, abaloparatide achieved a statistically significant fracture-rate reduction of 43% in the adjudicated non-vertebral fracture subset of patients; a statistically significant reduction of 45% in the adjudicated clinical fracture group; and a significant difference in the time to first incident of non-vertebral fracture in both the adjudicated non-vertebral fracture and the clinical fracture subset of patients in this trial. On April 28, 2015, additional positive data from the Phase 3 ACTIVE study of our investigational drug abaloparatide-SC, "Treatment with Abaloparatide Significantly Reduces Wrist Fractures Compared to Teriparatide", was presented in the HOT TOPICS Session at the ECTS-IBMS 2015 Congress. This presentation focused on data from a post-hoc analysis (not prespecified in the study protocol or the original or amended statistical analysis plan for the ACTIVE trial) relating to the effects seen for abaloparatide on BMD and fracture risk at the wrist. The post-hoc analysis showed that abaloparatide, as compared to teriparatide, showed a significant 72% reduction in wrist fractures. Any potential clinical significance of these data will be evaluated during the anticipated regulatory review of these and all other data from the ACTIVE clinical trial.

We are currently conducting a 6-month extension trial in which patients from the abaloparatide and placebo groups from this trial are receiving an approved alendronate therapy for osteoporosis management. We currently anticipate the first results from the first six months of the extension trial to be available at the end of the second quarter of 2015. Following completion of the first six months of the extension trial, we plan to

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submit a new drug application in the United States, and a marketing authorization application in Europe, during the second half of 2015. We hold worldwide commercialization rights to abaloparatide-SC, other than in Japan, and subject to a regulatory review and favorable regulatory outcome, we anticipate our first commercial sales of abaloparatide-SC will take place in 2016. We believe that, subject to further research and development, abaloparatide may have potential applications across a variety of skeletal or bone related diseases or medical conditions.

- *Abaloparatide-TD*- During 2014, we reported progress towards the development of an optimized, short-wear-time transdermal patch that may be capable of demonstrating comparability to abaloparatide-SC injection. In preliminary, nonhuman primate pharmacokinetic studies, we achieved a desirable pharmacokinetic profile, with comparable AUC, Cmax, Tmax and T1/2 relative to abaloparatide-SC. We believe that these results support continued clinical development of abaloparatide-TD toward future global regulatory submissions as a potential post-approval line extension of the investigational drug abaloparatide-SC. We expect to commence the clinical evaluation of the optimized abaloparatide-TD patch in the second half of 2015, with the goal of achieving comparability to abaloparatide-SC. We hold worldwide commercialization rights to abaloparatide-TD technology.

RAD1901

RAD1901 is a novel potent SERD that is being evaluated for potential use in the treatment of metastatic breast cancer and other estrogen receptor mediated oncology applications. RAD1901 has been shown to bind with good selectivity to the estrogen receptor and to have both estrogen-like and estrogen-antagonistic effects in different tissues. We hold worldwide commercialization rights to RAD1901.

In June 2014, we commenced a Phase 1 maximum tolerated dose, or MTD, study of RAD1901 in healthy volunteers. The study is designed to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also to use 18F-estradiol positron emission tomography, or FES-PET, imaging to provide a pharmacodynamic assessment of estrogen receptor turnover following administration of RAD1901. Levels of RAD1901 in cerebrospinal fluid samples taken from study subjects will be measured to confirm that RAD1901 has crossed the blood-brain barrier. Based upon initial study results, FES-PET imaging of RAD1901 has shown potent activity as a SERD. As of March 31, 2015, 40 subjects had completed dose escalation in the ongoing MTD study, and FES-PET imaging had been completed in a total of five subjects across two different doses. Each of these five subjects showed, based on FES-PET imaging, suppression of the FES-PET signal to background levels after six days of dosing. In addition, RAD1901, at the doses that showed suppression of the FES-PET signal, was well tolerated in these subjects.

In December 2014, we commenced a Phase 1, multicenter, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced estrogen receptor positive and HER2-negative breast cancer in the United States to determine the recommended dose for a Phase 2 clinical trial and to make a preliminary evaluation of the potential anti-tumor effect of RAD1901. We continue to enroll and dose patients in this study and expect to provide an update at the American Society of Clinical Oncology Annual Meeting in May 2015 and to report further progress in the second half of 2015. We also expect to commence Phase 1 clinical development in the European Union of RAD1901 in metastatic breast cancer patients in 2015.

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Financial Overview

Research and Development Expenses

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

None of the research and development expenses in relation to our product candidates are currently borne by third parties. Our lead product candidate is the investigational drug abaloparatide, and it represents the largest portion of our research and development expenses for our product candidates. We began tracking program expenses for abaloparatide-SC in 2005, and program expenses from inception to March 31, 2015 were approximately $181.1 million. We began tracking program expenses for abaloparatide-TD in 2007, and program expenses from inception to March 31, 2015 were approximately $31.6 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to March 31, 2015 were approximately $18.6 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to March 31, 2015 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, stock-based compensation and research and development support services are not directly charged to programs as they benefit multiple research programs that share resources.

We estimate that future development costs for abaloparatide-SC may exceed $47.0 million, including $14.0 million for clinical costs, $21.0 million for license and milestone payments and NDA submission fees, $9.0 million for manufacturing costs and $3.0 million for preclinical costs. For abaloparatide-TD, we estimate that future development costs may exceed $29.0 million, including $18.0 million for clinical costs, $7.0 million for manufacturing costs, and $4.0 million for preclinical costs and NDA submission fees.

