Radius Health, Inc.
Form S-1/A
October 28, 2011

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**As filed with the Securities and Exchange Commission on October 27, 2011**

**Registration No. 333-175091**

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

**Amendment No. 3 to**

# FORM S-1

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

# Radius Health, Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | **2834** | **80-0145732** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification Number) |

**201 Broadway, 6th Floor**
**Cambridge, MA 02139**
**(617) 551-4700**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**C. Richard Lyttle, Ph.D.**
**Chief Executive Officer**
**Radius Health, Inc.**
**201 Broadway, 6th Floor**
**Cambridge, MA 02139**
**(617) 551-4700**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Copies to:**

**Julio E. Vega, Esq.**
**Matthew J. Cushing, Esq.**
**Bingham McCutchen LLP**

**One Federal Street**
**Boston, MA 02110**
**(617) 951-8000**

**Approximate date of commencement of proposed sale to the public:**
**Promptly after the effective date of this Registration Statement, subject to applicable contractual lock-up agreements.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of check the following box. ý

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. 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 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 o | Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company ý |
|---|---|---|---|

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.**

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**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**OFFERING PROSPECTUS**
**SUBJECT TO COMPLETION, DATED OCTOBER 27, 2011**

# Radius Health, Inc.

## 5,320,600 Shares
## Common Stock

The selling stockholders identified on pages 99-101 of this prospectus are offering on a resale basis a total of up to 5,320,600 shares of our Common Stock, $0.0001 par value per share ("Common Stock"), consisting of (i) 195,552 currently issued shares of our Common Stock to be offered for resale by certain selling stockholders, (ii) 5,112,120 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the conversion of 511,212 outstanding shares of our convertible preferred stock, $0.0001 par value per share ("Preferred Stock"), (iii) 88 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the exercise of outstanding common stock purchase warrants, and (iv) 12,840 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the conversion of 1,284 shares of our Preferred Stock to be issued upon exercise of outstanding preferred stock purchase warrants.

There is not currently, and there has never been, any market for any of our securities. Our securities are not eligible for trading on any national securities exchange, the Nasdaq or other over-the-counter markets, including the OTC Bulletin Board®. The selling stockholders identified herein will be required to sell the common stock (including shares of common stock issued upon conversion of preferred stock and exercise of warrants) registered hereunder at a fixed price of $8.142 per share until such time as such securities are traded on a national securities exchange, the Nasdaq or the OTC Bulletin Board®. At and after such time that such securities are eligible for trading in such a manner, the selling stockholders may sell such securities at the prevailing market price or at a privately negotiated price.

**The securities offered by this prospectus involve a high degree of risk.**
**See "Risk Factors" beginning on page 5.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined that this prospectus is truthful or complete. A representation to the contrary is a criminal offense.**

The date of this Prospectus is , 2011.

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## PROSPECTUS SUMMARY

*The following summary highlights selected information contained elsewhere in this Prospectus. This summary does not contain all the information that you should consider before investing in our securities. You should carefully read the entire Prospectus, paying particular attention to the risks referred to under the heading "Risk Factors."*

**About This Offering**

This Prospectus relates to the resale of up to 5,320,600 shares of our Common Stock to be offered by the selling stockholders consisting of (i) 195,552 currently issued shares of our Common Stock to be offered for resale by certain selling stockholders, (ii) 5,112,120 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the conversion of 511,212 outstanding shares of our Preferred Stock, (iii) 88 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the exercise of outstanding common stock purchase warrants, and (iv) 12,840 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the conversion of 1,284 shares of our Preferred Stock to be issued upon exercise of outstanding preferred stock purchase warrants.

**Summary of the Shares offered by the Selling Stockholders.**

The following is a summary of the shares being offered by the selling stockholders:

| | |
|---|---|
| Securities Offered | 5,320,600 shares of our Common Stock to be offered by the selling stockholders consisting of:<br><br>(i) 195,552 currently issued shares of our Common Stock to be offered for resale by certain selling stockholders,<br><br>(ii) 5,112,120 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the conversion of 511,212 outstanding shares of our Preferred Stock,<br><br>(iii) 88 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the exercise of outstanding common stock purchase warrants,<br><br>(iv) 12,840 unissued shares of our Common Stock to be offered for resale by certain selling stockholders upon the conversion of 1,284 shares of our Preferred Stock to be issued upon exercise of outstanding preferred stock purchase warrants. |
| Capital Stock | As of October 6, 2011 there were 592,581 shares of our Common Stock issued and outstanding. Assuming conversion of all outstanding Preferred Stock on the date hereof there would be 16,083,881 shares of Common Stock outstanding. |
| Use of Proceeds | We will not receive any proceeds from the sale of the Common Stock offered by the selling stockholder. However, we will generate proceeds in the event of a cash exercise of the warrants by the selling stockholder. We intend to use those proceeds, if any, for general corporate purposes. |
| Risk Factors | The securities offered hereby involve a high degree of risk. See "Risk Factors" beginning on page 5. |
| Offering Price | All or part of the shares of Common Stock offered hereby may be sold from time to time in amounts and on terms to be determined by the selling stockholder at the time of sale. |

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| | |
|---|---|
| Market for Our Shares | There is not now and never has been any market for our securities and an active market may never develop. |

**The Company**

We were incorporated in the state of Delaware on February 4, 2008 under the name MPM Acquisition Corp. In May 2011, we entered into a reverse merger transaction (the "Merger") with Radius Health, Inc., a Delaware corporation formed on October 3, 2003 (the "Former Operating Company") pursuant to which the Former Operating Company became a wholly-owned subsidiary of ours. Immediately following the merger transaction, the Former Operating Company was merged with and into us, we assumed the business of the Former Operating Company and changed our name to "Radius Health, Inc."

**Recent Developments**

At the effective time of the Merger (the "Effective Time"), all of the shares of the Former Operating Company's common stock, par value $.01 per share (the "Former Operating Company Common Stock"), and shares of the Former Operating Company's preferred stock, par value $.01 per share (the "Former Operating Company Preferred Stock"), that were outstanding immediately prior to the Merger were cancelled and each outstanding share of the Former Operating Company Common Stock outstanding immediately prior to the Effective Time was automatically converted into the right to receive one share of our Common Stock, par value $.0001, and each outstanding share of the Former Operating Company Preferred Stock outstanding immediately prior to the Effective Time was automatically converted into the right to receive one-tenth of one share of our corresponding series of Preferred Stock, par value $.0001, as consideration for the Merger. In the Merger, we assumed all options and warrants of the Former Operating Company outstanding immediately prior to the Effective Time. Prior to the Merger, pursuant to the terms of a Redemption Agreement dated April 25, 2011, we completed the repurchase of all of our capital stock issued and outstanding immediately prior to the Merger from our former sole stockholder, MPM Asset Management LLC. Upon completion of the Merger and the redemption, the former stockholders of the Former Operating Company held 100% of the outstanding shares of our capital stock. Pursuant to the Merger, we assumed all of the the Former Operating Company's obligations under its existing contracts, including those filed herewith as material contracts. In particular, we have assumed the rights and obligations of the Former Operating Company under that certain Series A-1 Convertible Preferred Stock Purchase Agreement (the "Original Purchase Agreement") with certain investors listed therein (the "Investors") pursuant to which, among other things, the Former Operating Company agreed to issue and sell to the Investors up to an aggregate of 7,895,535 shares of Series A-1 Convertible Preferred Stock, par value $.01 per share, to be completed in three closings (the initial closing, the "Stage I Closing", the second closing, the "Stage II Closing" and the final closing, the "Stage III Closing") (collectively, the "Series A-1 Financing"). The Original Purchase Agreement was subsequently amended by Amendment No. 1 thereto to eliminate all closing conditions previously provided for in the Original Purchase Agreement (as so amended, the "Purchase Agreement"). Upon notice from us, the Investors are obligated to purchase, and we are obligated to issue, 263,178 shares of our Series A-1 Convertible Preferred Stock ("Series A-1 Preferred Stock") at the Stage II Closing and 263,180 shares of our Series A-1 Preferred Stock at the Stage III Closing, each at a purchase price per share of $81.42. There are no conditions to funding if we notify the Investors of any such closing.

As a final step in the reverse merger process, we completed a short-form merger with the Former Operating Company and changed our name to "Radius Health, Inc." as the surviving entity of the short-form merger.

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The foregoing description of the Merger Agreement, the Redemption Agreement, Purchase Agreement and the transactions contemplated thereby do not purport to be complete and are qualified in their entireties by reference to the Merger Agreement and the Redemption Agreement, respectively.

On May 23, 2011, the Company entered into a Loan and Security Agreement with General Electric Capital Corporation ("GECC") as agent and a lender, and Oxford Finance LLC ("Oxford" and together with GECC, the "Lenders") as a lender, pursuant to which the lenders agreed to make available to the Company $25,000,000 in the aggregate over three term loans. The initial term loan was made on May 23, 2011 in an aggregate principal amount equal to $6,250,000 (the "Initial Term Loan") and is repayable over a term of 42 months, including a six month interest only period. The Initial Term Loan bears interest at 10%. Pursuant to the Agreement, the Company may request two (2) additional term loans, the first, which must be funded not later than November 23, 2011, in an aggregate principal amount equal to $6,250,000 (the "Second Term Loan") and the second, which must be funded not later than May 23, 2012, in an aggregate principal amount equal to $12,500,000 (the "Third Term Loan"). In the event the Second Term Loan is not funded on or before November 23, 2011, the Lenders' commitment to make the Second Term Loan shall be terminated and the total commitment shall be reduced by $6,250,000. In the event the Third Term Loan is not funded on or before May 23, 2012, the Lenders' commitment to make the Third Term Loan shall be terminated and the total commitment shall be further reduced by $12,500,000. Pursuant to the agreement, the Company agreed to issue to the Lenders (or their respective affiliates or designees) stock purchase warrants (collectively, the "Warrants") to purchase in the aggregate a number of shares of our Series A-1 Preferred Stock equal to the quotient of (a) the product of (i) the amount of the applicable term loan multiplied by (ii) four percent (4%) divided by (b) the exercise price equal to $81.42 per share. The exercise period of each Warrant to be issued will expire ten (10) years from the date such Warrants are issued. On May 23, 2011, the Company issued a Warrant to each of GECC and Oxford for the purchase of 3,070 shares of Series A-1 Preferred stock.

**Business Overview**

Our business is focused on acquiring and developing new therapeutics for the treatment of osteoporosis and other women's health conditions. Our lead product candidate is BA058 Injection for the prevention of fracture in women suffering from osteoporosis. BA058 Injection is a daily subcutaneous injection of our novel synthetic peptide analog of human parathyroid hormone-related protein ("hPTHrP"). In April 2011, we began dosing of patients in a pivotal, multinational Phase 3 clinical study and expect to report top-line data from this study in the first quarter of 2014. Based on our clinical and preclinical results to date, we believe that BA058 stimulates the rapid formation of new high quality bone in patients suffering from osteoporosis and may restore bone into the normal range in patients suffering from osteoporosis. In addition to BA058 Injection, we are developing BA058 Microneedle Patch, a short wear time, transdermal form of BA058 that is delivered by using a microneedle technology from 3M Drug Delivery Systems ("3M"). The BA058 Microneedle Patch is currently being studied in a Phase 1b clinical study which began in December 2010. The BA058 Microneedle Patch may eliminate the need for daily injections and lead to better treatment compliance for patients. We believe that development costs for the BA058 Microneedle Patch will be lower than development costs for BA058 Injection as it will not be necessary to conduct an additional fracture study for this follow-on product. As a result of the compressed pathway for the BA058 Microneedle Patch, we expect that marketing approval of the BA058 Microneedle Patch can occur soon after the BA058 Injection.

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to an increase in fractures. The prevalence of osteoporosis is growing in developed nations with the aging of the populations. The National Osteoporosis Foundation ("NOF") has estimated that (i) 10 million people in the United States, comprising eight million women and two

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million are men, already have osteoporosis and another 34 million have low bone mass placing them at increased risk for osteoporosis and (ii) osteoporosis was responsible for more than 2 million fractures in the United States in 2005 resulting in an estimated $19 billion in costs. The NOF expects that the number of fractures due to osteoporosis will rise to more than 3 million by 2025.

