

Radius Health, Inc.  
Form S-1/A  
June 02, 2014

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As filed with the Securities and Exchange Commission on June 2, 2014

Registration No. 333-194150

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**AMENDMENT NO. 5  
TO**

**FORM S-1**

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

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**Radius Health, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**2834**

(Primary Standard Industrial  
Classification Code Number)

**80-0145732**

(I.R.S. Employer  
Identification Number)

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

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

**Robert E. Ward  
Chief Executive Officer  
Radius Health, Inc.  
201 Broadway, 6th Floor  
Cambridge, Massachusetts 02139  
(617) 551-4700**

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

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**Approximate date of commencement of proposed sale to the public:  
As soon as practicable after this Registration Statement becomes effective.**

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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 1933, check the following box.

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.

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.

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.

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. (Check one):

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(Do not check if a smaller reporting company)

**CALCULATION OF REGISTRATION FEE**

<b>Title of Each Class of Securities To Be Registered</b>	<b>Proposed Maximum Aggregate Offering Price(1)</b>	<b>Amount of Registration Fee(2)(3)</b>
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Common Stock, \$0.0001 par value per share	\$59,800,000	\$7,703
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- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of additional shares that the underwriters have the option to purchase.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.
- (3) A registration fee of \$11,850 was previously paid.

**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 Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this preliminary 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 jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED, JUNE 2, 2014

**PRELIMINARY PROSPECTUS**

**6,500,000 Shares**

**Radius Health, Inc.**

**Common Stock**

We are offering 6,500,000 shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. We expect the initial public offering price to be \$8.00 per share. We have applied to list our common stock on the NASDAQ Global Market under the symbol "RDUS."

**Investing in our common stock involves a high degree of risk. Please read "Risk factors" beginning on page 13 of this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission nor any other regulatory body has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

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	<b>PER SHARE</b>	<b>TOTAL</b>
Public Offering Price	\$	\$
Underwriting Discounts and Commissions <sup>(1)</sup>	\$	\$
Proceeds to Radius Health, Inc. (Before Expenses)	\$	\$

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(1) The underwriters will also be reimbursed for certain expenses incurred in this offering. See "Underwriting" for details.

Delivery of the shares of common stock is expected to be made on or about \_\_\_\_\_, 2014. We have granted the underwriters an option for a period of 30 days to purchase an additional 975,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ \_\_\_\_\_, and the total proceeds to us, before expenses, will be \$ \_\_\_\_\_.

Certain of our existing stockholders or their affiliates, including BB Biotech AG, Brookside Capital Partners Fund, L.P., F2 Ventures and The Wellcome Trust, have indicated an interest in purchasing an aggregate of up to \$25 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these stockholders may determine to purchase fewer shares than they indicate an interest in purchasing or may determine not to purchase any shares in this offering. It is also possible that these stockholders could indicate an interest in purchasing more shares of our common stock. In addition, the underwriters could determine to sell fewer shares to any of these stockholders than the stockholders indicate an interest in purchasing or could determine not to sell any shares to these stockholders.

*Joint Book-Running Managers*

**Jefferies**

*Co-Lead Manager*

**Canaccord Genuity**

**Cowen and Company**

*Co-Manager*

**Cantor Fitzgerald & Co.**

Prospectus dated \_\_\_\_\_, 2014

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus. We do not, and the underwriters do not, take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus outside of the United States.

In this prospectus, references to "dollar" or "\$" are to the legal currency of the United States, and references to "euro" or "€" are to the single currency introduced on January 1, 1999 at the start of the third stage of European Economic and Monetary Union, pursuant to the Treaty establishing the European Communities, as amended by the Treaty on European Union and the Treaty of Amsterdam. Unless otherwise indicated, the financial information in this prospectus has been expressed in U.S. dollars. Unless otherwise stated, the U.S. dollar equivalent information translating euros into U.S. dollars has been made, for convenience purposes, on the basis of the noon buying rate published by the Board of Governors of the Federal Reserve as of March 31, 2014, which was €1.00 = \$1.3777. Such translations should not be construed as a representation that the euro has been, could have been or could be converted into U.S. dollars at the rate indicated, any particular rate or at all.

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**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. Investing in our common stock involves a high degree of risk. You should carefully read this entire prospectus, including our financial statements and the related notes included in this prospectus and the information set forth under the headings "Risk factors" and "Management's discussion and analysis of financial condition and results of operations."*

*Unless the context requires otherwise, the terms "Radius," "Company," "we," "us" and "our" refer to Radius Health, Inc.*

**OUR BUSINESS**

We are a science-driven biopharmaceutical company focused on developing novel differentiated therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases. Our lead product candidate is abaloparatide (BA058), a bone anabolic for the treatment of osteoporosis delivered via subcutaneous injection, which we refer to as Abaloparatide-SC. We are currently in Phase 3 development of Abaloparatide-SC and expect to announce top-line data from this study in late 2014. If the results are positive, we plan to submit a new drug application, or NDA, in the United States, and a marketing authorization application, or MAA, in Europe, in mid-2015. We hold worldwide commercialization rights to Abaloparatide-SC, other than in Japan, and with a favorable regulatory outcome, we anticipate our first commercial sales of Abaloparatide-SC will take place in 2016. We are leveraging our investment in Abaloparatide-SC to develop Abaloparatide-TD. We expect this line extension will provide improved patient convenience by enabling administration of abaloparatide through a short-wear-time transdermal patch. We have recently completed a successful Phase 2 proof of concept study of Abaloparatide-TD.

Our current clinical product portfolio also includes a novel oral agent, RAD1901, a selective estrogen receptor down-regulator/degrader, or SERD. We are developing RAD1901 at higher doses, for the treatment of breast cancer brain metastases, or BCBM, and intend to advance its development with the initiation of two Phase 1 clinical trials – a maximum tolerated dose study that has commenced patient screening, and a Phase 1b clinical trial in BCBM, which is expected to commence in late-2014. At low doses, RAD1901 acts as a selective estrogen-receptor modulator, or SERM. Low-dose RAD1901 has shown efficacy for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study.