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

The following table sets forth our research and development expenses related to abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140 for the three months ended March 31, 2015 and 2014 (in thousands):

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	Three Months Ended March 31,	
	2015	2014
Abaloparatide-SC	$ 5,134	$ 8,107
Abaloparatide-TD	480	185
RAD1901	800	
RAD140		

General and Administrative Expenses

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

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

Interest Income and Interest Expense

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

Interest expense for the three months ended March 31, 2015 reflects interest due under our loan and security agreement, entered into on May 30, 2014 and amended on July 10, 2014 and February 13, 2015, or the New Credit Facility, with Solar Capital Ltd., or Solar, as agent and lender, and Oxford Finance LLC, or Oxford, as lender. Under the New Credit Facility, we drew $21.0 million under an initial term loan on May 30, 2014 and $4.0 million under a second term loan on July 10, 2014. Interest expense for the three months ended March 31, 2014 reflects interest due under our loan and security agreement, entered into on May 23, 2011 with General Electric Capital Corporation, or GECC, as agent and lender, and Oxford, as a lender, or the Original Credit Facility. Under the Original Credit Facility, we drew $12.5 million under an initial and second term loan during the year ended December 31, 2011 and an additional $12.5 million under a third term loan during the year ended December 31, 2012. On May 30, 2014, we used approximately $9.3 million of the New Credit Facility to repay all the amounts owed under the Original Credit Facility.

Other (Expense) Income

For the three months ended March 31, 2014, other (expense) income reflects changes in the fair value of our warrant liability and the series A-6 convertible preferred stock liability and stock asset from the date of the initial accrual to the reporting date.

Critical Accounting Policies and Estimates

Management s discussion and analysis of financial condition and results of operations is based upon our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or

GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, as well as related disclosures. We evaluate our policies and estimates on an ongoing basis, including those related to accrued clinical expenses, research and development expenses, stock-based compensation and fair value measures, which we discussed in our Annual Report on Form 10-K for the year ended December 31, 2014. Management bases its estimates on historical experience and other various assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We have reviewed our policies and estimates to determine our critical accounting policies for the three months ended March 31, 2015. We have made no material changes to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2014.

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Results of Operations

Three Months Ended March 31, 2015 and March 31, 2014 (in thousands, except percentages)

	Three Months Ended March 31,		Change	
	2015	2014	$	%
Operating expenses:				
Research and development	$ 11,559	$ 9,717	$ 1,842	19%
General and administrative	4,756	2,139	2,617	122%
Loss from operations	(16,315)	(11,856)	4,459	38%
Other (expense) income:				
Other income (expense), net	(50)	(2,233)	(2,183)	-98%
Interest (expense) income, net	(692)	(399)	293	73%
Net Loss	$ (17,057)	$ (14,488)	$ 2,569	18%

Research and development expenses For the three months ended March 31, 2015, research and development expense was $11.6 million compared to $9.7 million for the three months ended March 31, 2014, an increase of $1.8 million, or 19%. This increase is primarily a result of an increase in compensation expense as a result of an increase in headcount and an increase in consulting costs incurred to support our NDA submission for our investigational product candidate abaloparatide-SC. These amounts were partially offset by a decrease in the total professional contract service costs associated with the development of abaloparatide-SC resulting from the completion of the Phase 3 18-month fracture study in October 2014. Additionally, fewer patients were enrolled in the extension study of abaloparatide-SC as of March 31, 2015 as compared to the three months ended March 31, 2014. We expect that costs associated with the development of abaloparatide-SC will continue to decrease over the course of the ACTIVExtend clinical trial as patients complete treatment. We expect that the costs associated with the development of abaloparatide-TD will increase as we begin to advance an optimized abaloparatide-TD product in additional clinical studies, followed by a Phase 3 bridging study. There was also an increase in contract service costs associated with the development of our investigational product candidate RAD1901 as a result of the initiation of various preclinical and manufacturing activities in 2014. We expect that the costs associated with the development of RAD1901 will increase as we begin to advance RAD1901 through various preclinical and clinical studies, including a Phase 1 study in metastatic breast cancer, which commenced in late 2014, and a Phase 2b study in vasomotor symptoms, which is expected to commence in the second half of 2015.

General and administrative expenses For the three months ended March 31, 2015, general and administrative expense was $4.8 million compared to $2.1 million for the three months ended March 31, 2014, an increase of $2.6 million, or 122%. This increase was primarily the result of an increase of approximately $1.5 million in consulting support costs and legal fees during the three months ended March 31, 2015. This increase can also be attributed to higher compensation costs, including non-cash stock-based compensation expense, due to an overall increase in employee headcount.

Other income (expense), net For the three months ended March 31, 2015, there was other expense, net of other income, of $0.1 million as compared to other expense, net of other income during the three months ended March 31, 2014 of $2.2 million. For the three months ended March 31, 2015, other expense, net of other income, primarily represents state tax expenses. The $2.2 million of other expense, net of income, as of March 31, 2014 was primarily due to an increase in the fair value of our stock liability and other liability as a result of an increase in the fair value of the underlying convertible preferred stock from December 31, 2013 to March 31, 2014.

Interest (expense) income, net For the three months ended March 31, 2015, interest expense, net of interest income, was $0.7 million compared to $0.4 million for the three months ended March 31, 2014, an increase of $0.3 million, or 73%. This increase was primarily a result of higher average debt outstanding during the three months ended March 31, 2015 as compared to the three months ended March 31, 2014.