In addition to BA058 Injection and BA058 Microneedle Patch, we are currently conducting one other clinical and one preclinical program. Our second clinical stage product candidate is RAD1901, a selective estrogen receptor modulator, or SERM, licensed from Eisai Co ("Eisai") in 2006 which has completed an initial Phase 2 clinical study for the treatment of vasomotor symptoms (commonly referred to as hot flashes) in women entering menopause. A Phase 2 study is designed to test the efficacy of a novel treatment and confirm the safety profile of the drug candidate established in a previous Phase 1 study. Our third product candidate, RAD140, is a pre-IND discovery. RAD140 is a selective androgen receptor modular, or SARM, that is an orally-active androgen agonist on muscle and bone and is a potential treatment for age-related muscle loss, frailty, weight loss associated with cancer cachexia and osteoporosis.

As of the date of this report, we employed seven full-time employees and three part-time employees, four of whom held Ph.D. or M.D. degrees. Four of our employees were engaged in research and development activities and six were engaged in support administration, including business development, and finance. In addition, we intend to use clinical research organizations and third parties to perform our clinical studies and manufacturing.

**Corporate Offices**

Our executive offices are located at 201 Broadway, 6th Floor, Cambridge, MA 02139. Our telephone number is (617) 551-4700.

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## RISK FACTORS

*An investment in our Common Stock is very risky. You may lose the entire amount of your investment. Prior to making an investment decision, you should carefully review this entire prospectus and consider the following risk factors. Set forth below are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Prospectus. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered as a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods:*

### Risks Relating to our Securities

***We have a history of operating losses, expect to incur significant and increasing operating losses in the future, and may never be consistently profitable.*** We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue from sales. We have primarily incurred operating losses. As of June 30, 2011, we had an accumulated deficit of $102.5 million. We have spent, and expect to continue to spend, significant resources to fund the research and development of BA058 Injection and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

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

***There is not now and never has been any market for our securities and an active market may never develop. You may therefore be unable to re-sell shares of our securities at times and prices that you believe are appropriate.*** There is no market active or otherwise for our Common Stock or our Preferred Stock and neither is eligible for listing or quotation on any securities exchange, automated quotation system (e.g., NASDAQ) or any other over-the-counter market, such as the OTC Bulletin Board® (the "OTCBB") or the Pink Sheets® (the "Pink Sheets"). Even if we are successful in obtaining approval to have our Common stock quoted on the OTCBB, it is unlikely that an active market for our Common Stock will develop any time soon thereafter. Accordingly, our Common Stock is highly illiquid. Because of this illiquidity, you will likely experience difficulty in re-selling such shares at times and prices that you may desire.

***There is no assurance that our Common Stock will be listed on NASDAQ or any other securities exchange.*** We plan to seek listing of our Common Stock on NASDAQ or another national securities exchange or listed for quotation on the OTCBB, as soon as practicable. However, there is no assurance we will be able to meet the initial listing standards of either of those or any other stock exchange or automated quotation systems, or that we will be able to maintain a listing of our Common Stock on either of those or any other stock exchange or automated quotation system. We anticipate seeking a listing of our Common stock on the OTCBB, the Pink Sheets or another over-the-counter quotation system, before our Common Stock is listed on the NASDAQ or a national securities exchange. An investor may find it more difficult to dispose of shares or obtain accurate quotations as to the market value of our Common Stock while our Common Stock is listed on the OTCBB. If our Common Stock is listed on the OTCBB, we would be subject to an SEC rule that, if it failed to meet the criteria set forth in such rule, imposes various practice requirements on broker-dealers who sell securities governed

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by the rule to persons other than established customers and accredited investors. Consequently, such rule may deter broker-dealers from recommending or selling our Common Stock, which may further limit its liquidity. This would also make it more difficult for us to raise additional capital.

***Shares of our Capital Stock issued in the Merger are not freely tradable under Securities Laws which will limit stockholders' ability to sell such shares of our Capital Stock.*** Shares of our Preferred Stock and our Common Stock issued as consideration in the Merger pursuant the Merger Agreement are deemed "Restricted Securities" under the federal securities laws, and consequently such shares may not be resold without registration under the Securities Act of 1933, as amended (the "Securities Act"), or without an exemption from the Securities Act. Further, Rule 144 covering resales of unregistered securities and promulgated under the Securities Act will not be available for resale of our capital stock unless or until one year following the date on which we file the information required by Form 10 as to the performance of our business. In addition, all shares of our Preferred Stock issued in the Merger will be subject to a lock-up provision set forth in the applicable stockholders' agreement (for a description of the material terms of the lock-up provisions, see "Description of Capital Stock Restrictions on Alienability" below). Each certificate evidencing shares of our capital stock to be issued pursuant to the Merger Agreement will bear a restrictive legend as to the nature of the restrictions on the transfer of such shares.

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

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

***We are subject to Sarbanes-Oxley and the reporting requirements of federal securities laws, which can be expensive.*** As a public reporting company, we are subject to the Sarbanes-Oxley Act of 2002, as well as the information and reporting requirements of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and other federal securities laws. The costs of compliance with the Sarbanes-Oxley Act and of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC, and furnishing audited reports to stockholders, will cause our expenses to be higher than they would be if we were privately held.

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***For so long as shares of our Preferred Stock remain outstanding, if we are sold in a transaction yielding less than the liquidation preference payable in the aggregate to holders of outstanding Preferred Stock, holders of our Common Stock may not receive any proceeds from such transaction and may lose their investment entirely.*** As of June 30, 2011, we have 591,644 shares of Common Stock; 413,254 shares of Series A-1 Convertible Preferred Stock (the "Series A-1 Preferred Stock"); 983,208 shares of Series A-2 Convertible Preferred Stock (the "Series A-2 Preferred Stock"); 142,227 shares of Series A-3 Convertible Preferred Stock (the "Series A-3 Preferred Stock"); 3,998 shares of Series Convertible A-4 Preferred Stock (the "Series A-4 Preferred Stock"); 6,443 shares of Series A-5 Convertible Preferred Stock (the "Series A-5 Preferred Stock"); assumed warrants to acquire 3,388 shares of Series A-1 Preferred Stock; and assumed warrants to acquire 266 shares of Common Stock. As more fully described herein and in our Certificate of Incorporation, shares of our Preferred Stock outstanding at the time of a sale or liquidation of the Company will have a right to receive proceeds, if any, from any such transactions, before any payments are made to holders of our Common Stock. In the event that there are not enough proceeds to satisfy the entire liquidation preference of our Preferred Stock, holders of our Common Stock will receive nothing in respect of their equity holdings in the Company.

**Risks Related to our Business**

***We currently have no product revenues and will need to raise additional capital to operate our business.*** To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities for its product candidates, we cannot sell our drugs and will not have product revenues. Currently, our only product candidates are BA058, RAD1901, and RAD140, and none of these products is approved by the FDA for sale. Therefore, for the foreseeable future, we will have to fund our operations and capital expenditures from cash on hand, licensing fees and grants and potentially, future offerings of our Common Stock or Preferred Stock. Currently, we believe that our cash balance as of June 30, 2011, which includes the $20.4 million in net proceeds received on May 17, 2011 from the first closing of the Series A-1 Financing, plus the proceeds of the two subsequent closings of the Series A-1 Financing which are available to us with no closing or other conditions, are sufficient to fund our operations into the second quarter 2012. However, changes may occur that would consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation.

***We will need to seek additional sources of financing, which may not be available on favorable terms, if at all.*** Notwithstanding the expected completion of the subsequent two closings of the Series A-1 Financing, if we do not succeed in timely raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders.

***We are not currently profitable and may never become profitable.*** We have a history of net losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability. For the years ended December 31, 2010 and 2009, we had a net loss of $14.6 million and $15.1 million, respectively. As of June 30, 2011 we had an accumulated deficit of approximately $102.5 million. Even if we succeed in developing and commercializing one or more product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

continue to undertake pre-clinical development and clinical trials for product candidates;

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seek regulatory approvals for product candidates;

implement additional internal systems and infrastructure; and

hire additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our securities.

***We have a limited operating history upon which to base an investment decision.*** We are a development-stage company 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 pre-clinical development and clinical trials;

participating in regulatory approval processes;

formulating and manufacturing products; and

conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing its proprietary technology and undertaking pre-clinical 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.

***We are heavily dependent on the success of the BA058 Injection, which is still under clinical development. We cannot be certain that BA058 Injection will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.*** BA058 Injection is our only product candidate in late stage development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop marketable drug products. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market BA058 Injection in the United States until it receives approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until it receives the requisite approval from such countries. In addition, the approval of BA058 Microneedle Patch as a follow-on product is dependent on an earlier approval of BA058 Injection. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. Obtaining approval of an NDA is an extensive, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of BA058 Injection for many reasons, including:

we may not be able to demonstrate that BA058 is safe and effective as a treatment for osteoporosis to the satisfaction of the FDA;

the results of its clinical studies may not meet the level of statistical or clinical significance required by the FDA for marketing approval;

the FDA may disagree with the number, design, size, conduct or implementation of our clinical studies;

the clinical research organization, or CRO, that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;

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- the FDA may not find the data from preclinical studies and clinical studies sufficient to demonstrate that BA058's clinical and other benefits outweigh its safety risks;

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

- the FDA may not accept data generated at its clinical study sites;

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

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

- the FDA may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or

- the FDA may change its approval policies or adopt new regulations.

Before we submit an NDA to the FDA for BA058 as a treatment for osteoporosis, we must initiate and complete our pivotal Phase 3 study, a thorough QT study (a study designed to assess the potential arrhythmia liability of a drug by measuring the effect on the start to finish time of the ventricular main part of the cardiac contraction, also known as the QT interval), a renal safety study, an osteosarcoma study in rats, and bone quality studies in rats and monkey. We have not commenced all of these required studies and the results of these studies will have an important bearing on the approval of BA058. In addition to fracture and BMD, our pivotal Phase 3 study will measure a number of other potential safety indicators, including anti-BA058 antibodies which will have an important bearing on the approval of BA058. In addition, the results from the rat carcinogenicity study, which includes hPTH(1-34), a daily subcutaneous injection of recombinant human parathyroid hormone as a comparator, may show that BA058 dosing results in more osteosarcomas than PTH which may have a material adverse bearing on approval of BA058.

***If we do not obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, we will not be able to sell our product candidates.*** We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates (BA058, RAD1901, and RAD140), or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government

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regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review. Delays in obtaining regulatory approvals may:

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

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We may never obtain regulatory clearance for any of our product candidates (BA058, RAD1901, and RAD140). 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 another 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 our product candidates for sale outside the United States.

***Most of our product candidates are in early stages of clinical trials.*** Except for BA058, each of our other product candidates (RAD1901 and RAD140), are in early stages of development and requires extensive pre-clinical and clinical testing. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for any of our product candidates or whether any such NDA will be accepted.

***Clinical trials are very expensive, time-consuming and difficult to design and implement.*** Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. A substantial portion of our BA058 development costs are denominated in euro and any adverse movement in the dollar/euro exchange rate will result in increased costs and require us to raise additional capital to complete the development of our products. The clinical trial process is also time consuming. We estimate that clinical trials of BA058 Injection will take at least three years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug, or IND, submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for future clinical trials.

***The results of our clinical trials may not support its product candidate claims.*** Even if our clinical trials are completed as planned, we cannot be certain that the results will support our product

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candidate claims. Success in pre-clinical 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 pre-clinical testing. Our Phase 3 study of BA058 Injection for fracture prevention may not replicate the positive efficacy results for BMD from our Phase 2 study. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date involve a small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

***Physicians and patients may not accept and use our drugs.*** Even if the FDA approves one or more of our product candidates, physicians and patients may not accept and use it. Acceptance and use of our product will depend upon a number of factors including:

perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug;

cost-effectiveness of our product relative to competing products;

availability of reimbursement for our product from government or other healthcare payers; and

effectiveness of marketing and distribution efforts by us and its licensees and distributors, if any.