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**OUR PRODUCT CANDIDATES**

The following table identifies the product candidates in our current product portfolio, their proposed indication and stage of development:

***Abaloparatide***

Abaloparatide is a novel synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a bone anabolic treatment for osteoporosis. Osteoporosis is a disease that affects nearly 10 million people in the United States, with an additional approximately 43 million people at increased risk for the disease. It is characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. Anabolic agents, like Forteo (teriparatide), are used to increase bone mineral density, or BMD, and to reduce the risk of fracture. We believe abaloparatide has the potential to increase BMD and bone quality to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis. Based upon various published studies, including studies published by Marc C. Hochberg, MD, MPH (2002) and John A. Kanis (2014), we believe that increases in BMD are predictive of reduction in fracture risk. We are developing two formulations of abaloparatide:

*Abaloparatide-SC* is an injectable subcutaneous formulation of abaloparatide. In August 2009, we announced positive Phase 2 data that showed Abaloparatide-SC produced faster and greater BMD increases at the spine and the hip with substantially less hypercalcemia than Forteo (teriparatide), which is the only approved subcutaneous injectable anabolic agent for the treatment of osteoporosis in the United States. A subsequent Phase 2 clinical trial announced in January 2014 also confirmed the results of our first clinical trial by demonstrating that Abaloparatide-SC produces BMD increases from baseline in the spine and hip that are comparable to our earlier Phase 2 clinical trial. In April 2011, we commenced a Phase 3 clinical trial of Abaloparatide-SC. Enrollment was completed in March 2013, and we expect to announce top-line data at the end of the fourth quarter of 2014. Assuming a favorable outcome, we plan to use the results from this Phase 3 clinical trial to support a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, and believe we could obtain approval of the NDA in 2016.

*Abaloparatide-TD* is a line extension of Abaloparatide SC in the form of a convenient, short-wear-time (approximately five minutes) transdermal patch. In a recent Phase 2 clinical trial, Abaloparatide-TD





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demonstrated a statistically significant mean percent increase from baseline in BMD as compared to placebo at the lumbar spine and at the hip. These results demonstrated a clear proof of concept by achieving a dose dependent increase in BMD. Following additional formulation development work, we intend to advance an optimized Abaloparatide-TD product in additional clinical studies and to a Phase 3 bridging study and to subsequently submit for approval. We hold worldwide commercialization rights to Abaloparatide-TD technology.

On May 9, 2014, we submitted a breakthrough therapy designation request to the FDA for Abaloparatide-SC for the treatment of postmenopausal osteoporosis. Abaloparatide-SC was selected for clinical development on the basis of its demonstrated marked effects on increasing bone mass in non-clinical models. The recently completed analyses of two abaloparatide Phase 2 clinical trials have confirmed these non-clinical results, demonstrating potentially important clinical benefits relative to current anabolic therapies, including faster and greater increases in hip (non-vertebral) and spine (vertebral) BMD. We believe these results could support a breakthrough therapy designation.

***RAD1901***

RAD1901 is a SERD that we believe crosses the blood-brain barrier and that we are evaluating for the treatment of BCBM. RAD1901 has been shown to bind with good selectivity to the estrogen receptor and to have both estrogen-like and estrogen-antagonistic effects in different tissues. In many cancers, hormones, like estrogen, stimulate tumor growth and a desired therapeutic goal is to block this estrogen-dependent growth while inducing apoptosis of the cancer cells. SERDs are an emerging class of endocrine therapies that directly induce estrogen receptor, or ER, degradation, enabling them to remove the estrogen growth signal in ER-dependent tumors without allowing ligand-independent resistance to develop. There is currently only one SERD, Faslodex (fulvestrant), approved for the treatment of hormone-receptor positive metastatic breast cancer; however, for patients with brain metastases (BCBM), there are no approved targeted therapies that cross the blood-brain barrier. We believe there is a significant opportunity for RAD1901 to be the first ER-targeted therapy that crosses the blood-brain barrier to more effectively treat ER-positive BCBM and potentially reduce both intracranial and extracranial BCBM tumors. We intend to commence a Phase 1 maximum tolerated dose study in healthy volunteers to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also use 18F-fluoroestradiol positron emission tomography (PET) in this study to provide a pharmacodynamic assessment of estrogen receptor turnover following RAD1901 treatment. Patient screening for this maximum tolerated dose study is currently underway. We also intend to commence a Phase 1 clinical trial in 2014 to evaluate high-dose RAD1901 for the treatment of BCBM. In March 2014, we submitted to the FDA an application for orphan-medicinal product designation of RAD1901 for the treatment of BCBM.

We are also developing RAD1901 at lower doses as a selective estrogen receptor modulator, or SERM, for the treatment of vasomotor symptoms. Historically, hormone replacement therapy, or HRT, with estrogen or progesterone was considered the most efficacious approach to relieving menopausal symptoms such as hot flashes. However, because of the concerns about the potential long-term risks and contraindications associated with HRT, we believe a significant need exists for new therapeutic treatment options to treat vasomotor symptoms. In a Phase 2 proof of concept study, RAD1901 at lower doses demonstrated a reduction in the frequency and severity of moderate and severe hot flashes. We believe RAD1901 is an attractive candidate for advancement into Phase 2b development as a treatment for vasomotor symptoms.

**OUR OPPORTUNITY**

***Osteoporosis***

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. 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. The debilitating effects of osteoporosis have substantial costs. Loss of mobility, admission to nursing homes and dependence on caregivers are all

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common consequences of osteoporosis. The prevalence of osteoporosis is growing and, according to the National Osteoporosis Foundation, or 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 and aromatase inhibitors that are increasingly used for breast cancer and the hormone therapies used for prostate cancer.

The NOF has estimated that 10 million people in the United States, composed of eight million women and two million men, already have osteoporosis, and another approximately 43 million have low bone mass placing them at increased risk for osteoporosis. In addition, the NOF has estimated that osteoporosis is responsible for more than two million fractures in the United States each year resulting in an estimated \$19 billion in costs annually. The NOF expects that the number of fractures in the United States due to osteoporosis will rise to three million by 2025, resulting in an estimated \$25.3 billion in costs each year. Worldwide, osteoporosis affects an estimated 200 million women according to the International Osteoporosis Foundation, or IOF, and causes more than 8.9 million fractures annually, which is equivalent to an osteoporotic fracture occurring approximately every three seconds. The IOF has estimated that 1.6 million hip fractures occur worldwide each year, and by 2050 this number could reach between 4.5 million and 6.3 million. The IOF estimates that in Europe alone, the annual cost of osteoporotic fractures could surpass €76 billion by 2050.

There are two main types of osteoporosis drugs currently available in the United States, anti-resorptive agents and anabolic agents. Anti-resorptive agents act to prevent further bone loss by inhibiting the breakdown of bone, whereas anabolic agents stimulate bone formation to build new, high-quality bone. According to industry sources, sales of these drugs in the United States, Japan and the five major markets in Europe exceeded \$6 billion in 2011. We believe there is a large unmet need in the market for osteoporosis treatment because existing therapies have shortcomings in efficacy, tolerability and convenience. For example, one current standard of care, bisphosphonates, an anti-resorptive agent, has been associated with infrequent but serious adverse events, such as osteonecrosis of the jaw and atypical fractures, especially of long bones. These side effects, although uncommon, have created increasing concern with physicians and patients. Many physicians are seeking alternatives to bisphosphonates. The two primary alternatives to bisphosphonates that are approved for the treatment of osteoporosis, Lilly's Forteo and Amgen's Prolia, had reported sales of approximately \$1.2 billion and \$700 million, respectively, in 2013. Forteo, a 34 amino acid recombinant peptide of human parathyroid hormone, is the only anabolic drug approved in the United States for the treatment of osteoporosis. We believe there is a significant opportunity for an anabolic agent that is able to increase BMD to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis with added advantages in convenience and safety.