Liquidity and Capital Resources

From inception to March 31, 2015, we have incurred an accumulated deficit of $361.3 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and expenses supporting those activities. Our total cash, cash equivalents and marketable securities balance as of March 31, 2015 was $243.1 million. We have financed our operations since inception primarily through the public offerings of our common stock, private sale of preferred stock, borrowings under our credit facilities and the receipt of $5.0 million in fees associated with an option agreement.

We believe that our cash, cash equivalents and marketable securities as of March 31, 2015, will be sufficient to fund our operations into the fourth quarter of 2016. We expect to finance the future development costs of abaloparatide-SC, abaloparatide-TD and RAD1901 with our existing cash and cash equivalents and marketable securities, or through strategic financing opportunities that

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could include, but are not limited to, partnering or other collaboration agreements, or the completion of an additional public offering of securities. However, there is no guarantee that any of these financing opportunities will be available to us on favorable terms, and some could be dilutive to existing stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development and commercialization activities, the results of our clinical trials, and the review and potential approval of our products by the FDA and EMA. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any investigational product candidates from the FDA and other foreign regulatory authorities.

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

	Three Months Ended March 31,		Change	
	2015	2014	$	%
Net cash (used in) provided by:				
Operating activities	$ (20,329)	$ (7,206)	$ 13,123	182%
Investing activities	(131,793)		131,793	100%
Financing activities	158,414	24,461	133,953	548%
Net increase in cash and cash equivalents	$ 6,292	$ 17,255		

Cash Flows from Operating Activities

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

Net cash used in operating activities for the three months ended March 31, 2014 was $7.2 million, which was primarily the result of a net loss of $14.5 million, partially offset by $5.5 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of $1.8 million. The $14.5 million net loss was primarily due to expenses incurred in connection with our Phase 3 clinical trial of abaloparatide-SC. The $5.5 million net non-cash adjustments to reconcile net loss to net cash used in operations included $2.7 million of research and development expenses settled in stock, a $2.2 million increase in the fair value of our warrant liability and stock liability as a result of an increase in the fair value of the underlying convertible preferred stock and common stock from December 31, 2013 to March 31, 2014, and stock-based compensation expense of $0.5 million.

Cash Flows from Investing Activities

Net cash used in investing activities during the three months ended March 31, 2015 was $131.8 million, which was primarily the result of $170.1 million of purchases of marketable securities, partially offset by $38.4 million of net proceeds received from the sale or maturity of marketable securities. There was no net cash provided by or used in investing activities for the three months ended March 31, 2014.

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 two years. Due to the short-term nature of our marketable securities, we would not expect our operational results or cash flows to be significantly affected by a change in market interest rates.

Cash Flows from Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2015 was $158.4 million, as compared to $24.5 million net cash provided by financing activities during the three months ended March 31, 2014.

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

Net cash provided by financing activities for the three months ended March 31, 2014 consisted of $27.4 million of net proceeds from the issuance of our series B-2 convertible preferred stock in February and March of 2014, partially offset by payments under our Original Credit Facility of $2.9 million.

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Financings

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

Future Financing Needs

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

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

Abaloparatide-SC is our only product candidate in late stage development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have not submitted an NDA to the FDA or comparable applications to foreign regulatory authorities. Obtaining approval of a product candidate is an extensive, lengthy, expensive and uncertain process, and any approval of abaloparatide-SC may be delayed, limited or denied for many reasons, including:

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

- the FDA or other foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;

- The FDA or other foreign regulatory authorities may not accept data generated at our clinical study sites;

- the FDA or other foreign regulatory authorities may not agree with our proposed labeling and may require labeling that undermines or otherwise significantly impairs the commercial value of the product if it were to be approved with such labeling;

- the FDA may require development of a Risk Evaluation and Mitigation Strategy as a condition of approval;

- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions; or

- the FDA or other foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

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

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Research and Development Agreements

Abaloparatide-SC Phase 3 Clinical Trial We have entered into agreements with Nordic Bioscience Clinical Development VII A/S, or Nordic, to conduct our Phase 3 clinical trial of abaloparatide-SC, or the Phase 3 Clinical Trial. On March 29, 2011, we entered into a Clinical Trial Services Agreement, or the Clinical Trial Services Agreement. On the same date, we also entered into Work Statement NB-1, as amended on December 9, 2011, June 18, 2012, March 28, 2014, May 19, 2014 and July 22, 2014, or Work Statement NB-1, and the Stock Issuance Agreement, as amended and restated on May 16, 2011, and as further amended on February 21, 2013, March 28, 2014, and May 19, 2014, or the Stock Issuance Agreement.

Pursuant to the Work Statement NB-1, we were required to make certain per patient payments denominated in both euros and U.S. dollars for each patient enrolled in the Phase 3 Clinical Trial followed by monthly payments for the duration of the study and final payments in two equal euro-denominated installments and two equal U.S. dollar-denominated installments. In addition, Nordic is entitled to a performance incentive payment, or Performance Incentive Payment, of $500,000 for every 50 patients that, subsequent to March 28, 2014, completed all end-of-study procedures, up to a maximum aggregate amount of $5.0 million. The Work Statement NB-1, provided for a total of up to approximately 41.2 million ($44.2 million) of euro-denominated payments and a total of up to approximately $3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus Performance Incentive Payments.

