Radius Health, Inc.
Form 8-K/A
October 28, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K/A

(Amendment No. 4)

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **May 17, 2011**

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-53173**	**80-0145732**
(State of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

201 Broadway, 6th Floor

Cambridge, MA 02139

(Address of principal executive offices) (Zip Code)

(617) 551-4700

(Registrant s telephone number, including area code)

MPM ACQUISITION CORP.

c/o MPM Asset Management LLC, 200 Clarendon Street, 54th Floor, Boston, MA 02116

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

The disclosures set forth under Item 2.01 hereof are hereby incorporated by reference in this Item 1.01.

Item 2.01. Completion of Acquisition or Disposition of Assets.

Pursuant to an Agreement and Plan of Merger dated April 25, 2011 (the **Merger Agreement**), by and among MPM Acquisition Corp. (referred to herein as the **Company**, **Radius** or the **Registrant**), RHI Merger Corp., a Delaware corporation and wholly owned subsidiary of the Company (**MergerCo**), and Radius Health, Inc., a Delaware corporation (**Target**), MergerCo merged with and into Target, with Target remaining as the surviving entity and a wholly-owned operating subsidiary of the Company. This transaction is referred to throughout this report as the Merger. The Merger was effective as of May 17, 2011, upon the filing of a certificate of merger with the Delaware Secretary of State.

At the effective time of the Merger (the Effective Time), the legal existence of MergerCo ceased and all of the shares of Target s common stock, par value $.01 per share (the **Target Common Stock**), and shares of Target s preferred stock, par value $.01 per share (the **Target Preferred Stock**), that were outstanding immediately prior to the Merger were cancelled and each outstanding share of Target Common Stock outstanding immediately prior to the Effective Time was automatically converted into the right to receive one share of the Company s Common Stock and each outstanding share of Target Preferred Stock outstanding immediately prior to the Effective Time was automatically converted into the right to receive one-tenth of one share of the Company s Preferred Stock from the Company as consideration for the Merger. More specifically, each share of Series A-1 Convertible Preferred Stock of Target outstanding immediately prior to the Effective Time was converted into the right to receive 0.1 shares of Series A-1 Convertible Preferred stock of the Company; each share of Series A-2 Convertible Preferred Stock of Target outstanding immediately prior to the Effective Time was converted into the right to receive 0.1 shares of Series A-2 Convertible Preferred stock of the Company; each share of Series A-3 Convertible Preferred Stock of Target outstanding immediately prior to the Effective Time was converted into the right to receive 0.1 shares of Series A-3 Convertible Preferred stock of the Company; each share of Series A-4 Convertible Preferred Stock of Target outstanding immediately prior to the Effective Time was converted into the right to receive 0.1 shares of Series A-4 Convertible Preferred stock of the Company; each share of Series A-5 Convertible Preferred Stock of Target outstanding immediately prior to the Effective Time was converted into the right to receive 0.1 shares of Series A-5 Convertible Preferred stock of the Company; and each share of Series A-6 Convertible Preferred Stock of Target outstanding immediately prior to the Effective Time was converted into the right to receive 0.1 shares of Series A-6 Convertible Preferred stock of the Company. The Company assumed all options and warrants of Target outstanding immediately prior to the Effective Time, which shall become exercisable for shares of the Company s Common Stock or Preferred Stock, as the case may be. See the description of the material terms of the options and warrants assumed in the merger in sections herein entitled 2003 Long-Term Incentive Plan and Description of Securities Stock Purchase Warrants, respectively. Target and the Company agreed to indemnify each of their officers and directors for their actions relating to the consideration, approval or consummation of the Merger Agreement, in accordance with an indemnity agreement (the **Indemnity Agreement**) entered into by and between Target, the Company and their respective officers before the closing of the merger. The Company s entry into the Merger Agreement was disclosed on the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 29, 2011, which is hereby incorporated by reference, including the copy of the Merger Agreement filed as Exhibit 10.1 thereto.

Contemporaneously with the closing of the Merger, pursuant to the terms of a Redemption Agreement dated April 25, 2011 by and among the Company and its then-current sole stockholder, the Company completed the repurchase of 5,000,000 shares of Common Stock (the **Redemption**) from its former sole stockholder, MPM Asset Management LLC, in consideration of an aggregate of $50,000 plus reimbursement of certain costs for prior audit and legal fees, SEC filing fees, taxes and postage in the aggregate amount of $110,724.81. The 5,000,000 shares constituted all of the issued and outstanding shares of the Company s capital stock, on a fully-diluted basis, immediately prior to the Merger. The Company s entry into the Redemption Agreement was disclosed on the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 29, 2011, which is hereby incorporated by reference, including the copy of the Redemption Agreement filed as Exhibit 10.2 thereto. Also in connection with the Merger, the Company entered into Indemnification Agreements with each member of its board of directors, copies of which are filed here with as Exhibits 10.52 to and including Exhibit 10.62.

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Upon completion of the Merger and the Redemption, the former stockholders of Target held 100% of the outstanding shares of capital stock of the Company. Accordingly, the Merger represents a change in control of the Company. As of the date of this report, there are 555,594 shares of our Common Stock and 1,549,130 shares of our Preferred Stock outstanding.

Pursuant to the Merger, we assumed all of the Target s obligations under its existing contracts, including those filed herewith as material contracts. In particular, we have assumed the rights and obligations of Target 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, we are obligated to issue and sell to the Investors up to an aggregate of 789,553 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 Closing at the Stage II Closing and 263,180 shares of our Series A-1 Convertible 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. A copy of the Purchase Agreement is attached hereto as Exhibit 10.26, and is incorporated herein by reference.

As a final step in the reverse merger process, we completed a Short-Form Merger with the Target and changed our name to Radius Health, Inc. as the surviving entity of the Short-Form Merger.

The Merger will be accounted for as a capital transaction. Upon effectiveness of the Merger, Target s business plan became our business plan.

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.

Following the Merger on May 17, 2011, our Board of Directors approved a transaction pursuant to which Target merged with and into the Company, leaving the Company as the surviving corporation (the Short-Form Merger). In connection with the Short-Form Merger, the Company relinquished its corporate name and assumed in its place the name Radius Health, Inc. The Short-Form and name change became effective on May 17, 2011, upon the filing of a Certificate of Ownership an Merger with the Delaware Secretary of State. Our certificate of incorporation, The Certificate of Ownership and Merger is filed as Exhibit 3.2 hereto.

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. Pursunt 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 the Company s 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.

DESCRIPTION OF THE BUSINESS OF RADIUS HEALTH, INC.

EXPLANATORY NOTE: *Unless otherwise provided in this current report, all references in the balance of this current report 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

Radius is 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 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 by using a microneedle technology from 3M Drug Delivery Systems (3M). The 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 the 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.

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 National Osteoporosis Foundation (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 more than 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 Co (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 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.

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.

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 other 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 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 Form 8-K 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 March 30, 2011, we have incurred $11.3 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 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 March 30, 2011, we have incurred $5.3 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 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 a 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, 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 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 arm provides 90% power at a two-sided alpha to detect 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.

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 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 ($p = 0.055$).

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

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 Forte