*Our Solution Abaloparatide*

We believe that abaloparatide is the most advanced PTHrP analog in clinical development for the treatment of osteoporosis and that it can provide the following advantages over other current standard of care treatments for osteoporosis:

improved efficacy greater bone build at hip and spine;

faster benefit for building bone;

shorter treatment duration;

less hypercalcemia;

no additional safety risks; and

no refrigeration required in use.

*Abaloparatide-SC.* Abaloparatide-SC is an injectable, subcutaneous formulation of abaloparatide. In April 2011, we began dosing patients in a pivotal, multinational Phase 3 clinical trial designed to show that Abaloparatide-SC prevents new vertebral fracture compared to placebo. We completed enrollment in this Phase 3 clinical study in March 2013 and expect to report top-line, 18-month fracture data at the end of the fourth quarter of 2014. If the data from this Phase 3 clinical trial are positive, we plan to submit the



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NDA and the MAA for Abaloparatide-SC in mid-2015. We expect commercial launch to follow in 2016 in the United States, if and when the FDA approves the NDA for Abaloparatide-SC, and in the EU if and when an MAA for Abaloparatide-SC is approved.

*Abaloparatide-TD.* Abaloparatide-TD is a convenient, short-wear-time transdermal patch formulation of abaloparatide with Phase 2 clinical results suggesting efficacy, safety and tolerability in the treatment of osteoporosis. We currently plan to optimize Abaloparatide-TD to achieve efficacy comparable to that of Abaloparatide-SC. If Abaloparatide-SC is approved by the FDA, we believe that we will only need to conduct a single non-inferiority Phase 3 clinical trial comparing the change in lumbar spine BMD at 12 months for patients dosed with Abaloparatide-TD to patients dosed with Abaloparatide-SC to show that the effect of Abaloparatide-TD treatment is comparable to that of Abaloparatide-SC. If our clinical trials of Abaloparatide-SC and Abaloparatide-TD are successful, we expect to seek marketing approval of Abaloparatide-TD as a line extension of Abaloparatide-SC. The FDA approval of Abaloparatide-TD, and the timing of any such approval, is dependent upon the approval of Abaloparatide-SC.

***Metastatic Breast Cancer***

According to the World Health Organization, breast cancer is the second most common cancer in the world and the most prevalent cancer in women, accounting for 16% of all female cancers. The major cause of death from breast cancer is metastases, most commonly to the bone, liver, lung and brain. About 5% of patients have distant metastases at the time of diagnoses, and these patients have a 5-year survival rate of only 24%, compared with a greater than 98% survival rate for patients with only local disease. Importantly, even patients without metastases at diagnosis are at risk for developing metastases over time.

Approximately, 70% of breast cancers express the estrogen receptor, or ER, and depend on estrogen signaling for growth and survival. There are three main classes of therapies for ER-positive tumors available: aromatase inhibitors, or AIs; SERMs; and SERDs. AIs, which block the generation of estrogen, and SERMs, which selectively inhibit an ER's ability to bind estrogen, both block ER-dependent signaling but leave functional ERs present on breast cancer cells. For this reason, although these classes of drugs are effective as adjuvants for breast cancer, patients' tumors often acquire resistance to them by developing the ability to signal through the ER in a ligand-independent manner. SERDs, in contrast, are an emerging class of endocrine therapies that directly induce ER degradation. Therefore, these agents should be able to treat ER-dependent tumors without allowing ligand-independent resistance to develop, and they should also be able to act on AI- and SERM-resistant ER-positive tumors. Symptomatic BCBM occur in 10% to 16% of patients with metastatic breast cancer and are associated with particularly high morbidity and mortality. Current standard of care involves a combination of whole-brain radiotherapy, surgery or stereotactic radiosurgery, depending on the clinical context. These treatments are often only marginally effective, and are themselves associated with significant morbidity and mortality.

There is currently only one SERD approved for the treatment of ER-positive metastatic breast cancer, but there are no approved targeted therapies that cross the blood-brain barrier and can treat patients with ER-positive BCBM. We believe a significant opportunity exists for a SERD that can cross the blood-brain barrier to more effectively treat ER-positive BCBM and potentially delay or eliminate the need for radiation or surgery.

*Our Solution RAD1901*

We are developing RAD1901 as a high-dose SERD in an oral formulation in Phase 1 clinical development for the treatment of BCBM. RAD1901 has been shown to bind with good selectivity to the estrogen hormone receptor and to have both estrogen-like and estrogen-antagonist effects in different tissues. In cell culture, RAD1901 does not stimulate replication of breast cancer cells, and antagonizes the stimulating effects of estrogen on cell proliferation. Furthermore, in breast cancer cell lines a dose dependent down regulation of ER, has been observed, a process we have shown to involve proteosomal mediated degradation pathway. In a model of breast cancer in which human breast cancer cells are implanted in mice and allowed to establish tumors in response to estrogen treatment, we have shown that treatment with RAD1901 results in decreased tumor growth. Studies with RAD1901 have established the pharmacokinetic profile,

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including demonstration of good oral bioavailability and the ability of RAD1901 to cross the blood-brain barrier, with therapeutic levels detectable in the brain. We believe that RAD1901 could offer the following advantages over other current standard of care treatments for BCBM:

ability to penetrate the blood-brain barrier;

oral administration; and

treatment of hormone-resistant breast cancers.

We intend to advance the development of RAD1901 with the initiation of two Phase 1 clinical trials – a maximum tolerated dose study that has commenced patient screening, and a Phase 1b clinical trial in BCBM, which is expected to commence in late-2014.

*Vasomotor symptoms*

Vasomotor symptoms, such as hot flashes and night sweats, are common during menopause, with up to 85% of women experiencing them during the menopause transition, for a median duration of four years. In 2010, approximately 11.5 million women in the United States were in the 45 to 49 year age range upon entering 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 go through menopause every year in the United States, 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.

*Our Solution – RAD1901*

We are developing RAD1901 as a low dose SERM in an oral formulation for the treatment of vasomotor symptoms. We conducted a Phase 2 proof of concept study in 100 healthy perimenopausal women using four doses of RAD1901 – 10 mg, 25 mg, 50 mg and 100 mg – and placebo. While a classic dose-response effect was not demonstrated, at the 10 mg dose level RAD1901 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 hot flashes at either the two-, three- or four-week time-points. A similar reduction in composite score – frequency × severity of hot flashes – was identified at all time-points, with a statistically significant difference from placebo achieved at the two-, three- or four-week time-points.