We recognized research and development expense for the amounts due to Nordic under the Work Statement NB-1 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 3 Clinical Trial, or a twenty-month period, except for research and development expense for the amounts due under the fourth amendment to the Work Statement NB-1, which we recognized on a per patient basis when the end-of-study visit and all other required procedures were completed. We recorded $4.5 million of research and development expense during the three months ended March 31, 2014, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Trial. As of March 31, 2015, all obligations due to Nordic under Work Statement NB-1 had been paid.

Abaloparatide-SC Phase 3 Clinical Extension Study On February 21, 2013, we entered into the Work Statement NB-3, as amended on March 4, 2014, or the Work Statement NB-3. Pursuant to the Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial, or the Extension Study, and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management, or the Second Extension.

Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to 7.5 million ($8.0 million) and $1.1 million, respectively. In addition, payments are due to Nordic in connection with the Work Statement NB-3 pursuant to the Stock Issuance Agreement, as discussed below.

We recognize research and development expense for the amounts due to Nordic under the Extension Study and the Second Extension ratably over the estimated per patient treatment periods beginning upon enrollment or over a nine-month and nineteen-month period, respectively. We recorded $1.4 million and $2.5 million of research and development expense during the three months ended March 31, 2015 and 2014 for per patient costs incurred for patients that had enrolled in the Extension Study and the Second Extension.

As of March 31, 2015, we had a liability of $6.0 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

Stock Issuance Agreement Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase 6,443 shares of our Series A-5 convertible preferred stock, or the Series A-5, and to receive quarterly stock dividends, payable in shares of our Series A-6 convertible preferred stock, or the Series A-6. In connection with the Work Statement NB-1, the Stock Issuance Agreement provided that Nordic was entitled to receive stock dividends, having an aggregate value of up to 36.8 million ($39.5 million), or the NB-1 Accruing Dividend. In connection with Work Statement NB-3, the Stock Issuance Agreement provided that, beginning with the quarter ended March 31, 2013, Nordic was entitled to receive stock dividends having an aggregate value of up to 7.5 million ($8.0 million) and $0.8 million, or the NB-3 Accruing Dividend, and together with the NB-1 Accruing Dividend, the Nordic Accruing Dividend. On March 28, 2014, we entered into the second amendment to the Stock Issuance Agreement, or the Second Stock Issuance Agreement Amendment. The Second Stock Issuance Agreement Amendment required that our board of directors declare, as soon as reasonably practical, a stock dividend of twenty-nine (29) shares of its Series A-6 for each share of our then-outstanding Series A-5, all of which were held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in connection with Work Statement NB-1 and Work Statement NB-3. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, our board of directors declared and issued a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment further provided that in the event an

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

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

License Agreement Obligations

Abaloparatide

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

In consideration for the rights to abaloparatide and in recognition of certain milestones having been met to date, we have paid to Ipsen an aggregate amount of $1.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. The range of milestone payments that could be paid under the agreement is 10.0 million to 36.0 million ($10.7 million to $38.7 million). Should abaloparatide be approved and subsequently become commercialized, we or our sublicensees will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense abaloparatide to a third party, we are obligated to pay a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, we will be obligated to pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of licensed patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

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

RAD1901

We exclusively licensed the worldwide rights to RAD1901 from Eisai Co. Ltd., or Eisai. On March 9, 2015, we entered into an amendment to the Eisai Agreement in which Eisai granted us an exclusive right and license to research, develop, manufacture and commercialize RAD1901 in Japan. In consideration for the rights to RAD1901 in Japan, we paid Eisai an initial license fee of $0.4 million upon execution of the contract, which was expensed during the three months ended March 31, 2015.

In consideration for the rights to RAD1901 and in recognition of certain milestones having been met to date, we have paid to Eisai an aggregate amount of $1.9 million. The range of milestone payments that could be paid under the agreement is $1.0 million to $20.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. Should RAD1901 be approved and subsequently become commercialized, we will be obligated to pay to Eisai a royalty in a variable mid-single digit range based on net sales of the product on a country-by-country basis for a period that expires on the later of (1) the date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the product is not covered by data protection clauses, and the sales of lawful generic version of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated. The latest valid claim is expected to expire, barring any extension thereof, on August 18, 2026. The royalty rate shall then be subject to reduction and the royalty obligation will expire at such time as sales of lawful generic version of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. We were also granted the right to grant

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sublicenses with prior written approval from Eisai. If we sublicense RAD1901 to a third party, we will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees we receive from such sublicensee and royalties in a variable mid-single digit range based on net sales of the sublicensee. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

Net Operating Loss Carryforwards

As of December 31, 2014, we had federal and state net operating loss carryforwards of approximately $319.7 million and $246.5 million, respectively. If not utilized, the net operating loss carryforwards will expire at various dates through 2034.

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

Off-Balance Sheet Arrangements

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

New Accounting Standards

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

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Item 3. Quantitative and Qualitative Disclosure about Market Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2015 and December 31, 2014, we had cash, cash equivalents, and marketable securities of $243.1 million and $105.3 million, respectively, consisting of cash, money market funds, domestic corporate debt securities, domestic corporate commercial paper and U.S. agency bonds. This exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10 percent change in interest rates would not have a material effect on the fair market value of our portfolio. We generally have the ability to hold our short-investments until maturity, and therefore we would not expect our operating results or cash flows to be affected by any significant degree by the effect of a change in market interest rates on our investments. We carry our investments based on publicly available information. As of March 31, 2015 and December 31, 2014, we do not have any hard to value investment securities or securities for which a market is not readily available or active.