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

***Our drug-development program depends upon third-party researcher, investigators and collaborators who are outside our control.*** We depend upon independent researchers, investigators and collaborators, such as Nordic Bioscience Clinical Development VII A/S ("Nordic"), to conduct our pre-clinical and clinical trials under agreements with us. These third parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist competitors at our expense, our competitive position would be harmed.

***We will rely exclusively on third parties to formulate and manufacture our product candidate.*** We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We have entered into agreements with contract manufacturers to manufacture BA058 Injection for use in clinical trial activities. These contract manufacturers are currently our only source for the production and formulation of BA058. We currently do not have sufficient clinical supplies of BA058 to complete the planned Phase 3 study for BA058 Injection but believe that our contract manufacturers will be able to produce sufficient supply of BA058 to complete all of the planned BA058 clinical studies. However, if our contract manufacturers are unable to produce, in a timely manner, adequate clinical supplies to meet the needs of our clinical studies, we would be required to seek new contract manufacturers that may require us to modify our finished product formulation and modify or terminate our clinical studies for BA058. Any modification of our finished product or modification or termination of our Phase 3 clinical study could adversely affect our ability to

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obtain necessary regulatory approvals and significantly delay or prevent the commercial launch of the product, which would materially harm our business and impair our ability to raise capital.

We depend on a number of single source contract manufacturers to supply key components of BA058. For instance, we depend on Lonza Group Ltd. ("Lonza"), which produces supplies of bulk drug product of BA058 to support the BA058 Injection and BA058 Microneedle Patch clinical studies and potential commercial launch. We also depend on Beaufort Ipsen Industrie S.A.S. and its subcontractor VETTER Pharma Fertigung GmbH & Co ("Vetter") for the production of finished supplies of BA058 Injection and we depend on 3M for the production of BA058 Microneedle Patch. Because of our dependence on Vetter for the "fill and finish" part of the manufacturing process for BA058 Injection, we are subject to the risk that Vetter may not have the capacity from time to time to produce sufficient quantities of BA058 to meet the needs of our clinical studies or be able to scale to commercial production of BA058. Because the manufacturing process for BA058 Microneedle Patch requires the use of 3M's proprietary technology, 3M is our sole source for finished supplies of BA058 Microneedle Patch.

While we are currently in discussions, to date, neither we nor our collaborators have entered into a long-term agreement with Lonza, Vetter or 3M, who each currently produces BA058 product on a purchase order basis for us. Accordingly, Lonza, Vetter and 3M could terminate their relationship at any time and for any reason. If our relationship with any of these contract manufacturers is terminated, or if they are unable to produce BA058 in required quantities, on a timely basis or at all, our business and financial condition would be materially harmed. If any of our current product candidates or any product candidates we may develop or acquire in the future receive FDA approval, we will rely on one or more third-party contractors to manufacture its drugs. 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 in the volume and of the quality required to meet our clinical needs and commercial needs, if any.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute its products.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We does not have control over third-party manufacturers' compliance with these regulations and standards.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

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

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

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resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

***If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.*** The market for our product candidates is characterized by intense competition and rapid technological advances. If any of our product candidates receives FDA approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. If we fail to develop BA058 Microneedle Patch, our commercial opportunity for BA058 will be limited. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have oncology 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 pre-clinical testing and human clinical trials;

obtaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

***Developments by competitors may render our products or technologies obsolete or non-competitive.*** The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Some of the drugs that we are attempting to develop, such as BA058, RAD1901 and RAD140 will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions,

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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.

***If our efforts to protect our intellectual property related to BA058, RAD1901 and/or RAD140 fail to adequately protect these assets, we may suffer the loss of the ability to license or successfully commercialize one or more of these candidates.*** Our commercial success is significantly dependent on intellectual property related to that product portfolio. We are either the licensee or assignee of numerous issued and pending patent applications that cover various aspects of our assets including BA058, RAD1901 and RAD140.

Patents covering BA058 as a composition of matter have been issued in the United States (US patent No. 5,969,095), Europe and several additional countries. Because the BA058 composition of matter case was filed in 1996, it is expected to have a normal expiry of approximately 2016 in the United States (this date does not include the possibility of Hatch-Waxman patent term extension of up to 5 years) and additional countries where it has issued.

We and Ipsen Pharma SAS (Ipsen SAS) are also coassignees to US patent No. 7,803,770 that we believe provides exclusivity until 2028 in the United States (absent any extensions) for the method of treating osteoporosis with the intended therapeutic dose for BA058 Injection. Because patents are both highly technical and legal documents that are frequently subject to intense litigation pressure, there is risk that one or more of the issued patents that are believed to cover BA058 Injection when marketed will be found to be invalid, unenforceable and/or not infringed. In the absence of product exclusivity in the market, there is a high likelihood of multiple competitors selling the same product with a corresponding drop in pricing power and/or sales volume.

Currently, additional intellectual property covering the BA058 Microneedle Patch is the subject of a US provisional patent application with a priority date of 2011 and any issued claims resulting from this application will expire no earlier than 2031. However, pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view claimed inventions are not always predictable. Additional intellectual property covering the BA058 Microneedle Patch technology exists in the form of proprietary information contained by trade secrets. These can be accidentally disclosed to, independently derived by or misappropriated by competitors, possibly reducing or eliminating the exclusivity advantages of this form of intellectual property, thereby allowing those competitors more rapid entry into the market place with a competitive product thus reducing our marketing advantage of the BA058 Microneedle Patch. In addition, trade secrets may in some instances become publicly available required disclosures in regulatory files. Alternatively, competitors may sometimes reverse engineer a product once it becomes available on the market. Even where a competitor does not use an identical technology for the delivery of BA058, it is possible that they could achieve an equivalent or even superior result using another technology. Such occurrences could lead to either one or more alternative competitor products available on the market and/or one or more generic competitor products on the market with a corresponding decrease in market share and/or price for the BA058 Microneedle Patch.

Patents covering RAD1901 as a composition of matter have been issued in the United States, Australia and is pending in Europe and several additional countries. The RAD1901 composition of matter patent in the United States expires in 2026 (not including any Hatch-Waxman extension). Additional patent applications relating to methods of treating vasomotor symptoms, clinical dosage strengths and combination treatment modalities all covering RAD1901 have been filed. Since patents are both highly technical and legal documents that are frequently subject to intense litigation pressure, there is risk that one or more of the issued patents that are believed to cover RAD1901 when marketed will be found to be invalid, unenforceable and/or not infringed when subject to said litigation. In the absence of product exclusivity in the market, there is a high likelihood of multiple competitors selling the same product with a corresponding drop in pricing power and/or sales volume. Pending

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patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of any claimed invention before that patent office are not always predictable. As a result, we could encounter challenges or difficulties in building, maintaining and/or defending its intellectual property rights protecting and defending our intellectual property both in the United States and abroad.

Patent applications covering RAD140 and other SARM compounds that are part of the SARM portfolio have been filed in the United States and elsewhere. Since the RAD140 composition of matter case was effectively filed in 2009, if issued, it is expected to have a normal expiry of approximately 2029 in the United States (this does not include the possibility of United States Patent and Trademark Office (USPTO) patent term adjustment or Hatch-Waxman extension) and additional countries if/when it issues. Since patents are both highly technical and legal documents that are frequently subject to intense litigation pressure, there is risk that even if one or more RAD140 patents does issue and is asserted that the patent(s) will be found invalid, unenforceable and/or not infringed when subject to said litigation. Finally, the intellectual property laws and practices can vary considerably from one country to another and also can change with time. As a result, we could encounter challenges or difficulties in building, maintaining and/or defending its intellectual property rights protecting and defending our intellectual property both in the United States and abroad.

***Payments, fees, submissions and various additional requirements must be met in order for pending patent applications to advance in prosecution and issued patents to be maintained. Rigorous compliance with these requirements is essential to procurement and maintenance of patents integral to the product portfolio.*** Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or 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 is an assignee or co-assignee, we employ competent legal help and related professionals as needed to comply with those requirements. Our outside patent counsel uses Computer Packages, Inc. for patent annuity payments. Failure to meet a required fee payment, document production of procedural requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances the defect can be cured through late compliance but there are situations where the failure to meet the required event cannot be cured. Such an occurrence could compromise the intellectual property protection around a preclinical or clinical candidate and possibly weaken or eliminate our ability to protect our eventual market share for that product.

***If we infringe the rights of third parties we could be prevented from selling products, 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 its products or processes to avoid infringement;

stop using the subject matter claimed in the patents held by others;

pay damages; or

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

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***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 its drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

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

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

***We may not successfully manage our growth.*** Our success will depend upon the expansion of our operations and the effective management of its growth, which will place a significant strain on our management and on administrative, operational and financial resources. To manage this growth, we may be required to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage this growth effectively, our business would be harmed.

***We may 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 its 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 its business, financial condition and results of operations.

***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 its principal scientific, regulatory and medical advisors. We do not have "key person" life 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 pre-clinical 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.

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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. If we cannot successfully defend our self 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.

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## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

*This Prospectus, 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 Prospectus may include, among other things, statements about:*

- *the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;*
- *the success of our clinical studies for our product candidates;*
- *our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards;*
- *our expectations regarding federal, state and foreign regulatory requirements;*
- *the therapeutic benefits and effectiveness of our product candidates;*
- *the safety profile and related adverse events of our product candidates;*
- *our ability to manufacture sufficient amounts of BA058, RAD1901, and RAD140 for commercialization activities with target characteristics;*
- *our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates;*
- *our expectations as to future financial performance, expense levels and liquidity sources;*
- *our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;*
- *anticipated trends and challenges in our potential markets;*
- *our ability to attract and motivate key personnel; and*
- *other factors discussed elsewhere in this Prospectus.*

*The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other 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 Prospectus under the caption "Risk Factors." You should read these factors and the other cautionary statements made in this Prospectus as being applicable to all related forward-looking statements wherever they appear in this Prospectus. These risk factors are not exhaustive and other sections of this Prospectus 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.*

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## DESCRIPTION OF THE BUSINESS OF RADIUS HEALTH, INC.

***EXPLANATORY NOTE:*** *Unless otherwise provided in this current report, all references in the balance of this Registration Statement to "we," "us," "our company," "our," or the "Company" refer to the combined Radius Health, Inc. entity after giving effect to the Merger and the Short-Form Merger.*

### *Overview*

We are a pharmaceutical company focused on acquiring and developing new therapeutics for the treatment of osteoporosis and other women's health conditions. Our lead product candidate is BA058 Injection, a daily subcutaneous injection of our novel synthetic peptide analog of human parathyroid hormone-related peptide, or hPTHrP, a naturally-occurring bone building hormone, for the treatment of osteoporosis. In April 2011, we began dosing of patients in a pivotal, multinational Phase 3 clinical study. A Phase 3 clinical study is designed to show advantages of a novel therapy over an inactive placebo and/or an existing therapy for the same medical indication and to identify any additional side effects not determined in earlier clinical trials. We expect to report top-line data from this Phase 3 clinical study in the first quarter of 2014. Based on our clinical and preclinical results to date, we believe that BA058 stimulates the rapid formation of new high quality bone in patients suffering from osteoporosis and may restore bone mineral density, or BMD, in these patients into the normal reference range. In addition to BA058 Injection, we are developing BA058 Microneedle Patch, a short wear time, transdermal form of BA058 that is delivered using a microneedle technology from 3M. BA058 Microneedle Patch is being studied in a Phase 1b clinical study which began in December 2010. The BA058 Microneedle Patch may eliminate the need for daily injections and lead to better treatment compliance for patients. We believe that development costs for the BA058 Microneedle Patch will be lower than the development costs for BA058 Injection as it will not be necessary to conduct an additional fracture study for registration of this follow-on product. As a result of the compressed pathway for the BA058 Microneedle Patch, we expect that marketing approval of the BA058 Microneedle Patch can occur soon after the BA058 Injection.