We anticipate our next clinical study will be a Phase 2b study conducted in approximately 200 perimenopausal women experiencing a high frequency of hot flashes at baseline. The main study endpoints would be an assessment of the change in the frequency and severity of moderate and severe hot flashes.

**OUR STRATEGY**

Our goal is to become a leading provider of therapeutics for osteoporosis and other serious endocrine-mediated diseases. To achieve this goal we plan to:

advance the development and obtain regulatory approval of Abaloparatide-SC;

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extend the lifecycle of abaloparatide through the continued development of Abaloparatide-TD;

establish internal sales and marketing capabilities to commercialize our product candidates in the United States;

selectively pursue collaborations to commercialize our product candidates outside the United States; and

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continue to expand our product portfolio through drug discovery, in-licensing, acquisitions or partnerships.

**RECENT DEVELOPMENTS**

On May 9, 2014, we submitted a breakthrough therapy designation request to the FDA for Abaloparatide-SC for the treatment of postmenopausal osteoporosis. Abaloparatide-SC was selected for clinical development on the basis of its demonstrated marked effects on increasing bone mass in non-clinical models. The recently completed analyses of two abaloparatide Phase 2 clinical trials have confirmed these non-clinical results, suggesting potentially important clinical benefits relative to current anabolic therapies, including faster and greater increases in hip (non-vertebral) and spine (vertebral) BMD. We believe these results could support a breakthrough therapy designation.

On May 18, 2014 at the European Calcified Tissue Society Congress, we presented the preliminary results from our 16-month monkey OVX study showing significant BMD gains, together with increases in bone strength at vertebral and non-vertebral sites. In this study, ovariectomy and a 9-month bone depletion period resulted in a marked osteopenia demonstrated by decreased BMD and decreased bone strength. Daily administration of abaloparatide resulted in marked bone anabolic effects. Spine and femoral neck BMD was comparable to, or above, pre-ovariectomy levels after 4 months of treatment, with further increases at 12 months, which were sustained at 16 months. Total tibia metaphysis BMD was also increased at all doses. These BMD gains were associated with increases in bone formation markers. As expected for osteopenic animals, decreases in bone mass were associated with decreased bone strength parameters for lumbar vertebral cores and vertebral bodies in compression. Abaloparatide treatment resulted in complete reversal of ovariectomy-induced strength loss at the spine with increased yield load for the vertebral core and at the vertebral body. At an important non-vertebral site, the femoral neck, peak load shear was decreased in control animals, relative to sham, while this loss was reversed with abaloparatide treatment. This study demonstrated that abaloparatide treatment rapidly builds high-quality new bone in osteopenic monkeys, with sustained gains over time, and improved bone strength at clinically relevant sites.

On May 30, 2014, we entered into a new credit facility with Solar Capital Ltd., as collateral agent and lender, and Oxford Finance LLC, as a lender. Under the new credit facility, an initial term loan was made for an aggregate principal amount equal to \$21.0 million. In connection with the new credit facility we also issued the lenders warrants to purchase an aggregate of up to 10,258 shares of our series B-2 convertible preferred stock at an exercise price of \$61.42 per share. We used approximately \$9.3 million of the term loan to repay all the amounts owed by us under our existing credit facility with General Electric Capital Corporation and Oxford Finance LLC. For additional description of the new credit facility and the warrants, see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Financings – New Credit Facility".

**RISK FACTORS**

Investing in our common stock involves a high degree of risk. These risks are discussed more fully in the "Risk factors" section of this prospectus. In particular, these risks include:

We have a short operating history. We currently have no commercial products, and we have not received regulatory approval for, nor have we generated commercial revenue from, any of our product candidates. If we do not obtain the necessary United States or worldwide regulatory approvals to commercialize any product candidate, we will not be able to sell our product candidates.

Most of our product candidates are in early stages of clinical trials. We cannot predict with any certainty if or when we might submit a New Drug Application, or NDA, for regulatory approval for any of our product candidates or whether any such NDA will be accepted.

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.





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

Clinical trials of our product candidates may not be successful. If we are unable to obtain required marketing approvals for, commercialize, obtain and maintain patent protection for or gain sufficient market acceptance by physicians, patients and healthcare payers of our product candidates, or experience significant delays in doing so, our business will be materially harmed and our ability to generate revenue will be materially impaired.

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

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

**OUR CORPORATE INFORMATION**

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

Our executive offices are located at 201 Broadway, 6th Floor, Cambridge, MA 02139. Our telephone number is (617) 551-4700. Our website address is [www.radiuspharm.com](http://www.radiuspharm.com). The information contained in, or that can be accessed through our website is not part of, and is not incorporated into, this prospectus and should not be considered part of this prospectus.

All trademarks appearing in this prospectus are the property of their respective holders.

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**The offering**

Common stock offered by us	6,500,000 shares
Common stock to be outstanding after the offering	28,938,899 shares (or 29,913,899 shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares of common stock	We have granted the underwriters a 30-day option to purchase up to an additional 975,000 shares of our common stock.
Use of proceeds	We estimate that our net proceeds from this offering will be approximately \$46.8 million at an assumed initial public offering price of \$8.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds of this offering to fund the clinical development of our most advanced product candidates and for other general corporate purposes.
Risk factors	See "Risk factors" beginning on page 13 of this prospectus for a discussion of factors you should carefully consider before you decide to invest in our common stock.
Proposed NASDAQ Global Market symbol	RDUS
The number of shares of our common stock outstanding after this offering is based on the 22,438,899 shares of our common stock outstanding as of March 31, 2014 and excludes the following potentially dilutive shares of common stock:	

2,694,647 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$7.28 per share as of March 31, 2014;

1,555,854 shares of our common stock reserved for future issuance under our 2011 equity incentive plan as of March 31, 2014, which includes options to purchase 576,748 shares of our common stock that we have granted effective upon and subject to the effectiveness of the registration statement of which this prospectus forms a part;

78,760 shares of common stock issuable upon the exercise of outstanding warrants to purchase shares of our series B-2 convertible preferred stock and the automatic conversion of such shares in connection with this offering, at an exercise price equal to the initial public offering price in this offering, as described in more detail in the section of this prospectus entitled "Capitalization Series B-2 Convertible Preferred Stock";

1,330,995 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$14.16 per share as of March 31, 2014; and

245,784 shares of our common stock issuable to the holders of our series B, B-2, A-1, A-2 and A-3 convertible preferred stock in connection with this offering in satisfaction of dividends accruing from April 1, 2014 to May 31, 2014, plus additional shares of our common stock issuable to such holders in satisfaction of dividends accruing after May 31, 2014, as described in more detail in the section of this prospectus entitled "Capitalization Preferred Stock Dividends".