On May 30, 2014, we entered into a Loan and Security Agreement, which was amended on July 10, 2014 and February 13, 2015, or the Credit Facility, with Solar Capital Ltd., or Solar, as collateral agent and a lender, and Oxford Finance LLC, or Oxford, as a lender, pursuant to which Solar and Oxford agreed to make available to us $30.0 million in the aggregate subject to certain conditions to funding. An initial term loan was made on May 30, 2014 in an aggregate principal amount equal to $21.0 million, or the Initial Term Loan. A second term loan was made on July 10, 2014 in an aggregate principal amount equal to $4.0 million, or the Second Term Loan. The Initial Term Loan and Second Term Loan bear interest per annum at 9.85% plus one-month LIBOR (customarily defined) and mature on June 1, 2018. Changes in interest rates can cause interest charges to fluctuate under our Credit Facility. As of March 31, 2015, principal payable under the Initial Term Loan was $25.0 million. A 10% increase in current interest rates would have resulted in less than $0.1 million in additional cash interest expense for the three months ended March 31, 2015.

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

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Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2015.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the three months ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

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

Risks Related to Our Business

Risks Related to Our Financial Position and Need for Capital

We are not currently profitable and may never become profitable.

We have a history of net losses and expect to incur substantial losses and have negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability. We had net losses of $17.1 million for the three months ended March 31, 2015 and $62.5 million and $60.7 million for the years ended December 31, 2014 and 2013, respectively. As of March 31, 2015, we had an accumulated deficit of $361.3 million. Until we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially 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 as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. Accordingly, unless and until we generate revenues and become profitable, we will need to raise additional capital to continue to operate our business. Our failure to achieve or maintain profitability or to raise additional capital could negatively impact the value of our securities.

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

To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or FDA, and other foreign regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Currently, our only product candidates are abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140, and none of these product candidates is approved by the FDA or other foreign regulatory authorities for sale. Therefore, for the foreseeable future, we will have to fund our operations and capital expenditures with our existing cash and cash equivalents and marketable securities, or through strategic financing opportunities, future offerings of our equity, and/or the incurrence of debt. We believe that our existing resources will be sufficient to fund our planned operations into the fourth quarter of 2016. We have based this estimate on assumptions that may prove to be wrong, and we could use up our available capital resources sooner than we currently expect. If we fail to obtain additional capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any product candidates from the FDA and other foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts for any product candidate that is approved, forego attractive business opportunities or discontinue our operations entirely. Any additional sources of financing may not be available or may not be available on favorable terms and will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies.

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

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

- dispose of our business or certain assets;

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

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

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

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

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

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

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

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

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 Risk Factors section could adversely affect our financial results and cause our stock price to fall.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance limit. While we monitor daily the cash balances in the operating accounts and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

Our investments in marketable securities are subject to market, interest and credit risk that may reduce their value.

The value of our investments in marketable securities may be adversely affected by changes in interest rates, downgrades in the creditworthiness of bonds we hold, turmoil in the credit markets and financial services industry and by other factors which may result in other than temporary declines in the value of our investments. Decreases in the market value of our marketable securities could have an adverse impact on our statements of financial position, results of operations and cash flow.

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

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

Abaloparatide-SC is our only product candidate in late-stage clinical development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop approved and marketable drug products. The research, testing, manufacturing, labeling, approval, sale, marketing and

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

- we may not be able to demonstrate that abaloparatide is safe and effective as a treatment for reduction of fracture risk in postmenopausal women with severe osteoporosis to the satisfaction of the FDA or other foreign regulatory authorities;

- the results of our clinical studies may not meet the level of statistical or clinical significance required for marketing approval;

- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;

- any clinical research organizations, or CROs, that we have retained or may in the future retain, to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;

- the FDA or other foreign regulatory authorities may not find the data from preclinical studies and clinical studies sufficient to demonstrate that abaloparatide s clinical and other benefits outweigh its safety risks;

- the FDA or other foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;

- the FDA or other foreign regulatory authorities may not accept data generated at our clinical study sites;

- the FDA or other foreign regulatory authorities may not agree with our proposed labeling and may require labeling that undermines or otherwise significantly impairs the commercial value of the product if it were to be approved with such labeling;

- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;

- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions; or

- the FDA or other foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

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

regulations that adversely affect any NDA that we may submit, the occurrence of any of which may further delay FDA approval.

Before we submit an NDA to the FDA for abaloparatide-SC as a proposed treatment for osteoporosis, we must complete the first six months of the alendronate extension study of the abaloparatide and placebo groups from our Phase 3 clinical and submit 24-month fracture data to the FDA. We also must complete several additional studies, including, but not limited to, a thorough QT Phase 1 study and a Phase 1 pharmacokinetic study in renal patients. The results of these studies will have an important bearing on the approval of abaloparatide.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140, or any product candidate we may acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its indicated use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for proposed uses. The FDA has substantial discretion in the drug approval process and may require us to

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conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review, such as the request we received from the FDA with respect to providing a minimum of 24-month fracture data for approval of abaloparatide. Delays in obtaining regulatory approvals may:

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

The abaloparatide-SC finished product is a drug/device combination product candidate with both a drug and device component and with the primary mode of action being provided by the investigational drug abaloparatide. Based on our discussions to date with the FDA, we believe that abaloparatide-SC will be regulated as a combination product by the FDA, and both drug and device components will be required for review as part of our NDA submission. We expect that our NDA would be submitted to the Center for Drug Evaluation and Research and be reviewed with support from the FDA Office of Combination Products and the FDA Center for Devices and Radiological Health for the device aspects of the abaloparatide-SC product candidate. In addition, there are device-related manufacturing and other regulatory requirements (e.g., cGMPs and adverse event reporting) to which we may be subject by virtue of the product s status as a drug/device combination product. As a result of these factors, we may experience delays in the product development and regulatory review and approval process in seeking a drug/device combination product approval under an NDA.