While there are a number of drugs that help to reduce the rate of bone loss in patients suffering from osteoporosis, there are few that are able to build bone. The only approved therapy in the United States that increases BMD into the normal reference range in these patients is Forteo®, a daily subcutaneous injection of recombinant human parathyroid hormone, or rhPTH(1-34). The product is marketed by Eli Lilly and had reported worldwide sales of $830 million in 2010. We believe that BA058 may offer a number of important advantages over Forteo®, including greater efficacy, a faster benefit, a shorter course of therapy, an improved safety profile and no need to refrigerate in use BA058 Injection. We believe, if approved, the BA058 Injection and the BA058 Microneedle Patch will offer an attractive bone anabolic treatment option for prescribing physicians and women with compelling advantages in safety, efficacy and delivery over Forteo®.

Based upon guidance we have received from the United States Food and Drug Administration, or the FDA, and the European Medicines Agency, or the EMA, we believe that a single pivotal placebo-controlled, comparative Phase 3 study will be sufficient to support registration of BA058 Injection for the treatment of osteoporosis in both the United States and the European Union. Our planned study will enroll a total of 2,400 patients to be randomized equally to receive daily doses of one of the following: 80 micrograms (µg) of BA058, a matching placebo, or the approved dose of 20 µg of Forteo® for 18 months. The study will be designed to support, or not, our belief that BA058 is superior to (i) placebo for fracture and (ii) Forteo® for greater BMD improvement at major skeletal sites and for a lower occurrence of hypercalcemia, a condition in which the calcium level in a patient's blood is above normal. We believe that the study will also show that BMD gains for BA058 patients will be earlier than for Forteo® patients.

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***Market Opportunity for BA058***

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to an increase in fractures. The prevalence of osteoporosis is growing in developed nations with the aging of the populations. The NOF has estimated that (i) 10 million people in the United States, comprising eight million women and two million men, already have osteoporosis and another 34 million have low bone mass placing them at increased risk for osteoporosis and (ii) osteoporosis was responsible for more than 2 million fractures in the United States in 2005 resulting in an estimated $19 billion in costs. The NOF expects that the number of fractures due to osteoporosis will rise to 3 million by 2025.

In 2011, Cowen and Company, an investment banking firm, estimated that total worldwide sales of osteoporosis products was $7.6 billion in 2010. There are two main types of osteoporosis drugs now available in the United States: (i) anti-resorptive agents such as bisphosphonates including Actonel®, Boniva® or Reclast®, and Prolia® (a nuclear factor kB ligand, or RANKL, inhibitor marketed by Amgen), as well as calcitonins and selective estrogen receptor modulators such as Evista® marketed by Lilly; and (ii) anabolic agents, with Forteo® being the only approved drug of this type. Anti-resorptive agents act to prevent further bone loss by inhibiting the breakdown of bone whereas anabolic agents stimulate bone formation to build high quality, new bone. The use of bisphosphonates have been associated with infrequent but serious adverse events such as osteonecrosis of the jaw, atrial fibrillation and anomalous fractures resulting from "frozen bone" that have created increasing concern with physicians and patients. Many physicians are seeking alternatives to current anti-resorptive therapies and we believe this will drive greater demand for bone anabolic agents in the future. We believe that there is a significant opportunity for a new anabolic agent such as BA058 that will increase bone mineral density to a greater degree and at a faster rate than Forteo® with added advantages in convenience and safety.

***Our Strategy***

We plan to build a pharmaceutical company focused on acquiring and developing new therapeutics for osteoporosis and women's health by:

- Completing the single, pivotal Phase 3 clinical trial of BA058 Injection for the treatment of osteoporosis in the first quarter of 2014;
- Pursuing the clinical development of BA058 Microneedle Patch as a follow-on product for the treatment of osteoporosis;
- Obtaining regulatory approval of BA058 Injection and BA058 Microneedle Patch for the treatment of osteoporosis, initially in the United States and subsequently in the European Union;
- Collaborating with third parties for the worldwide commercialization of BA058; and
- Collaborating with third parties for the further development and commercialization of RAD1901 and RAD140 on a worldwide basis.

To execute on our strategy, we have built a strong management team and Board of Directors with significant pharmaceutical development, regulatory and commercial experience.

***Our Solution***

In addition to BA058 Injection and BA058 Microneedle Patch, we are currently conducting one other clinical and one preclinical program. Our second clinical stage product candidate is RAD1901, a selective estrogen receptor modulator, or SERM, which we licensed from Eisai in 2006. We previously completed an initial Phase 2 clinical study for the treatment of vasomotor symptoms (commonly known as hot flashes) in women entering menopause. A Phase 2 study is designed to test the efficacy of a novel treatment and to confirm the safety profile established in a Phase 1 study. Our third product

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candidate, RAD140, is a pre-Investigational New Drug, or IND, Application discovery stage of development. RAD140 is a selective androgen receptor modular, or SARM, that is an orally-active androgen agonist on muscle and bone and is a potential treatment for age-related muscle loss, frailty, weight loss associated with cancer cachexia and osteoporosis.

The following table summarizes the target indications, dosage forms, and stages of development for our product candidates.

**Radius Product Pipeline**

***Research and Development Expenses***

The following table sets forth our research and development expenses related to BA058 injection, BA058 Microneedle Patch, RAD1901 and RAD140 for the years ended December 31, 2009 and 2010 and the six months ended June 30, 2010 and 2011. We began tracking program expenses for BA058 Injection in 2005, and program expenses from inception to June 30, 2011 were approximately $43.1 million. We began tracking program expenses for BA058 Microneedle Patch in 2007, and program expenses from inception to June 30, 2011 were approximately $8.2 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to June 30, 2011 were approximately $15.3 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to June 30, 2011 were approximately $5.2 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs. Costs related to facilities, depreciation, share-based compensation, and research and development support services are not directly charged to programs as they benefit multiple research programs that share resources.

| | Year ended December 31, | | Six Months ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2010 | 2010 | 2011 |
| | (in thousands) | | | |
| BA058 Injection | $ 3,671 | $ 4,664 | $ 661 | $ 16,774 |
| BA058 Microneedle Patch | 2,819 | 1,863 | 857 | 2,758 |
| RAD1901 | 2,185 | 1,654 | 1,040 | |
| RAD140 | 2,031 | 313 | 287 | 23 |

See "Management's Discussion and Analysis Financial Overview Research and Development Costs" for a more detailed discussion related to our research and development expenses and uncertainties related to predicting how much research and development expense we may incur in connection with our existing or future, in any, product candidates.

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***BA058***

BA058 is a novel synthetic peptide analog of human Parathyroid hormone-related peptide, or hPTHrP, being developed by us as a bone anabolic treatment for osteoporosis. hPTHrP is critical in the formation of the embryonic skeleton and is involved in the regulation of bone formation, able to rebuild bone with low associated risk of inducing the presence of too much calcium in the blood, known as hypercalcemia, as a side-effect. Human PTHrP is different to hPTH in its structure and role. In 2009, the medical journal, Nature Chemical Biology, published results of a study indicating that PTH and PTHrP activate the same PTHR1 receptor but produce divergent effects in bone due to differences in downstream cell signaling. We believe that BA058 is the most advanced hPTHrP analog in clinical development for the treatment of osteoporosis. We acquired and maintain exclusive worldwide rights (except Japan) to certain patents, data and technical information related to BA058 through a license agreement with SCRAS SAS, a French corporation on behalf of itself and its affiliates (together with Ipsen SAS and its other affiliates) dated September 2005. Based on clinical and preclinical data to date, we believe that BA058 has the following important potential advantages over Forteo® rhPTH(1-34), the only approved anabolic agent for osteoporosis in the US:

Greater efficacy,

Faster benefit,

Shorter treatment duration,

Less hypercalcemia,

No additional safety risks, and

No refrigeration required in use.

***BA058 Injection***

In August 2009, we announced positive Phase 2 data that showed BA058 Injection produced faster and greater BMD increases at the spine and the hip after 6 months and 12 months of treatment than did Forteo®, which was a comparator in our study. Key findings were that the highest dose of BA058, which was 80 µg, increased mean lumbar spine BMD at 6 and 12 months by 6.7% and 12.9% compared to the increases seen with Forteo® trial arms of 5.5% and 8.6%, respectively. BA058 also produced increases in mean femoral neck BMD at the hip at 6 and 12 months of 3.1% and 4.1% compared to increases for Forteo® of 1.1% and 2.2%, respectively. We believe there to be a strong correlation between an increased level of BMD and a reduction in the risk of fracture for patients with osteoporosis. BA058 was generally safe and well tolerated in this study, with adverse events similar between the BA058, placebo and Forteo® groups. In addition, the occurrence of hypercalcemia as a side-effect was half that seen with Forteo® for the 80 µg dose of BA058.

In March 2011, we entered an agreement with Nordic Bioscience, or Nordic, to manage the Phase 3 study of BA058 Injection. The study will be conducted in 10 countries at 13 centers operated by the Center for Clinical and Basic Research, or CCBR. CCBR is a leading global clinical research organization with extensive experience in global osteoporosis registration studies. We expect to report top-line data from the Phase 3 study of BA058 Injection in the first quarter of 2014. Before we submit an NDA to the FDA for BA058 as a treatment for osteoporosis, we must complete our pivotal Phase 3 study, a thorough QT study, a renal safety study, an osteosarcoma study in rats, and bone quality studies in rats and monkey. We have not commenced all of these required studies and the results of these studies will have an important bearing on the approval of BA058.

The FDA approval process is lengthy and expensive. While the date of FDA approval of BA058 cannot be predicted, FDA approval is not expected before late 2015 and may not be granted, if ever, for several years thereafter. If we do not obtain the necessary regulatory approvals to commercialize

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BA058, we will not be able to sell the product candidate. Given BA058 is our lead product candidate and the only one currently in late stage development, failure to obtain FDA approval of BA058 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 another product candidate. See our discussion of timing of approval, including factors that may result in potential delays, and related research and development costs matters set forth in this registration statement under "Management's Discussion and Analysis Financial Overview Research and Development Costs". As result of the uncertainties discussed there, we are unable to determine the duration and costs to complete current or future clinical stages of our BA058 product candidate or when, or to what extent, we will generate revenues from the commercialization and sale of any of BA058. Notwithstanding the foregoing, future research and development costs related to BA058 Injection is estimated to be at least an additional $160 million. From January 1, 2009 through June 30, 2011, we have incurred $25.1 million in research and development costs related to BA058 Injection. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for BA058 Injection would significantly increase our need to raise additional working capital funds and materially adversely affect our product development efforts and our business overall. Our continued operations, including the development of the BA058 Injection, will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing and potential collaboration agreements. We will seek to continue to fund operations from cash on hand and through additional equity and/or debt financing and potential collaboration agreements To date, a significant portion of our financing has been through private placements of Preferred Stock. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. If we do not succeed in timely raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders.

***BA058 Microneedle Patch***

In December 2010, we initiated a combined single and seven-day repeat-dose Phase 1 clinical study of the BA058 Microneedle Patch in healthy subjects with top-line data expected to be available in the fourth quarter of 2011. Following this Phase 1 study, we plan to select a dose range to conduct a Phase 2 clinical study comparing multiple daily doses of the BA058 Microneedle Patch to placebo and BA058 Injection using lumbar spine BMD at 6 months as the primary endpoint. We expect to begin the Phase 2 BA058 Microneedle Patch clinical study in mid 2012 with top-line data available in mid 2013. If the BA058 Injection product is already approved by the FDA, we believe that we will only need to conduct a single non-inferiority Phase 3 clinical study comparing the change in lumbar spine BMD at 12 months for patients dosed with the BA058 Microneedle Patch to patients dosed with the BA058 Injection to show that the effect of the BA058 Microneedle Patch treatment is not worse than that of BA058 Injection.