Except as otherwise indicated, all information in this prospectus reflects or assumes the following:

the automatic conversion of all outstanding shares of our convertible preferred stock at March 31, 2014 into 19,465,131 shares of our common stock in connection with this offering;

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the series B-2 convertible preferred stock will convert into shares of common stock on a 7.678-for-one basis, based upon the initial public offering price in this offering being equal to \$8.00 per share. If the initial public offering price per share in this offering is less or greater than \$8.00, then the number of shares issuable upon conversion of the series B-2 convertible preferred stock will increase or decrease, respectively. See "Capitalization Series B-2 Convertible Preferred Stock";

the issuance of 2,588,104 shares of our common stock to the holders of our series B, B-2, A-1, A-2 and A-3 convertible preferred stock in connection with this offering in satisfaction of accumulated dividends as of March 31, 2014, all of which is described in more detail in the section of this prospectus entitled "Capitalization Preferred Stock Dividends";

a one-for-2.28 reverse stock split of our common stock effected on April 24, 2014;

the effectiveness of our restated certificate of incorporation and amended and restated bylaws, which will occur concurrently with the closing of this offering;

no exercise of the outstanding options or warrants described above; and

no exercise of the underwriters' option to purchase an additional 975,000 shares of our common stock.

Certain of our existing stockholders or their affiliates, including BB Biotech AG, Brookside Capital Partners Fund, L.P., F2 Ventures, and The Wellcome Trust, have indicated an interest in purchasing an aggregate of up to \$25 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these stockholders may determine to purchase fewer shares than they indicate an interest in purchasing or may determine not to purchase any shares in this offering. It is also possible that these stockholders could indicate an interest in purchasing more shares of our common stock. In addition, the underwriters could determine to sell fewer shares to any of these stockholders than the stockholders indicate an interest in purchasing or could determine not to sell any shares to these stockholders.

Table of Contents**Summary financial data**

You should read the following summary financial data in conjunction with "Selected financial data," "Management's discussion and analysis of financial condition and results of operations" and our financial statements and related notes, all included elsewhere in this prospectus.

We derived the statements of operations data for the years ended December 31, 2013, 2012 and 2011 and the balance sheet data as of December 31, 2013 from our audited financial statements included elsewhere in this prospectus. We derived the statement of operations data for the three months ended March 31, 2014 and 2013 and the balance sheet data as of March 31, 2014 from our unaudited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future and our interim results are not necessarily indicative of our full year results.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS DATA:	YEARS ENDED DECEMBER 31,			THREE MONTHS ENDED MARCH	
	2013	2012	2011	2014	2013
	(in thousands, except share and per share amounts)			(unaudited)	
Operating expenses:					
Research and development	\$ 60,536	\$ 54,961	\$ 36,179	\$ 9,717	\$ 11,856
General and administrative	6,829	9,469	5,330	2,139	1,856
Income from operations	(67,365)	(64,430)	(41,509)	(11,856)	(11,856)
Income (expense), net	9,085	(2,095)	(236)	(2,233)	1,856
Net (expense) income, net	(2,410)	(2,603)	(731)	(399)	1,856
Loss	\$ (60,690)	\$ (69,128)	\$ (42,476)	\$ (14,488)	\$ (14,488)
Comprehensive loss, net of tax:					
Realized (loss) gain from available-for-sale securities		(5)	8		
Comprehensive loss	\$ (60,690)	\$ (69,133)	\$ (42,468)	\$ (14,488)	\$ (14,488)
Earnings attributable to common stockholders - basic and diluted	\$ (78,161)	\$ (83,120)	\$ 113	\$ (19,457)	\$ (19,457)
Earnings per share - basic	\$ (203.91)	\$ (225.71)	\$ 0.51	\$ (50.45)	\$ (50.45)
Earnings per share - diluted	\$ (203.91)	\$ (225.71)	\$ 0.06	\$ (50.45)	\$ (50.45)
Weighted average shares - basic	383,310	368,261	219,254	385,664	385,664
Weighted average shares - diluted	383,310	368,261	1,774,935	385,664	385,664
Pro forma loss attributable to common stockholders - basic and diluted(1)	\$ (60,690)			\$ (19,457)	
Pro forma loss per share - basic(1) (unaudited)	\$ (3.97)			\$ (1.00)	
Pro forma loss per share - diluted(1) (unaudited)	\$ (3.97)			\$ (1.00)	
Weighted-average common shares used in computing pro forma earnings per share (1) (unaudited)	15,277,598			19,445,393	

Weighted-average common shares used in computing pro forma earnings per share		
(1) (unaudited)	15,277,598	19,445,393

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(1)

For a description of the calculation of basic and diluted pro forma loss attributable to common stockholders and basic and diluted pro forma loss per share, see note 2 to our audited financial statements and note 2 to our unaudited financial statements, each of which are included elsewhere in this prospectus.

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BALANCE SHEET DATA:	AS OF MARCH 31, 2014		
	ACTUAL	PRO	PRO FORMA
		FORMA(1)	AS ADJUSTED(1)(2)
(unaudited, in thousands)			
Cash, cash equivalents and marketable securities	\$ 29,558	\$ 29,558	\$ 76,323
Working capital	2,275	2,275	49,040
Total assets	31,906	31,906	78,671
Total convertible preferred stock	294,032		
Total stockholders' (deficit) equity	(296,247)	(2,215)	44,550

(1)

Gives effect to:

the automatic conversion of all outstanding shares of our convertible preferred stock as of March 31, 2014, into 19,465,131 shares of our common stock in connection with this offering; and

the issuance of 2,588,104 shares of our common stock to the holders of our series B, B-2, A-1, A-2 and A-3 convertible preferred stock in connection with this offering in satisfaction of accumulated dividends as of March 31, 2014, all of which is described in more detail in the section of this prospectus entitled "Capitalization Preferred Stock Dividends."

The first bullet above assumes that the series B-2 convertible preferred stock will convert into shares of common stock on a 7.678-for-one basis, which is dependent upon the the initial public offering price in this offering being equal to \$8.00 per share. If the initial public offering price per share in this offering is less or greater than \$8.00, then the number of shares issuable upon conversion will increase or decrease, respectively. See "Capitalization Series B-2 Convertible Preferred Stock."

Does not give effect to additional borrowings of \$21.0 million under our new credit facility, entered into on May 30, 2014, or the repayment of the \$9.3 million outstanding under our credit facility with General Electric Capital Corporation and Oxford Finance LLC. See "Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Financings New Credit Facility".