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

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

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

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

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

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

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

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

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

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

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

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

All of our product candidates are still in preclinical or clinical development. Undesirable side effects caused by our product candidates could cause us, regulatory authorities, and/or ethics committees to interrupt, delay or halt clinical trials and could result in a more restrictive label or cause the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. 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. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices, or cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if we obtain marketing approval of a product candidate, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety and/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

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use and, if we market our products for other than their approved indications, we may be subject to enforcement action for off-label marketing.

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

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

In addition, the FDA s policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

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

- perceptions by members of the healthcare community, including physicians and key opinion leaders, 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.

If any of our product candidates are commercialized and unexpected adverse events are reported in connection with the use of any of those products, physician and patient acceptance of the product could deteriorate and the commercial success of such product could be adversely affected. We are required to report to the FDA or similar bodies in other countries events associated with our products relating to death or serious injury. Adverse events could result in additional regulatory controls, such as for the imposition of costly post-approval clinical studies or revisions to approved labeling which could limit the indications or patient population for a product or could even lead to the withdrawal of a product from the market. 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 or, once gained, a decrease in market acceptance would harm our business and would require us to seek additional financing.

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

We depend upon independent researchers, investigators and collaborators, to conduct our preclinical and clinical trials under agreements with us. These third parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and requirements, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and our third party researchers, investigators and collaborators are required to comply with good clinical practice, or GCP, requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. In addition, these third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA or foreign regulatory authority applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist competitors at our expense, our competitive position would be harmed.

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

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

In consideration of Nordic s management of our Phase 3 clinical trial and subsequent extension studies, we agreed to make various cash payments to Nordic denominated in both euros and U.S. dollars over the course of the Phase 3 study equal to a total of up to approximately 48.6 million ($52.2 million) and a total of up to approximately $4.4 million plus up to an additional $5.0 million in aggregate performance incentive payments, payable in cash or stock depending on the timing of the closing of an underwritten offering of shares of our common stock. We also agreed to sell shares of capital stock to Nordic that were exchanged in May 2011 for 6,443 shares of our series A-5 convertible preferred stock for proceeds of approximately $0.5 million. These shares of our series A-5 convertible preferred stock automatically converted into 28,258 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market. Pursuant to the terms of our agreements with Nordic, we were required to issue to Nordic shares of stock with an aggregate value of up to approximately 44.3 million ($47.6 million) and $0.8 million in consideration of Nordic s management of the Phase 3 clinical trial. These shares of stock accrued at a quarterly rate based on the progress of the Phase 3 clinical trial and were issuable at a price per share equal to the greater of (1) the fair market value of our common stock as of the applicable

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accrual date or (2) $81.42 and rounding down the resulting quotient to the nearest whole number. On each of December 31, 2013 and March 31, 2014, our Board of Directors declared a stock dividend to pay all shares of stock that had accrued as of such dates and that were anticipated to accrue through December 31, 2014, representing an aggregate of 682,958 shares of our Series A-6 convertible preferred stock that automatically converted into 2,995,453 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market. Following the completion of our initial public offering of shares of our common stock on June 11, 2014, or our initial public offering, all compensation remaining payable to Nordic in consideration of their management of our Phase 3 clinical trial became payable in cash.

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

Because of the potential decrease in the value of the common stock issued to Nordic upon a negative outcome of the Phase 3 study, Nordic, CCBR and the clinical trial investigators may be viewed as having a financial interest in the outcome of the study. We have obtained written acknowledgments from the clinical trial investigators certifying that they have no financial interest in the outcome of the Phase 3 clinical trial. However, if the FDA, the EMA, or any other similar regulatory or governmental authority determines that Nordic, CCBR or the clinical trial investigators have a financial interest that affected the reliability of the data from the Phase 3 clinical trial, we could be subject to additional regulatory scrutiny and the utility of the Phase 3 clinical trial for purposes of our planned regulatory submissions could be compromised, which could have a material adverse effect on our business and the value of our common stock.

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

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We have entered into agreements with contract manufacturers to manufacture abaloparatide for use in clinical trial activities. These contract manufacturers are currently our only source for the production and formulation of abaloparatide. We may not have sufficient clinical supplies of abaloparatide but believe that our contract manufacturers will be able to produce sufficient supply of abaloparatide to complete all of the planned abaloparatide clinical studies. If our contract manufacturers are unable to produce, in a timely manner, adequate clinical supplies to meet the needs of our clinical studies, we would be required to seek new contract manufacturers that may require us to modify our finished product formulation and modify or terminate our clinical studies for abaloparatide. Any modification of our finished product or modification or termination of our clinical studies could adversely affect our ability to obtain necessary regulatory approvals and significantly delay or prevent the commercial launch of the product if it were to be approved, which would materially harm our business and impair our ability to raise capital. In addition, the facilities and processes and controls used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA and our MAA to EMA. We do not control the facilities or manufacturing process and controls of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

- We may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Our third-party manufacturers might be unable to formulate and manufacture our drugs or related components in the volume and of the quality required to meet our clinical needs and commercial needs, if any.