We believe that development costs for the BA058 Microneedle Patch will be lower than the injectable version as it will not be necessary to conduct an additional fracture study for this follow-on product. As a result of the compressed pathway, we expect that marketing approval of the BA058 Microneedle Patch can occur soon after the BA058 Injection. Therefore, the FDA approval, and the timing of any such approval, is dependent upon the approval of BA058 Injection and therefore is not likely to receive FDA approval, if ever, until at least two years following approval of BA058 Injection, however, any such time estimate is subject to the same potential delays discussed under Management's Discussion and Analysis Financial Overview Research and Development Costs". As result of the uncertainties discussed there, we are unable to determine the costs to complete current or future

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clinical stages of the BA058 Microneedle Patch candidate or when, or to what extent, we will generate revenues from the commercialization and sale of any of BA058. Notwithstanding the foregoing, future research and development costs related to BA058 Microneedle Patch is estimated to be at least an additional $50 million. From January 1, 2009 through June 30, 2011, we have incurred $7.4 million in research and development costs related to the BA058 Microneedle Patch. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for BA058 Microneedle Patch could significantly increase our need to raise additional working capital funds and materially adversely affect our product development efforts and our business overall. Our continued operations, including the development of the BA058 Microneedle Patch, will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing and potential collaboration agreements. We will seek to continue to fund operations from cash on hand and through additional equity and/or debt financing and potential collaboration agreements. To date, a significant portion of our financing has been through private placements of Preferred Stock. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. If we do not succeed in timely raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders.

***Background on Osteoporosis***

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which can lead to an increase in fractures. A bone density test is the only non-invasive test that can diagnose osteoporosis before a broken bone occurs and is reported using T-scores. The test uses a procedure called bone densitometry (DXA) performed in the radiology or nuclear medicine departments of hospitals or clinics. A BMD t-score is the number of standard deviations above or below the mean BMD for a healthy 30 year old adult of the same sex and ethnicity as the patient. A t-score of -1.0 or above is normal bone density, whereas a t-score of -2.5 or below is a diagnosis of osteoporosis.

On its website, www.nof.org, the National Osteoporosis Foundation (NOF) has estimated that 10 million people in the United States, comprising eight million women and two million men, already have osteoporosis and another 34 million have low bone mass placing them at increased risk for osteoporosis and broken bones. All bones become more fragile and susceptible to fracture as the disease progresses. People tend to be unaware that their bones are getting weaker, and a person with osteoporosis can fracture a bone from even a minor fall. Fractures due to osteoporosis are most likely to occur in the hip, spine and wrist. According to the NOF: osteoporosis was responsible for more than 2 million fractures in the United States in 2005; vertebral (spinal) fractures may result in severe back pain, loss of height or spinal deformities; there were approximately 293,000 Americans age 45 and over admitted to hospitals in 2005 with a fracture of the femoral neck, a common type of hip fracture that is associated with osteoporosis; a women's lifetime risk of a hip fracture is equal to her combined risk of breast, uterine and ovarian cancer; and an average of 24 percent of hip fracture patients aged 50 and over dies in the year following their fracture, while additional 20 percent of patients who were ambulatory before their hip fracture require long-term care.

The debilitating effects of osteoporosis have substantial costs. Loss of mobility, admission to nursing homes and dependence on caregivers are all common consequences of osteoporosis. The NOF has estimated that osteoporosis-related fractures were responsible for $19 billion in costs in 2005.

The prevalence of osteoporosis is growing and, according to the NOF, is significantly under-recognized and under-treated in the population. While the aging of the population is a primary driver of an increase in cases, osteoporosis is also increasing from the use of drugs that induce bone loss, such

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as chronic use of glucocorticoids for asthma, aromatase inhibitors that are increasingly used for breast cancer and the hormone therapies used for prostate cancer.

The range of treatment and prevention options for osteoporosis has expanded in recent years from anti-resorptive drugs that act to prevent bone loss by blocking bone resorption, which is the process by which bone is broken down in the body and the resulting minerals, including calcium, are released into the blood, and now includes bisphosphonates, selective estrogen receptor modulators, calcitonins, and most recently in 2010, a genetic-based therapy known as receptor activator of nuclear factor kappa-B ligand, known as a RANKL inhibitor. Bisphosphonates remain the current standard of care with 2010 world-wide total sales of approximately $4.2 billion according to Cowen and Company's report dated March 2011 and entitled Therapeutic Categories Outlook, led by Actonel®, Boniva®, and Fosamax®. Generic versions of Fosamax® (alendronate) became available in the US in 2008 and have now gained share from branded oral bisphosphonates.

The only anabolic (i.e., stimulating bone formation) drug approved in the U.S. for osteoporosis is Forteo®, which was approved by the FDA in December 2002. In 2011, the medical journal, *Osteoporosis International*, published results of a study indicating that patients' preferences for osteoporosis medications are strongly influenced by the mode of administration. In particular, when given the choice of subcutaneously injected Forteo® versus other therapies, patients preferred the alternative drugs over Forteo, which requires once-daily, self-administered injections and must be refrigerated for storage in use. We believe that this research suggests that there is a substantial opportunity to optimize patient outcomes and expand the market by improved treatment compliance with a bone anabolic drug that offers an alternative to daily injection, is room-temperature-stable and requires a shorter treatment duration, such as the BA058 Microneedle Patch. Forteo® had world-wide sales of $594 million in 2006 and grew to $830 million in sales for 2010.

***Clinical Development Program for BA058***

Radius is developing BA058 for the prevention of fractures in postmenopausal women at risk of fracture from severe osteoporosis. Recognizing both the therapeutic potential of BA058 in this indication as well as the drawbacks inherent in self-injection therapies in this population, Radius is also developing the BA058 Microneedle Patch for transdermal administration of the product using a microneedle technology from 3M. We plan to develop and register BA058 Injection as our lead product, with the BA058 Microneedle Patch as a fast-following product that provides greater patient convenience. The ability of the Microneedle Patch to capitalize on the more extensive fracture study data of BA058 Injection will allow the patch product to be accelerated though later phase development without requiring its own fracture study.

***Planned and Completed BA058 Studies***

***Planned Studies***
***BA058 Injection, Phase 3***

The Phase 3 study for BA058 Injection (Study BA058-05-003) was submitted as a draft protocol to IND 73,176 on December 18, 2009, and was the subject of a Type B End of Phase 2 Meeting conducted with the FDA on January 21, 2010. The protocol was subsequently revised and submitted to the FDA on December 17, 2010. The study is planned to enroll 2,400 patients at 13 medical centers in 10 countries in Europe, Latin America and Asia.

***Study Objectives***

The primary objective of this study is to determine the safety and efficacy of BA058 Injection at a dose of 80 μg when compared to a matching placebo for prevention of vertebral fracture in otherwise healthy ambulatory postmenopausal women at risk of fracture from severe osteoporosis. Patients,

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investigators and independent assessors will be blinded as to treatment for that outcome. The secondary objectives of this study are to determine the safety and efficacy of BA058 at a dose of 80 µg when compared to placebo for prevention of non-vertebral fractures and for change in vertical height. Additional key secondary efficacy outcomes include BMD of spine, hip and femoral neck and hypercalcemia when compared to Forteo®.

***Study Population***

The study will enroll otherwise healthy ambulatory postmenopausal (≥ 5 years) women from 50 to 85 years of age (inclusive) who meet the study entry criteria and have provided written informed consent. The women will have a BMD T-score ≤ -2.5 and > -5.0 at the lumbar spine or hip (femoral neck) by DXA and radiological evidence of two or more mild or one or more moderate lumbar or thoracic vertebral fractures, or history of low trauma forearm, humerus, sacral, pelvic, hip, femoral, or tibial fracture within the past 5 years. Postmenopausal women older than 65 who meet the above fracture criteria but have a T-score ≤ -2.0 and > -5.0 may be enrolled. Women older than 65 who do not meet the fracture criteria may also be enrolled if their T-score is ≤ -3.0 and > -5.0. Osteoporosis is defined as when a patient's T-score is -2.5 or lower, meaning that the patient has a BMD that is two and a half standard deviations below the mean of a thirty year old man or woman, as applicable.

All patients are to be in good general health as determined by medical history, physical examination (including vital signs) and clinical laboratory testing.

***Study Design***

The planned 2,400 eligible patients will be randomized equally to receive one of the following: BA058 at a dose of 80 µg, a matching placebo, or Forteo® at a dose of 20 µg for 18 months. Study drug will be blinded to patients and medical personnel until the randomization process is completed. Treatment with BA058 at a dose of 80 µg or placebo will remain blinded to all parties throughout the study. Forteo® comes as a proprietary prefilled drug and device combination that cannot be repackaged and therefore, its identity cannot be blinded to treating physicians and patients once use begins. Study medication will be self-administered daily by subcutaneous, or SC, injection for a maximum of 18 months.

The dosages of study medications and the number of patients per group are shown in below.

***Study BA058-05-003 Medication Doses and Number of Patients per Group***

| Treatment Regimen | Study Medication | Daily Dose (SC) | Duration | Number of Patients |
|---|---|---|---|---|
| 1 | BA058 | 80 µg | 18 months | 800 |
| 2 | Placebo | | 18 months | 800 |
| 3 | Forteo® | 20 µg | 18 months | 800 |
| | | | Total | 2,400 |

All enrolled patients will also receive Calcium and Vitamin D supplementation from the time of enrollment until the end of the Treatment Period; it will be recommended to patients that they also continue these supplements through the one month follow-up period.

***Primary Efficacy Outcomes***

The primary efficacy endpoint will be the number of BA058-treated patients showing new vertebral fractures at End-of-Treatment when compared to placebo as evaluated by a blinded assessor according to a standardized graded scale of severity of the vertebral deformity. The sample size per treatment

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arm provides 90% power at a two-sided alpha to detect a superiority difference between placebo patients and those who receive BA058 at a dose of 80 μg on vertebral fracture incidence.

***Secondary Efficacy Endpoints***

Secondary efficacy parameters will also include reduction in the incidence of non-vertebral fractures to the wrist, hip and rib, for example, and reduction in moderate and severe vertebral fractures. Other secondary efficacy endpoints will include changes in BMD of the spine, hip, femoral neck and wrist from baseline to end-of-treatment as assessed by DXA.

Additional secondary endpoints will include change in standing height and changes in serum bone formation markers across treatment, such as N-terminal propeptide of type I procollagen PINP, osteocalcin and bone-specific alkaline phosphatase. The frequency of hypercalcemia across treatment groups will also be assessed.

***Safety Outcomes***

Safety evaluations to be performed will include physical examinations, vital signs, 12-lead electrocardiograms, or ECGs, clinical laboratory tests and monitoring and recording of adverse events. Specific safety assessments will include post-dose (4 hours) determination of serum calcium, determination of creatinine clearance, post-dose ECG assessments at selected visits and assessments of postural hypotension (60 minutes post-dose) at selected clinic visits.

Bone biopsy of the iliac crest will be performed in a subset of patients receiving BA058 at a dose of 80 μg and Placebo (up to 100 per group) for assessment of quantitative bone histomorphometry which is the quantative study of the microscopic organization and structure of the bone tissue, and will be read blinded to treatment by an independent blinded assessor. Renal safety will be further evaluated in a subset of 100 patients in each treatment group by renal computed tomography, or CT, scan.

Overall study safety will be monitored by an independent Data Safety Monitoring Board.

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***BA058 Microneedle Patch Phase 2***

We plan to conduct a Phase 2 randomized, placebo-controlled, parallel group dose-finding clinical trial in mid-2012. The study will evaluate the safety and efficacy of the daily BA058 Microneedle Patch in women with osteoporosis. We intend to enroll about 250 patients and the study will be similar in design to the Phase 2 study for BA058 Injection. The study will evaluate the effects of 3 doses of the BA058 Microneedle Patch, compared to placebo and BA058 Injection 80 µg on change in BMD and anabolic bone markers over 6 months of treatment. The study will be powered to detect clinically meaningful changes in BMD and biomarkers as efficacy measures.