(2)

Gives further effect to the issuance and sale of 6,500,000 shares of our common stock in this offering at an assumed public offering price of \$8.00 per share, which is the price set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase or decrease in the assumed public offering price of \$8.00 per share would increase or decrease each of the pro forma as adjusted cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by approximately \$6.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of one million shares in the number of shares to be offered by us would increase or decrease each of the pro forma as adjusted cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by approximately \$7.4 million, assuming that the initial public offering price is \$8.00 per share and after deducting the estimated underwriting discounts and

commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering.



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**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should carefully consider the following risk factors, together with the other information contained in this prospectus, including our financial statements and the related notes and the information set forth under the heading "Management's discussion and analysis of financial condition and results of operations." Our business results are subject to the following risks, and if any of them occur, our business, financial condition and results of operations could be materially and adversely affected. In this case, the price of our common stock could decline and you could lose all or a part of your investment.*

**RISKS RELATED TO OUR BUSINESS**

**Risks related to our financial position and need for capital**

**We currently have no product revenues and the report of our independent auditors expresses doubt about our ability to continue as a going concern. We will need to raise additional capital, which may not be available on favorable terms, if at all, in order to continue operating our business.**

To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Currently, our only product candidates are Abaloparatide-SC, Abaloparatide-TD, RAD1901 and RAD140, and none of these product candidates is approved by the FDA for sale. Therefore, for the foreseeable future, we will have to fund our operations and capital expenditures from cash on hand, borrowings, licensing fees and grants and, potentially, future offerings of our securities. We believe that our existing resources will be sufficient to fund our planned operations into the third quarter of 2014. However, our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern, which is expressed in the report of our independent auditors. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we fail to obtain additional capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities or discontinue our operations entirely, in which case you would lose your investment.

We believe that the proceeds from this offering, together with our existing resources, will be sufficient to fund our planned operations into the third quarter of 2015. We have based this estimate on assumptions that may prove to be wrong, and we could use up our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies.

**We are not currently profitable and may never become profitable.**

We have a history of net losses and expect to incur substantial losses and have negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability. We had net losses of \$14.5 million for the three months ended March 31, 2014, and \$60.7 million, \$69.1 million and \$42.5 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of March 31, 2014, we had an accumulated deficit of \$296.2 million. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

continue to undertake preclinical development and clinical trials for product candidates;

seek regulatory approvals for product candidates;

implement additional internal systems and infrastructure; and

hire additional personnel.



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We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. Accordingly, unless and until we generate revenues and become profitable, we will need to raise additional capital to continue to operate our business, including after the consummation of this offering. Our failure to achieve or maintain profitability or to raise additional capital could negatively impact the value of our securities.

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

In May 2014, we entered into our new \$30.0 million credit facility with Solar Capital Ltd., as collateral agent and lender, and Oxford Finance LLC, as lender. We drew \$21.0 million under our new credit facility on May 30, 2014, and used approximately \$9.3 million to repay our existing credit facility. Our new credit facility contains a number of covenants that impose significant operating and financial restrictions on us. These covenants limit our ability to:

dispose of our business or certain assets;

change our business, management, ownership or business locations;

incur additional debt or liens;

make certain investments or declare dividends;

acquire or merge with another entity;

enter into licensing arrangements;

engage in transactions with affiliates; or

encumber our intellectual property.

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability

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to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or we may need to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

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

continuing to undertake preclinical development and clinical trials;

participating in regulatory approval processes;

formulating and manufacturing products; and

conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing further in our securities.

**Our financial results may fluctuate from quarter to quarter, which makes our results difficult to predict and could cause our results to fall short of expectations.**

Our financial results may fluctuate as a result of a number of factors, many of which are outside of our control. For these reasons, comparing our financial results on a period-to-period basis may not be meaningful, and you should not rely on our past results as an indication of our future performance. Our revenues, if any, may fluctuate from quarter to quarter and our future quarterly and annual expenses as a percentage of our revenues may be significantly different from those we have recorded in the past or which we expect for the future. Our financial results in some quarters may fall below expectations. Any of these events as well as the various risk factors listed in this "Risk Factors" section could adversely affect our financial results and cause our stock price to fall.

**Risks related to the discovery, development and commercialization of our product candidates**

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

Abaloparatide-SC is our only product candidate in late stage clinical development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop 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 Abaloparatide-SC in the United States unless and until we receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in foreign countries. In addition, the approval of Abaloparatide-TD as a line extension to Abaloparatide-SC is dependent on the earlier approval of Abaloparatide-SC. We have not submitted an NDA to the FDA or comparable applications to regulatory authorities in other countries. Obtaining approval of an NDA is an extensive, lengthy, expensive and uncertain process, and any approval of Abaloparatide-SC may be delayed, limited or denied for many reasons, including:

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

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

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

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

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

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

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

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

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

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

In addition, the FDA may change its approval policies or adopt new regulations. For example, on February 15, 2012, we received a letter from the FDA stating that, after internal consideration, the agency believes that a minimum of 24-month fracture data are necessary for approval of new products for the treatment of postmenopausal osteoporosis. Our ongoing Abaloparatide-SC pivotal Phase 3 clinical study is designed to produce fracture data based on an 18-month primary endpoint. Based on our discussions with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from a 6-month extension of the abaloparatide 80 µg and placebo groups in our Phase 3 study, which groups will receive an approved alendronate (generic Fosamax) therapy for osteoporosis management. We plan to submit our NDA with the 24-month fracture data. We cannot be certain that the FDA will be supportive of this plan, will not change this approval policy again or will not adopt other approval policies or regulations that adversely affect any NDA that we may submit, the occurrence of any of which may further delay FDA approval.

Before we submit an NDA to the FDA for Abaloparatide-SC as a treatment for osteoporosis, we must complete our pivotal Phase 3 study based upon 18-month fracture data, a carcinogenicity study in rats, and bone quality studies in rats and monkeys. We also may need to complete several additional studies, including, but not limited to, a thorough QT Phase 1 study, a Phase 1 pharmacokinetic, or PK, study in renal patients, a Phase 1 absolute bioavailability PK study and several drug interaction studies. Not all of these studies have commenced and the results of these studies will have an important bearing on the approval of abaloparatide. In addition to fracture and bone mineral density, or BMD, our pivotal Phase 3 study will measure a number of other potential safety indicators, including blood calcium levels, orthostatic hypotension, nausea, dizziness and anti-abaloparatide antibodies, which may have an important bearing on the approval of abaloparatide.

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

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

delay commercialization of, and our ability to derive product revenues from, our product candidates;

impose costly procedures on us; and

diminish any competitive advantages that we may otherwise enjoy.