- Our 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, for any controlled substances, and corresponding state agencies to ensure strict compliance with cGMP, and other government regulations and corresponding foreign standards, and failure to comply with cGMP or corresponding foreign standards can result in compliance actions that may limit a manufacturer s production or prohibit a manufacturer from producing some or all products at a facility and/or importing it into the United States or a foreign country. 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, any such improvement(s) could be subject to FDA review and prior approval, and 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 other foreign regulatory authority 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 Related to Marketing and Sale of Our Products

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

We currently have no sales, marketing or distribution capabilities. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborators strategic interest in the products under development and such collaborators ability to successfully market and sell any such products. We intend to build an internal sales force to market and sell our products to specialists within the target indications if approved and to pursue collaborative arrangements to market and sell

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our products to primary care physicians within the target indications if approved. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and we cannot assure you that their efforts will be successful. In addition, we cannot assure you that we will be able to establish or maintain relationships with such third party collaborators or that we would be able to market and sell our products in the United States or overseas through an in-house sales force in lieu of such relationships.

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

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

If approved, 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 our investigational product candidates abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140, will have to compete against existing therapies if they are approved. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies doing business in different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or

other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business. These risks could render our products or technologies obsolete or non-competitive.

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

Our ability to commercialize our product candidates if approved, alone or with collaborators, will depend in large part on the extent to which coverage and reimbursement will be available post-approval 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 or other foreign regulatory authority, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover the costs of our drug. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our product candidates, once approved, market acceptance of our products could be reduced.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

We and Ipsen are also co-assignees to US Patent No. 7,803,770 that we believe provides exclusivity until October 3, 2027 and may be extended to March 26, 2028 in the United States (absent any Hatch-Waxman patent term extension) for the method of treating osteoporosis with the intended therapeutic dose for abaloparatide-SC.

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

We and 3M are co-assignees to several foreign and corresponding U.S. patent applications with the earliest priority date of April 22, 2011, which cover various aspects of abaloparatide for microneedle application. Any issued patents resulting from these applications will expire in 2032. However, pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of claimed inventions are not always predictable. Additional intellectual property covering abaloparatide-TD technology exists in the form of proprietary information protected as trade secrets. These can be accidentally disclosed to, independently derived by or misappropriated by competitors, possibly reducing or eliminating the exclusivity advantages of this form of intellectual property, thereby allowing those competitors more rapid entry into the marketplace with a competitive product thus reducing our advantage with abaloparatide-TD. In addition, trade secrets may in some instances become publicly available through required disclosures in regulatory files. Alternatively, competitors may sometimes reverse engineer a product once it becomes available on the market. Even where a competitor does not use an identical technology for the delivery of abaloparatide, it is possible that they could achieve an equivalent or even superior result using another technology. Such occurrences could lead to either one or more alternative competitor products becoming available on the market and/or one or more generic competitor products on the market gaining market share and causing a corresponding decrease in market share and/or price for abaloparatide-TD even if it were to be successfully developed and approved by FDA.

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Patents covering RAD1901 as a composition of matter, as well as the use of RAD1901 for the treatment of estrogen-dependent breast cancer, have been issued in the United States, Canada, Australia, and Europe, and are pending in India. The RAD1901 composition of matter patents in the United States expire in 2023 and 2026 (absent any Hatch-Waxman patent term extension). One patent has been issued in the United States (the US Patent No. 8,933,130) for treating vasomotor disturbances or hot flashes on January 13, 2015 (statutory term expires on June 22, 2027, and may be extended to October 19, 2031 with 1,580 days of patent term adjustment due to delays in patent prosecution by the USPTO). Additional patent applications relating to methods of treating vasomotor symptoms and clinical dosage strengths using RAD1901 have been filed. Pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of any claimed invention before a patent office are not always predictable. As a result, we could encounter challenges or difficulties in building, maintaining and/or defending our intellectual property both in the United States and abroad.

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

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

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

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

Our success depends in large part on our and our licensors ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties.

Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain these patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors patent rights are highly uncertain. Our and our licensors pending and future patent applications may not result in patents being issued that protect our technology or products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States, prior to March 16, 2013, the first to make the claimed invention was entitled to the patent (a first-to-invent system), while outside the United States, the first to file a patent application is entitled to the patent (a first-to-file system). With the implementation of the Leahy-Smith America Invents Act, the United States now has a first-to-file system for patent applications filed on or after March 16, 2013. We may become involved in opposition, interference or derivation proceedings

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challenging our patent rights or the patent rights of others. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

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

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

In addition to our patented technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to our trade secrets, such as our corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for any breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or

independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by a competitor, our competitive position would be harmed.

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;

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- pay damages; or

- defend litigation or administrative proceedings which may be costly whether we win or lose, which could result in a substantial diversion of our financial and management resources.

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid and/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 and/or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute these types of claims, and we may be reliant on them to do so.

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

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

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

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

Risks Related to Legislation and Administrative Actions

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

From time to time, legislation is implemented to reign in rising healthcare expenditures. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA. PPACA includes a number of provisions affecting the pharmaceutical industry, including annual, non-deductible fees on any entity that manufactures or imports some types of branded prescription drugs and biologics 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 and conduct comparative clinical effectiveness research. In addition, other legislative changes have been proposed and adopted since PPACA was enacted. The full impact on our business of these new laws is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the pharmaceutical industry generally or our business in particular.