Safety will be assessed as changes in incidence of adverse events, changes in laboratory parameters, in particular serum calcium, change from baseline in the patient's vital signs and physical examination.

Study participation will be preceded by 4 weeks of pretreatment with Calcium and Vitamin D supplements and treatment conclusion will be followed by a one month period of safety observation.

***Completed BA058 Studies***
***BA058 Injection, Phase 2***

A Phase 2 dose-finding clinical trial (Study BA058-05-002) was conducted as a randomized, placebo-controlled, parallel group dose-finding study in the United States, Argentina, India and the United Kingdom. The purpose of the study was to evaluate the safety and efficacy of daily injections of BA058 Injection in women with osteoporosis. Postmenopausal women between the ages of 55 to 85 inclusive who had a BMD T-score less than or equal to -2.5 at the lumbar spine or hip (femoral neck) by DXA or a BMD T-score of less than or equal to -2 and a prior low trauma fracture, or an additional risk factor were candidates for this study. The study evaluated the effects of BA058 Injection at multiple doses (0, 20, 40 and 80 µg) on recovery of BMD, a marker of fracture risk, and on biomarkers of anabolic and resorptive activity in bone. The study also included a Forteo® treatment arm for reference. These efficacy measures (BMD and bone biomarkers) were designed for statistical significance. After the initial 24 weeks of treatment, eligible patients were offered a second 24 weeks of their assigned treatment. Safety was assessed throughout the study and reported on at both 6 months and 12 months. BA058 Injection and BA058-placebo were self-administered using a prefilled cartridge in a pen-injector device. Forteo® was self-administered as the marketed product at the approved dose of 20 µg per day by SC injection. Four weeks prior to start of treatment, patients began taking Calcium and Vitamin D supplements that continued throughout the study.

A total of 270 patients (mean age: 65 years) entered the pretreatment period, 222 patients were randomized, and 221 patients received study treatment and were analyzed in the intent to-treat, or ITT, population with 55 continuing into an additional 24 weeks of treatment. A total of 155 patients were included in the Efficacy Population (Per Protocol) in the initial 24 weeks of treatment.

***Initial 24 weeks of treatment***

The efficacy results of Study BA058-05-002 confirm the preclinical and early clinical hypothesis that BA058 Injection induces a dose-dependent increase in BMD and in markers of bone remodeling measurable at both the 12-week and 24-week assessments.

At week 12, in the ITT population the mean percent change in total analyzable spine BMD increased with dose, Figure A. The mean gains in BMD (active treatment  placebo) for the BA058 Injection 40 µg and 80 µg groups were statistically significant ($p = .0013$ and $p < 0.001$, respectively). The difference was not statistically significant in the BA058 20 µg group and just missed significance in the Forteo® group ($p = 0.055$).

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At week 24, the percent change from baseline continued to increase and was statistically significantly proportional to dose (p<0.001), see Figure A below. Again, the mean gain in total analyzable spine BMD was statistically significant for the BA058 Injection 40 µg (p = <0.001) and 80 µg (p < 0.001) groups. The BMD gain at week 24 was also significant for the Forteo® group (p < 0.001), but not for the BA058 Injection 20 µg group.

***Figure A Mean Standard Error of the Mean (SEM) Percent Change from Baseline at weeks 12 and 24 in Total Analyzable Spine BMD***

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An even greater proportional response in BMD was elicited in the hip region. By week 24, mean percent changes in total analyzable hip BMD were 0.4%, 1.4%, 2.0% and 2.6% for the placebo, BA058 at a dose of 20 µg, BA058 at a dose of 40 µg, and BA058 at a dose of 80 µg groups, respectively; mean percent change in the Forteo® (0.5%) group was similar to placebo, see Figure B below. Total hip showed a clear dose response to BA058 and a more than five-fold benefit of BA058 at a dose of 80 µg over Forteo®. A similar relative benefit of BA058 at a dose of 80 µg over Forteo® was seen in all regions of the hip.

***Figure B Mean (SEM) Percent Change from Baseline at weeks 12 and 24 in Total Analyzable Hip BMD (ITT Population, N=221)***

BA058 Injection also induced a dose-dependent rise in major markers of bone anabolic activity studied (N-terminal propeptide of type I procollagen PINP, bone specific alkaline phosphatase BSAP, and osteocalcin). The response to Forteo® was generally somewhat greater for all anabolic markers but also bone resorption markers (C-telopeptides of type I collagen crosslinks, or CTX, and N-telopeptides of type I collagen crosslinks, or NTX), consistent with published data on later gradual loss of Forteo® BMD benefit.

BA058 Injection was well tolerated at all doses and safety events were consistent with usual medical events in a study population of this age and gender. The safety profile was also similar to that of Forteo® and there were no treatment-related significant (serious) adverse events, or SAEs however, adverse events were reported by 74% of patients in the first 6 months of treatment, with a similar incidence across all treatment groups. The majority of on-treatment events were mild to moderate in severity and there were no deaths reported. Seven subjects discontinued due to adverse events,1in the BA058 20 µg group, 1 in the BA058 40 µg group, 3 in the BA058 80 µg group and 2 in the teriparatide group Eight patients (4%) experienced at least 1 severe adverse event and the incidence of such events was similar across treatment groups. Five SAEs, unrelated to treatment, were reported in 3 patients. Local tolerance at the injection site was similar across treatment groups and fewer than 20% of subjects reported any symptoms, such as redness, at the injection site across the many months of injections.

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The level of calcium in the blood, known as serum calcium levels, were monitored throughout the study and clinically significant elevated levels (≥10.5 milligrams per deciliter, or mg/dL) were observed in 40% of the Forteo® group while also observed in 4%, 12%, 19% and 18% of the placebo, BA058 Injection at a dose of 20 µg, 40 µg and 80 µg groups, respectively. Most elevations were noted at the 4-hour post-injection time point.

Blood pressure was assessed throughout the study for postural change. Postural changes in blood pressure (predetermined level of change in systolic or diastolic from lying to standing) were reported in 7 patients, including 0%, 5%, 2%, 2% and 7% of patients in the placebo, BA058 Injection 20 µg, 40 µg, 80 µg and Forteo® groups, respectively. Pre-dose postural changes in blood pressure were similar across treatment groups. There were no clinically meaningful differences in ECG parameters between the placebo and active treatment groups.

Seventeen patients had low titer antibodies against BA058 after 6 months of treatment. Of these, 1 was in the placebo group, 2 were in the BA058 20 µg group, 8 were in the BA058 40 µg group and 6 were in the BA058 80 µg group. There were no associated safety events and no attenuation of treatment efficacy. One antibody-positive patient in the BA058 Injection 40 µg group was found to have evidence of neutralizing activity at 24 weeks without evidence of attenuation of drug efficacy, having a 9.3% gain in total analyzable spine BMD at the week 24 assessment.

***Extended 24 weeks of treatment***

Patients who completed the initial 24 weeks of treatment and continued to meet eligibility criteria were offered participation in the 24-week extension study in which they would continue their assigned treatment. On completion of the regulatory process to approve the study extension, 69 patients remained eligible and 55 participated, including 13, 10, 7, 11 and 14 patients in the BA058 Injection 20 µg, 40 µg, 80 µg, placebo and Forteo® groups, respectively. Forty-eight patients completed the extended treatment period.

BMD continued to increase during the extended 24 weeks of treatment, with the largest percent increases in total analyzable spine BMD, femoral neck BMD and total analyzable hip BMD observed in the BA058 Injection 80 µg group. By week 48, mean percent changes in spine BMD were 0.7%, 5.1%, 9.8% and 12.9% for the placebo, BA058 20 µg, BA058 40 µg and BA058 80 µg, groups, respectively, while mean percent change from baseline in the Forteo® group was 8.6%. At week 48, the mean femoral neck BMD in the BA058 Injection 80 µg group gained 4.1% compared to the mean of the Forteo® group at 2.2%. The respective results for total analyzable hip BMD were 0.7%, 2.2%, 2.1% and 2.7% for the placebo, BA058 20 µg, BA058 40 µg and BA058 80 µg groups, respectively; compared to 1.3% for the Forteo® group.

No treatment-related SAEs or deaths were reported during this time period. Two patients discontinued treatment, one for bilateral femoral hernias (BA058 Injection 80 µg) and one for moderate syncope (BA058 Injection 40 µg). TEAEs occurred in a similar proportion of patients in each treatment group across the 52-week study period and the majority of events were mild or moderate in severity. The profile of events was not different in the second 6 months of study treatment.

Local tolerance of study drug injections was also similar in the second 6 months of treatment. There were no safety signals observed in the evaluation of clinical laboratory parameters.

***Conclusions***

In conclusion, this study demonstrated that treatment with BA058 Injection induces a substantial positive change in BMD at both spine and hip in women with osteoporosis, with a particular advantage over Forteo® at the hip, and achieves this benefit safely and with substantially less hypercalcemia effect than Forteo®.

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***BA058 Injection Phase 1 Trials***

***The First Phase 1 Trial***

The first Phase 1 clinical trial was a single-dose study conducted as a randomized, double-blind, placebo-controlled, parallel-group dose escalation study of BA058 Injection in a vial formulation administered as a single SC dose to healthy male and female subjects with a mean age of 61 years. The study administered single SC doses of 2, 5, 7.5, 10, 15, 20, 40, 60, 80, and 100 µg BA058 Injection or placebo. Sixteen subjects also received 2.5 µg of BA058 Injection by the intravenous, or IV, route and 15 µg subcutaneously in separate study periods. In total, 76 subjects received BA058 while 20 received a placebo. No elevation in serum calcium was observed at doses of 80 µg or lower and no clinically relevant effects of BA058 Injection on ECG or continuous monitoring through the use of a Holter monitor, readings were observed. In summary, this study demonstrated that BA058 Injection is 100% bioavailable when administered by the SC route. BA058 Injection did not induce hypercalcemia and was well tolerated at doses up to 80 µg subcutaneously.

***The Second Phase 1 Trial***

The second Phase 1 clinical trial administered BA058 Injection once daily for seven days. There were 39 study subjects, all healthy postmenopausal women with an average age of 60. Four doses of BA058 Injection (5, 20, 40 or 80 µg) and a matching placebo were studied, with 7 or 8 women receiving each dose for the 7 days of the study. BA058 Injection was well tolerated at all doses and there were no medically important adverse events. All other adverse events were mild or moderate in intensity and did not appear to be related to the dose of study drug. No subjects dropped out or discontinued the study.

BA058 was rapidly absorbed following injection and reached peak blood levels within 1 hour. The drug was rapidly cleared from the circulation, resulting in half-life values ranging from 1.05 to 2.59 hours. Following BA058 administration, serum parathyroid hormone decreased, as would be expected, and serum 1,25-dihydroxyvitamin D and serum P1NP rose in an dose-related manner. 1,25-dihydroxyvitamin D is an activated form of Vitamin D and PINP is a bone protein that is increased when new bone is being formed; both are expected and beneficial effects of the study drug and its class. Serum calcium showed a slight rise following BA058 administration, also an expected effect, but remained within the normal range at all times in all patients other than isolated minor and transient elevations in 2 of 7 placebo and 3 of 32 BA058 subjects.

***The Third Phase 1 Trial***

The third Phase 1 clinical trial was a multi-dose study, with the same design as the Second Phase 1 Trial, but using a liquid prefilled multidose cartridge of BA058 and conducted at doses of 80, 100 and 120 µg. BA058 Injection or placebo was administered daily as a SC dose for 7 days to healthy postmenopausal women. Thirty healthy postmenopausal women with a mean age of 61 years were enrolled and 29 completed treatment.

BA058 Injection was well tolerated at doses of up to 100 µg but not at 120 µg which met criteria for termination of dose escalation. One patient in the 120 µg group was intolerant of study drug and was discontinued. All adverse events were mild or moderate in intensity. No study subject developed serum antibodies to BA058 following the 7 days of exposure. BA058 pharmacokinetics was again characterized by rapid absorption, reaching mean peak plasma concentration within approximately 0.5 hours; mean half-life values ranged from 1.13 to 1.65 hours. Similar responses in serum PTH, 1,25-dihydroxy Vitamin D and serum P1NP were observed. These higher doses of BA058 Injection were not associated with occurrence of hypercalcemia. In summary, BA058 Injection was well tolerated at up to 100 µg once daily for 7 days.