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

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

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

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

changes in government regulation, administrative action or changes in FDA policy with respect to clinical trials that change the requirements for approval;

unforeseen safety issues;

determination of dosing issues;

lack of effectiveness during clinical trials;

slower than expected rates of patient recruitment and enrollment;

inability to monitor patients adequately during or after treatment; and

inability or unwillingness of medical investigators to follow our clinical protocols.



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

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

Except for Abaloparatide-SC and Abaloparatide-TD, each of our other product candidates (i.e., RAD1901 and RAD140) is in early stages of development and requires extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for any of our product candidates or whether any such NDA will be accepted.

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

Even if our clinical trials are completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. For example, our Phase 3 trial of Abaloparatide-SC for fracture prevention may not replicate the positive efficacy results for BMD from our two Phase 2 trials. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date have involved small patient populations. Because of the small sample sizes, the results of these clinical trials may not be indicative of future results.

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

All of our product candidates are still in preclinical or clinical development. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval, if ever. If our product candidates result in undesirable side effects or have characteristics that are unexpected, we may need to abandon their development.

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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices, or cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if we obtain marketing approval of a product candidate, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and, if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing.

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

restrictions on such products, manufacturers or manufacturing processes;

restrictions on the labeling or marketing of a product;

restrictions on product distribution or use;

requirements to conduct post-marketing clinical trials;

warning or untitled letters;

withdrawal of the products from the market;

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refusal to approve pending applications or supplements to approved applications that we submit;

voluntary or mandatory recall of products and related publicity requirements;

fines, restitution or disgorgement of profits or revenue;

suspension or withdrawal of marketing approvals;

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

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

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

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

cost-effectiveness of our product relative to competing products;

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

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

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

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

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

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

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

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

**Risks related to our dependence on third parties**

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

We depend upon independent researchers, investigators and collaborators, such as Nordic, to conduct our preclinical and clinical trials under agreements with us. These third parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA



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applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist competitors at our expense, our competitive position would be harmed.

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

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

In consideration of Nordic's management of our Phase 3 clinical trial and subsequent extension studies, we have agreed to make various cash payments to Nordic denominated in both euros and U.S. dollars over the course of the Phase 3 study equal to a total of up to approximately €48.6 million (\$67.0 million) and a total of up to approximately \$4.4 million plus up to an additional \$5.0 million in aggregate performance incentive payments, payable in cash or stock depending on the timing of the closing of this offering. We also agreed to sell shares of capital stock to Nordic that were exchanged in the Merger for 6,443 shares of our series A-5 convertible preferred stock for proceeds of approximately \$0.5 million. These shares of our series A-5 convertible preferred stock will automatically convert into 28,258 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market. Pursuant to the terms of our agreements with Nordic, we will also issue to Nordic shares of stock with an aggregate value of up to approximately €44.3 million (\$61.0 million) and \$0.8 million in consideration of Nordic's management of the Phase 3 clinical trial. These shares of stock accrue or have accrued at a quarterly rate based on the progress of the Phase 3 clinical trial at a price per share equal to \$81.42. On each of December 31, 2013 and March 31, 2014, our board of directors declared a stock dividend to pay all shares of stock that had accrued as of such dates and that are anticipated to accrue through December 31, 2014, representing an aggregate of 682,958 shares of our series A-6 convertible preferred stock that will automatically convert into 2,995,453 shares of our common stock in connection with this offering. Following the consummation of this offering, all compensation remaining payable to Nordic in consideration of their management of our Phase 3 clinical trial will be paid in cash.

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

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

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

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We have entered into agreements with contract manufacturers to manufacture abaloparatide for use in clinical trial activities. These contract manufacturers are currently our only source for the production and formulation of abaloparatide. We may not have sufficient clinical supplies of abaloparatide but believe that our contract manufacturers will be able to produce sufficient supply of abaloparatide to complete all of the planned abaloparatide clinical studies. If our contract manufacturers are unable to produce, in a timely manner, adequate clinical supplies to meet the needs of our clinical studies, we would be required to seek new contract manufacturers that may require us to modify our finished product formulation and modify or terminate our clinical studies for abaloparatide. Any modification of our finished product or modification or termination of our Phase 3 clinical study could adversely affect our ability to obtain necessary regulatory approvals and significantly delay or prevent the commercial launch of the product, which would materially harm our business and impair our ability to raise capital.

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

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

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

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

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

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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 GMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

**If we are not able to establish additional collaborations, we may have to alter our development plans.**

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

**Risks related to marketing and sale of our products**

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

We currently have no sales, marketing or distribution capabilities. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborators' strategic interest in the products under development and such collaborators' ability to successfully market and sell any such products. We intend to build an internal sales force to market and sell our products to specialists and to pursue collaborative arrangements to market and sell our products to primary care physicians. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and we cannot assure you that their efforts will be successful. In addition, we cannot assure you that we will be able to establish or maintain relationships with such third party collaborators or that we would be able to market and sell our products in the United States or overseas through an in-house sales force in lieu of such relationships.

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

The market for our product candidates is characterized by intense competition and rapid technological advances. If any of our product candidates receives FDA approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to



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capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

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

developing drugs;

undertaking preclinical testing and human clinical trials;

obtaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

**Developments by competitors may render our products or technologies obsolete or non-competitive.**

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Some of the drugs that we are attempting to develop, such as Abaloparatide-SC, Abaloparatide-TD, 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 doing business in different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business. These risks could render our products or technologies obsolete or non-competitive.

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

Our ability to commercialize our drugs, alone or with collaborators, will depend in large part on the extent to which coverage and reimbursement will be available from:

government and health administration authorities;

private health maintenance organizations and health insurers; and

other healthcare payers.

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

acceptance of our products could be reduced.

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

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators.

**Risks related to our intellectual property**

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

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

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

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

Patents covering abaloparatide as a composition of matter have been issued in the United States (US Patent No. 5,969,095), Europe and several additional countries. Because the abaloparatide composition of matter patent was filed in 1996, it is expected to have a normal expiration in approximately 2016 in the United States (this date does not include the possibility of Hatch-Waxman patent term extension, which could extend the expiration in the United States into the first quarter of 2021 if an application for extension is made and the maximum extension is granted by the United States Patent and Trademark Office, or USPTO) and additional countries where it has issued.

We and Ipsen Pharma SAS, or Ipsen, are also co-assignees to US Patent No. 7,803,770 that we believe provides exclusivity until 2028 in the United States (absent any Hatch-Waxman patent term extensions) for the method of treating osteoporosis with the intended therapeutic dose for Abaloparatide-SC. We and Ipsen are also co-assignees to US Patent No. 8,148,333 that we believe provides exclusivity until 2027 in the United States (absent any Hatch-Waxman patent term extensions) for the intended therapeutic formulation for Abaloparatide-SC.