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

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

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- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of various electronic healthcare transactions and protects the security and privacy of protected health information;

- the federal healthcare programs Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;

- the federal Physician Payment Sunshine Act, or the Sunshine Act, requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Data from the first reporting period, which began in August 2013, is now publicly available. Manufacturers will be required to submit subsequent reports to the government by the 90th day of each calendar year; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Our operations and future commercial activities in connection with any product candidate that is approved will be subject to comprehensive compliance obligations under state and federal fraud and abuse, false claims, physician payment transparency laws and government pricing regulations, as described above. If we are found to be in violation of these regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

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

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

Risks Related to Employee Matters and Managing Growth

As we evolve from a company primarily involved in drug discovery and development into one that is also involved in the commercialization of pharmaceutical products, we may have difficulty managing our growth and expanding our operations successfully.

Our success will depend upon the expansion of our operations and the effective management of our growth, and if we are unable to manage this growth effectively, our business will be harmed. As we advance our product candidates through the development process,

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we will need to expand our development, regulatory, manufacturing, quality, distribution, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborators, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. For example, some jurisdictions, such as the District of Columbia, have imposed licensing requirements for sales representatives. In addition, the District of Columbia and the Commonwealth of Massachusetts, as well as the federal government by way of the Sunshine Act, have established reporting requirements that would require public reporting of compensation and other transfers of value paid to health care professionals and teaching hospitals, as well as ownership and investment interests held by such professionals and their immediate family members. Because the reporting requirements vary in each jurisdiction, compliance will be complex and expensive and may create barriers to entering the commercialization phase. The need to build new systems as part of our growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Such requirements may also impact our opportunities to collaborate with physicians at academic research centers as new restrictions on academic-industry relationships are put in place. In the past, collaborations between academia and industry have led to important new innovations, but the new laws may have an effect on these activities. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability.

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

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

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

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

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

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

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

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

Risks Relating to Our Securities

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

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

- results of clinical trials of our product candidates or those of our competitors;
- our operating performance and the operating performance of similar companies;

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

In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the companies whose shares trade in the stock market. These fluctuations may be even more pronounced in the trading market for our stock shortly following the initial public offering. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company s securities. Such litigation, if instituted against us, could result in very substantial costs, divert our management s attention and resources and harm our business, operating results and financial condition.

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

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

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

As a public company listed on the NASDAQ Global Market, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company and prior to the listing of our common stock on the NASDAQ Global Market. In addition,

the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission, or the SEC, and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and are making some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common shares, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain.

Our directors and executive officers, together with their affiliates, have substantial influence over us and could delay or prevent a change in corporate control.

Our directors and executive officers, together with their affiliates, beneficially own a significant portion of our outstanding common stock. As a result, these stockholders, acting together, would have the ability to significantly influence 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, would have the ability to significantly influence 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;

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

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our equity incentive plans, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. We have reserved 4,559,510 shares of our common stock for issuance under our equity incentive plans as of March 31, 2015, which includes 3,625,200 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2015, and will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, as of March 31, 2015, warrants to purchase 848,616 shares of our common stock were outstanding. Shares of our common stock issued upon exercise of these warrants may be sold in the public market, subject to prior registration, or under an exemption from registration. If any of these additional shares are sold, or if it is perceived that they will be sold, the price of our common stock could decline substantially.

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

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

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

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

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

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

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

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

As of December 31, 2014, we had $319.7 million of federal and $246.5 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

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

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

Use of Proceeds from Public Offering of Common Stock

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

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

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Item 6. Exhibits.

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

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
3.1	Restated Certificate of Incorporation, filed on June 11, 2014	8-K	001-35726	3.1	6/13/14	
3.2	Amended and Restated By-Laws	8-K	001-35726	3.2	6/13/14	
10.1	Second Amendment to Loan and Security Agreement, dated February 13, 2015, by and among the Company, Solar Capital Ltd., and Oxford Finance LLC					*
10.2	Third Amendment to Loan and Security Agreement, dated April 8, 2015, by and among the Company, Solar Capital Ltd., and Oxford Finance LLC					*
10.3	License Agreement Amendment No. 1, dated March 9, 2015, by and between the Company and Eisai Co., Ltd.					*
10.4	Amendment No. 9 to Work Statement NB-1, effective as of March 12, 2015, by and between the Company and Nordic Bioscience Clinical Development VII A/S					*
10.5	Amendment No. 2 to Work Statement NB-3, effective as of March 23, 2015, by and between the Company and Nordic Bioscience Clinical Development VII A/S					*
10.6	Change Order Form #22, dated March 2, 2015, to the Development and Clinical Supplies Agreement, dated June 19, 2009, by and among the Company and 3M Co. and 3M Innovative Properties Co.	10-K	001-35716	10.18	3/10/15	
10.7	Work Order #7, dated February 24, 2015, to the Development and Manufacturing Agreement, dated October 16, 2007, by and between the Company, as successor to Radius Health, Inc., and LONZA Sales Ltd.	10-K	001-35716	10.17	3/10/15	
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a)					*

31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)/15d-	*

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	14(a)	
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
101.INS	XBRL Instance Document	*
101.SCH	XBRL Taxonomy Extension Schema Document	*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	*

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* Filed herewith.

** Furnished herewith.

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

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SIGNATURES

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

RADIUS HEALTH, INC.

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

Date: May 6, 2015

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

Date: May 6, 2015