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***BA058 Microneedle Patch***

***First Phase 1 Trial***

The objectives of the Microneedle Patch Phase 1 study were to determine the safety, pharmacokinetics, or PK and time course of delivery of BA058 Microneedle Patch in healthy postmenopausal women and to compare the PK profiles of BA058 Microneedle Patch delivered transdermally to BA058 Injection administered subcutaneously.

This study was a randomized, double-blind, placebo-controlled, ascending single-dose study and enrolled 38 healthy postmenopausal women with a mean age of 57.6. Subjects underwent up to 3 single dose exposures to BA058 Microneedle Patch, Placebo Microneedle Patch or BA058 Injection 80 µg over the course of 3 Study Periods.

***Pharmacokinetic Results***

BA058 Microneedle Patch was characterized by a rapid absorption and elimination. The Cmax and half-life times were shorter than for BA058 Injection administration.

***Safety Results***

The BA058 Microneedle Patch was well tolerated. Safety events were similar between the BA058 Microneedle Patch and BA058 Injection, with the majority of adverse events being mild (99%) and, of these, most were reactions at the application site. There was no clinically notable difference in laboratory or cardiac safety parameters across doses of BA058 or routes of administration.

In conclusion, the first Phase 1 study of the BA058 Microneedle Patch demonstrated that BA058 can safely be delivered by this route of administration.

***Second Phase 1 Trial***

A second Phase 1 single day and 7-day application study of the BA058 Microneedle Patch is currently being conducted in the United States using an optimized Microneedle Patch system. The study is designed as a safety, dose-ranging and time-course pharmacokinetic and pharmacodynamic study. This Phase 1 study will investigate optimal dose, wear time and application site for transdermal delivery of BA058 using an optimized microneedle array.

The study will use a matrix design and will first establish optimal wear time before exploring the impact of application site in the range of doses chosen for evaluation. The results obtained using the BA058 Microneedle Patch will be referenced to those of BA058 Injection at a dose of 80 µg.

***Preclinical Pharmacology of BA058***

In pharmacology studies conducted with BA058, the following has been shown:

BA058 is a potent selective agonist of the human PTHR 1 receptor;

In models of calcium mobilization, BA058 has significantly less calcium mobilizing activity at higher doses than the native hPTHrP(1-34), and less activity than hPTH(1-34);

BA058 Injection stimulates the formation of normal, well-organized bone and restores BMD in ovariectomized, osteopenic rats and primates. Additionally, mechanical testing of bones from ovariectomized rats after treatment with BA058 revealed a significant increase in femur and vertebral bone strength. BA058 exhibited the majority of its effects through the growth of trabecular bone without compromising cortical bone. Similar studies in rats with BA058 Microneedle Patch show comparable restoration of bone;

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BA058 Injection was well tolerated over a wide range of doses in two species, rats and primates, for up to 6 months and 9 months, respectively;

Safety pharmacology studies demonstrated no respiratory, gastroenterologic, hematologic, renal or CNS effects. Tachycardia and hypotension were observed in dogs following both intravenous and subcutaneous administration, however such effects were not observed in other species;

The No Observed Adverse Effect Level was 15, 25 and 25 μg/kg/day in rats in the 4-, 13 and 26-week studies, respectively, and 100, 50 and < 10 μg/kg/day in monkeys in the 4-, 13- and 39-week studies;

Repeat SC dose studies in both rats and cynomolgus monkeys at doses up to 300 and 450 μg/kg/day, respectively, revealed a relatively fast absorption (Tmax from 0.083 to 1.0 hr); peak serum concentration and Area under the Curve, a measure of drug exposure, increased as the dose increased.

These preclinical studies suggest that compared to hPTH(1-34), BA058 Injection can potentially be used to restore lost BMD with a reduced risk of hypercalcemia and loss of cortical bone.

***Planned and Active Preclinical Safety Studies for BA058***

A two-year subcutaneous injection carcinogenicity study of BA058 in Fischer 344 albino rats is currently on-going and will assess the carcinogenic potential of BA058. The study is being conducted according to the provisions set forth in Guidance ICH-S1A, ICH-S1B, and ICH-S1C(R2), and the design was accepted by FDA on 15 July 2009. This study will evaluate 3 BA058 dose levels, and the doses were selected based upon findings and tolerance in completed long-term rat toxicology studies and the anticipated tolerance over a 2-year dosing period and, furthermore, represents a good exposure multiple over maximum clinical doses. An active comparator arm is also included; a cohort of rats will be dosed with hPTH (1-34), because it is anticipated that osteosarcoma will be observed over time. The active comparator will allow confirmation of the sensitivity of the model. This study will be conducted in parallel to the Phase 3 clinical program.

Two preclinical bone quality studies will also be conducted, one in female rats who have had their ovaries removed, referred to as ovariectomized, or OVX, rats for up to 12 months of daily BA058 subcutaneous injection, the second study in adult OVX monkeys for up to 18 months. The primary objective of these studies is to demonstrate that long-term treatment with BA058 Injection will not lead to deleterious effects on bone quality by determining BA058's effect on the mass, architecture and strength of bones. These studies will be conducted in parallel to the Phase 3 clinical program and, in both studies, BA058 will be compared to placebo. The 12-month rat study is being performed in OVX skeletally mature Sprague-Dawley rats, an appropriate species for osteoporosis studies as a result of the cancellous bone changes and bone strength changes similarly noted in humans. In this study, a 13-week bone depletion period will occur after ovariectomy/sham surgery and prior to initiation of daily SC injection dosing with vehicle or three different dose levels of BA058.

The 16-month nonhuman primate study is being performed in OVX monkeys, a larger remodeling species whose bone depletion can be induced by estrogen deficiency, as in human menopause. In this study, an approximate 9-month bone depletion period will occur after OVX/sham surgery and prior to initiation of daily SC injection dosing with vehicle or three dose levels of BA058. The specific objectives and measured outcomes of both studies are to investigate the potential safety and efficacy of BA058 on prevention of bone loss. Retention of bone mass, both cortical bone  dominant in long bones, and cancellous bone  dominant in spinal bone, will be assess by BMD. Preservation of cortical and cancellous bone on strength will be determined by biomechanical testing. The mechanisms by which BA058 affects bone will be assessed by evaluation of biomarkers of bone turnover and

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histomorphometric indices of bone turnover. Pharmacokinetics of BA058 and development of antidrug antibodies will also be evaluated.

***Manufacturing of BA058***

BA058 API is manufactured on a contract basis by Lonza, under Good Manufacturing Practices conditions using a solid phase peptide synthesis assembly process, and purification by high pressure liquid chromatography. BA058 Injection is supplied as a liquid in a multi-dose cartridge for use in a pen delivery device. The multi-dose cartridges are manufactured by Vetter. The BA058 Microneedle Patch is manufactured by 3M based on their patented microneedle technology to administer drugs through the skin, as an alternative to subcutaneous injection.

***Patents relating to BA058***

Composition of matter of BA058 is claimed in issued patents in the United States (US 5,969,095), Europe, Australia, Canada, China, Hong Kong, Israel, South Korea, New Zealand, Poland, Russia, Singapore and Taiwan. These cases have a normal patent expiration date of 2016 absent the possibility of patent term extension. The phase 3 clinical dosage of BA058 by the subcutaneous route for use in treating osteoporosis is covered by US 7,803,770 until 2027 in the United States (absent extensions) and a related case is currently pending in Europe, China, Australia, Canada, Japan, Brazil, Mexico, Singapore, South Korea, India, Israel, New Zealand, Norway, Russia and Ukraine. A priority patent application covering various aspects of the BA058 for microneedle patch application has been filed in 2011 in the United States (US app. # 61/478,466). Any claims that might issue from app. # 61/478,466 will have a normal expiry date no earlier than 2031.

***Competition for BA058***

The development and commercialization of new products to treat osteoporosis and women's health is highly competitive, and there will be considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have substantially more resources than we do, including both financial and technical. In addition, many of these companies have longer operating histories and more experience than us in preclinical and clinical development, manufacturing, regulatory, and global commercialization. ***See, "Risk Factors  If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer" above.*** Competition for highly qualified employees is intense.

Potential competitors with BA058 include, but are not limited to, Amgen, Merck & Co., Novartis, Lilly and Zosano. Lilly launched Forteo® in December 2002 as the first-to-market anabolic or bone-building agent for the treatment of osteoporosis. Lilly has also announced that it is investigating a transdermal method of delivery of Forteo®. Zosano is also developing a transdermal form of rhPTH(1-34) that would compete with the BA058 Microneedle Patch. We have no products approved for sale and therefore have no share of any therapeutic markets in which we hope to introduce BA058.

***Clinical Development Program for RAD1901***

In June 2006, we exclusively licensed the worldwide rights (except Japan) to RAD1901 from Eisai. In particular, we have licensed US Patent No. 7,612,114 (effective filing date 12/25/2003, statutory term extended to 8/18/26 with 967 days of patent term adjustment due to delays by USPTO). RAD1901 is a selective estrogen receptor modulator, or SERM, being developed by us in an oral formulation as a treatment for vasomotor symptoms commonly known as hot flashes.

***Background on Vasomotor Symptoms***

Hot flashes and night sweats are a common symptom during menopause, with up to 85% of women experiencing them during the menopause transition, for a median duration of four years. In

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2008, more than 11.5 million women in the United States were in the 45 to 49 age range to enter menopause. In addition, most women receiving systemic therapy for breast cancer suffer hot flashes, often with more severe or prolonged symptoms than women experiencing menopause. These symptoms can disrupt sleep and interfere with quality of life. An estimated two million women undergo menopause every year in the U.S., with a total population of 50 million postmenopausal women.

Historically, hormone replacement therapy, or HRT, with estrogen and/or progesterone was considered the most efficacious approach to relieving menopausal symptoms such as hot flashes. However, data from the Women's Health Initiative, or WHI, identified increased risks for malignancy and cardiovascular disease associated with estrogen therapy. Sales of HRT declined substantially after the release of the initial WHI data but HRT remains the current standard of care for many women suffering from hot flashes; however, due to concerns about the potential long-term risks and contraindications associated with HRT, we believe that there is a significant need for new therapeutic options to treat vasomotor symptoms. Pfizer's Premarin family remains the market leader for drugs to manage menopausal symptoms with 2010 worldwide sales of $1 billion.

***Pharmacologic Characteristics of RAD1901***

RAD1901 has been shown to bind to the estrogen receptor alpha, or ERα, and to have both estrogen-like and estrogen antagonist effects in different tissues. RAD1901 has also been shown to have both estrogen-like behavioral effects in animals and to reduce vasomotor signs in an animal model of menopausal hot flashes. In bone, RAD1901 protects against castration-induced bone loss while showing no unwanted stimulation of the endometrium. In cell culture, RAD1901 does not stimulate replication of breast cancer cells and antagonizes the stimulating effects of estrogen. Overall, therefore, RAD1901 exhibits a number of properties that would make it a suitable drug candidate for the management of menopausal symptoms, in particular the treatment of vasomotor symptoms.

***Phase 1***

A Phase 1 safety, pharmacokinetic and bioavailability study was conducted in 80 healthy postmenopausal women over a range of doses of RAD1901, including placebo. After single dosing with RAD1901 by mouth, the mean half-life ranged between 27.4 and 32.5 h. Bioavailability was determined to be approximately 10%. Food effect was also investigated and the presence of food was determined to increase absorption and delay clearance of RAD1901.

RAD1901 was generally well tolerated. All TEAEs were of mild intensity, with some increase in frequency at the higher doses in the multiple dose group, most commonly gastrointestinal symptoms and headache. There were no serious adverse events observed.

***Phase 2***

A Phase 2 proof of concept study was conducted in 100 healthy postmenopausal women using 4 doses of RAD1901 (10, 25, 50 and 100 mg) and placebo. The primary study outcome was reduction in the frequency and severity of moderate and severe hot flashes. While a classic dose-response effect was not demonstrated, efficacy was determined to occur at the 10 mg dose level which achieved a statistically significant reduction in the frequency of moderate and severe hot flashes both by linear trend test and by comparison to placebo and in overall (mild-moderate-severe) hot flashes at either the 2-, 3- or 4-week time-points. A similar reduction in composite score (frequency × severity) was identified at all time-points, with a statistically significant difference from placebo achieved at the 2-, 3- or 4-week time-points. Numerical reductions in mean severity and mean daily severity were observed, but did not reach statistical significance.

No serious adverse events were reported during the course of the study. Overall, 69% of patients had an adverse event, generally mild or moderate in severity, with some evidence of dose dependency, and events were most commonly gastrointestinal symptoms and headache. Three severe adverse events

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occurred, one in a placebo patient, and were not considered treatment related. Two patients discontinued treatment due to an adverse event, neither in relation to the 10 mg dose.

As discussed elsewhere in this prospectus, the FDA approval process is lengthy and expensive. Our current strategy is to collaborate with third parties for the further development and commercialization of RAD1901 so the date of FDA approved of RAD1901 cannot be predicted at this time. As a result of the uncertainties around the completion of a partnership arrangement for RAD1901 with third parties, we are unable to determine the duration and costs to complete current or future clinical stages of our RAD1901 product candidate or when, or to what extent, we will generate revenues from the commercialization and sale of RAD 1901. From January 1, 2009 through June 30, 2011, we have incurred $4.9 million in research and development costs related to RAD1901. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for RAD1901 could significantly increase our need to raise additional working capital funds and materially adversely affect our product development efforts and our business overall. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. If we do not succeed in timely raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of any product candidates, including RAD1901 from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders.

***Manufacturing of RAD1901***

RAD1901 API is manufactured for Radius on a contract basis by Irix Pharmaceuticals, Inc. The present GMP manufacture of RAD1901 comprises 9 synthetic steps from a non-GMP starting material. The current process of manufacture requires no chromatographic separations. RAD1901 is a chiral material present as essentially one enantiomer.

***Patents related to RAD1901***

RAD1901 as a composition of matter is covered by US patent 7,612,114 (normal expiry 2026 absent Hatch-Waxman extensions). A corresponding case has also been issued in Australia with related cases pending in Canada, India and Europe. A patent application covering methods of using RAD1901 for the treatment of hot flush has been filed in the US (published as US 2010/0105733A1), Europe and Canada and any claims issuing will have a normal expiry of 2027. In addition, a provisional dosage form application has been filed in the United States (US app# 61/334,095) and any claims that might issue from applications claiming priority to US app# 61/334,095 will have a normal expiry date no earlier than 2031.

***Competition for RAD1901***

The development and commercialization of new products to treat women's health is highly competitive, and there will be considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have substantially more resources than we do, including both financial and technical. In addition, many of these companies have longer operating histories and more experience than us in preclinical and clinical development, manufacturing, regulatory and global commercialization. See, "Risk Factors  If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business may suffer" above.

Potential competitors to Radius in relation to RAD1901 include, but are not limited to, Pfizer (NDA under review) and Depomed (Phase 3) who both have agents in more advanced stages of development than RAD1901. We believe that RAD1901 will be able to compete with other agents for

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the treatment of hot flashes because we expect it to have a similar efficacy and better safety profile than estrogen products, as well as a better efficacy and safety profile than non-estrogen products. We have no products approved for sale and therefore have no share of any therapeutic markets in which we hope to introduce RAD1901.

***RAD140***

***Pharmacologic Characteristics of RAD140***

RAD140 is a nonsteroidal, selective androgen receptor modulator that resulted from an internal drug discovery program that began in 2005. RAD140 has demonstrated potent anabolic activity on muscle and bone in preclinical studies and has completed 28-day preclinical toxicology studies in both rats and monkeys. Because of its high anabolic efficacy, receptor selectivity, potent oral activity and long duration half life, it is believed that RAD140 has clinical potential in a number of indications where the increase in lean muscle mass and/or bone density is beneficial such as treating the weight loss due to cancer cachexia, muscle frailty and osteoporosis.

As discussed elsewhere in this prospectus, the FDA approval process is lengthy and expensive. Our current strategy is to collaborate with third parties for the further development and commercialization of RAD140 so the date of FDA approval of RAD140 cannot be predicted at this time. As a result of the uncertainties around the completion of a partnership arrangement for RAD140 with third parties, we are unable to determine the duration and costs to complete current or future clinical stages of our RAD140 product candidate or when, or to what extent, we will generate revenues from the commercialization and sale of RAD140. From January 1, 2009 through June 30, 2011, we have incurred $2.6 million in research and development costs related to RAD140. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for RAD140 could significantly increase our need to raise additional working capital funds and materially adversely affect our product development efforts and our business overall. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. If we do not succeed in timely raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of any product candidates, including RAD140 from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders.

***Patents related to RAD140***

RAD140 as a composition of matter and methods of using RAD140 is covered by pending patent applications in the US (e.g. US app#12/378,812)) and numerous additional countries worldwide. Any patents issued from these filings will have a normal expiry of 2029 absent any extensions.

***Competition for RAD140***

The development and commercialization of new products to treat women's health is highly competitive, and there will be considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have substantially more resources than we do, including both financial and technical. In addition, many of these companies have longer operating histories and more experience than us in preclinical and clinical development, manufacturing, regulatory and global commercialization. See, "Risk Factors  If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business may suffer" above.

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Potential competitors to Radius in relation to RAD140 include, but are not limited to, GTx (Phase 3) and Ligand (Phase 1/2) who both have agents in more advanced stages of development than RAD140. We believe that RAD140 will be able to compete with other SARM agents because we expect it to have high potency to increase muscle and bone with a strong safety profile. We have no products approved for sale and therefore have no share of any therapeutic markets in which we hope to introduce RAD140.

**Collaborations and License Agreements**

***Nordic Bioscience***

We entered into a Letter of Intent with Nordic on September 3, 2010, pursuant to which we funded preparatory work by Nordic in respect of a Phase 3 clinical study of BA058 Injection. The Letter of Intent was extended on December 15, 2010 and on January 31, 2011. Pursuant to the Letter of Intent and the two extensions, we funded an aggregate $1,500,000 of preparatory work by Nordic during 2010 and funded and additional $750,000 of preparatory work by Nordic during 2011. On March 29, 2011, we entered into a Clinical Trial Services Agreement (which superseded and subsumed the Letter of Intent and its two extensions), a Work Statement NB-1 under such Clinical Trial Services Agreement and a related Stock Issuance Agreement with Nordic. Pursuant to Work Statement NB-1, Nordic is managing the Phase 3 clinical study of BA058 Injection and the Company is required to make various payments denominated in both euros and U.S dollars over the course of the Phase 3 study of total €33.9 million and $4.9 million. Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase the equivalent of €371,864 of our Series A-5 Convertible Preferred Stock at a price per share equal to $8.142. Nordic purchased 64,430 shares of Series A-5 Convertible Preferred Stock on May 17, 2011 for proceeds of $525,154 to the Company. The Stock Issuance Agreement provides that Nordic will receive additional shares of equity, having an aggregate value of up to €36.8 million, which shall initially be in the form of shares of Series A-6 Convertible Preferred Stock, at certain times during the performance of the Phase 3 clinical study that is the subject of Work Statement NB-1.

The Clinical Trial Services Agreement has a 5-year term unless it is sooner terminated. The Clinical Trial Services Agreement or any Work Statement may be terminated by mutual agreement of the parties at any time. Either party may also terminate any Work Statement upon a material breach by the other party with respect to such Work Statement unless such other party cures the alleged breach within the notice period specified in the Clinical Trial Services Agreement or if not capable of being cured within such period the party alleged to be in breach commences efforts to cure and makes diligently proceeds to cure. Termination of any Work Statement does not result in termination of the Clinical Services Agreement or any other Work Statements, which remain in force until terminated. Either party may also terminate a Work Statement if force majeure conditions have prevented performance by the other party for more than a specified period of time. We may also terminate a Work Statement with notice to Nordic if authorization and approval to perform any clinical study that is the subject of such Work Statement is withdrawn by the FDA or other relevant health authorities or human or toxicological test results support termination of the clinical study relating to such Work Statement for reasons of safety or if the emergence of any adverse event or side effect in the clinical study relating to such Work Statement is of such magnitude or incidence in our opinion as to support termination. The Clinical Trial Services Agreement contains customary risk allocation clauses with each party indemnifying the other in respect of third party claims arising out of or resulting from: (i) the negligence or intentional misconduct of such party, its employees, agents or representatives in performing its obligations under the Clinical Services Agreement or any Work Statement; and (ii) any breach by such party of its representations and warranties under the Clinical Trial Services Agreement. We have agreed to indemnify Nordic in respect of third party claims for product liability or personal injury arising from or relating to our products or our use of any deliverables. In addition, we separately provide indemnification to the investigative sites performing services pursuant to Work Statement NB-1

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in respect of third party claims of injury, illness or adverse side effects to a patient in the study that is the subject of Work Statement NB-1 that are attributable to the Radius study drug under indemnification letters with such investigative sites. The Clinical Services Agreement contains other customary clauses and terms as are common in similar agreements in the industry.

***3M***

In December 2008, we entered into a Feasibility Agreement with 3M whereby 3M assessed the feasibility of developing a BA058 microneedle patch product and supplying the product for preclinical studies in an animal model. Upon completion of the feasibility study, during June 2009, we entered into a Development and Clinical Supplies Agreement with 3M under which 3M is responsible to develop a BA058 microneedle patch product and manufacture clinical and toxicology supplies of such patch product for preclinical, Phase 1 and Phase 2 studies on an exclusive basis. We pay 3M for services delivered pursuant to the Development and Clinical Supplies Agreement on a fee for service or a fee for deliverable basis as specified in the Development and Clinical Supplies Agreement. The Feasibility Agreement expired on or around September 2009. We have paid 3M approximately $4,003,000 in respect of services and deliverables delivered pursuant to the Feasibility Agreement and the Development and Clinical Supplies Agreement.

The Development and Clinical Supplies Agreement remains in effect until the completion of the workplan that the parties are performing thereunder, unless it is sooner terminated. Either party may terminate the Development and Clinical Supplies Agreement upon a material breach by the other party unless such other party cures the alleged breach within the notice period specified in the Development and Clinical Supplies Agreement. We are permitted to terminate the Development and Clinical Supplies Agreement without cause by delivering notice to 3M a specified period before the termination date. We are also permitted to terminate within a specified period of time following a specified date with notice to 3M in the event that we have determined that the Phase 1 clinical study for the BA058 microneedle patch product needs to be repeated or that additional clinical data is required with respect thereto in order to initiate the Phase 2 clinical study for the BA058 microneedle patch product. The Development and Clinical Supplies Agreement contains customary risk allocation clauses with 3M indemnifying us in respect of third party claims arising from any personal injury to the extent that such claim results from 3M's breach of warranty with respect to the BA058 Microneedle Patch meeting applicable specifications; and us indemnifying 3M in respect of third party claims arising with from our or our agent's use, testing or clinical studies of the BA058 Microneedle Patch. The Development and Clinical Supplies Agreement contains other customary clauses and terms as are common in similar agreements in the industry.

***Ipsen Pharma***

In September 2005, we entered into a License Agreement with Ipsen under which we exclusively licensed certain Ipsen compound technology and related patents covering BA058 to research, develop, manufacture and commercialize certain compounds and related products in all countries, except Japan (where we do not hold commercialization rights) and France (where our commercialization rights are subject to certain co-marketing and co-promotion rights retained by Ipsen). Ipsen also granted us 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 us an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling us to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan (where we do not hold commercialization rights) and France (where our 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 reve