We and 3M are co-assignees to several foreign and corresponding U.S. patent applications with a priority date of April 22, 2011, which cover various aspects of abaloparatide for microneedle application. Any issued claims resulting from these applications will expire no earlier than 2032. However, pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of claimed inventions are not always predictable. Additional intellectual property covering Abaloparatide-TD technology exists in the form of proprietary information protected as trade secrets. These can be accidentally disclosed to, independently derived by or misappropriated by competitors, possibly reducing or eliminating the exclusivity advantages of this form of

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intellectual property, thereby allowing those competitors more rapid entry into the marketplace with a competitive product thus reducing our advantages with Abaloparatide-TD. In addition, trade secrets may in some instances become publicly available through required disclosures in regulatory files. Alternatively, competitors may sometimes reverse engineer a product once it becomes available on the market. Even where a competitor does not use an identical technology for the delivery of abaloparatide, it is possible that they could achieve an equivalent or even superior result using another technology. Such occurrences could lead to either one or more alternative competitor products becoming available on the market and/or one or more generic competitor products on the market gaining market share and causing a corresponding decrease in market share and/or price for Abaloparatide-TD. See "Business Intellectual Property Abaloparatide."

Patents covering RAD1901 as a composition of matter, as well as the use of RAD1901 for the treatment of estrogen-dependent breast cancer, have been issued in the United States, Canada and Australia and are pending in Europe and India. The RAD1901 composition of matter patents in the United States expire in 2023 and 2026 (absent any Hatch-Waxman patent term extension). Additional patent applications relating to methods of treating vasomotor symptoms and clinical dosage strengths using RAD1901 have been filed. Pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of any claimed invention before a patent office are not always predictable. As a result, we could encounter challenges or difficulties in building, maintaining and/or defending our intellectual property both in the United States and abroad. See "Business Intellectual Property RAD1901."

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

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

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

For example, we are aware of a provisional patent application recently filed with the USPTO that could be relevant to the use of RAD1901 to treat indications for which we are developing RAD1901. If a patent issues from this patent application with claims covering the use of RAD1901 to treat indications for which we are developing RAD1901, including BCBM, we may need to license the patent in order to commercialize RAD1901 specifically for the treatment of such indications. We are evaluating whether to enter into negotiations for such license. We cannot assure you that we will be able to secure a license on reasonable

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terms, if at all. If we need a license of such patent in order to commercialize RAD1901 and are unable to secure one on reasonable terms, our business would be materially harmed.

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

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain these patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States, prior to March 16, 2013, the first to make the claimed invention was entitled to the patent (a "first-to-invent" system), while outside the United States, the first to file a patent application is entitled to the patent (a "first-to-file" system). With the implementation of the Leahy-Smith America Invents Act, the United States now has a first-to-file system for patent applications filed on or after March 16, 2013. We may become involved in opposition, interference or derivation proceedings challenging our patent rights or the patent rights of others. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

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

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

In addition to our patented technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to our trade secrets, such as our corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for any breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by a competitor, our competitive position would be harmed.

**If we infringe the rights of third parties, we could be prevented from selling products and could be forced to pay damages and defend against litigation.**

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and may have to:

obtain licenses, which may not be available on commercially reasonable terms, if at all;

abandon an infringing drug candidate;

redesign our products or processes to avoid infringement;

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

pay damages; or

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

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute these types of claims and we may be reliant on them to do so.

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

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

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

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

**Risks related to legislation and administrative actions**

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

From time to time, legislation is implemented to reign in rising healthcare expenditures. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA. PPACA includes a number of provisions affecting the pharmaceutical industry, including annual, non-deductible fees on any entity that manufactures or imports some types of branded prescription drugs and biologics, beginning in 2011, and increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program. In addition, among other things, PPACA also establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research. Congress has proposed a number of legislative initiatives to alter PPACA, including possible repeal of PPACA. At this time, it remains unclear whether

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there will be any changes made to particular provisions of PPACA or its entirety. In addition, other legislative changes have been proposed and adopted since PPACA was enacted. Most recently, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which may result in such changes as aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, starting in 2013. The full impact on our business of PPACA and the Budget Control Act is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the pharmaceutical industry generally.

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

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

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

the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

the federal transparency requirements under PPACA, which require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

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

federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

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

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



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**Risks related to employee matters and managing growth**

**We may not successfully manage our growth.**

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we may be required to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage this growth effectively, our business would be harmed.

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

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

the difficulty of integrating the operations and personnel of the acquired companies;

the potential disruption of our ongoing business and distraction of management;

the potential for unknown liabilities and expenses;

the failure to achieve the expected benefits of the combination or acquisition;

the maintenance of acceptable standards, controls, procedures and policies; and

the impairment of relationships with employees as a result of any integration of new management and other personnel.

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

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

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

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

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

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**RISKS RELATING TO OUR COMMON STOCK AND THIS OFFERING**

**There is no public market for our common stock, and an active trading market may not develop or be sustained after this offering is completed.**

Prior to this offering, there has been no public market for our common stock. The public offering price for our common stock will be determined through negotiations with the underwriters. Although we expect that our common stock will be listed on the NASDAQ Global Market, an active, liquid and orderly trading market for our common stock may never develop or be sustained, which could depress the trading price of our common stock following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell the shares you purchase in this offering without depressing the market price for the shares or at all.

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

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

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

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

**We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.**

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The amount and timing of our actual expenditures will depend upon numerous factors, including the results of our ongoing clinical studies and clinical studies that we may commence, feedback from regulatory agencies, the timing of approval of any of our product candidates, the results of any commercialization efforts and other factors. The

failure by our management to apply the net proceeds from this offering effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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

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

**If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.**

The public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent outstanding options or warrants are exercised, you will incur further dilution. Based on an assumed public offering price of \$8.00 per share, you will experience immediate dilution of \$6.46 per share, representing the difference between our pro forma net tangible book value per share as of March 31, 2014 after giving effect to this offering and the assumed public offering price.

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

As a public company listed on the NASDAQ Global Market, we will incur significant legal, accounting and other expenses that we did not incur as a private company and prior to the listing of our common stock on the NASDAQ Global Market. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission, or the SEC, and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and in the future will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm at such time as we no longer qualify as a smaller reporting company. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage additional outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that our independent registered public accounting firm will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

**Our directors, executive officers and principal stockholders will continue to have substantial control over us after this offering and could delay or prevent a change in corporate control.**

After this offering, our directors, executive officers and holders of more than five percent of our common stock, together with their affiliates, will beneficially own, in the aggregate, approximately 59.6% of our outstanding common stock assuming none of them purchase shares in this offering. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or

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substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

delaying, deferring or preventing a change in corporate control;

impeding a merger, consolidation, takeover or other business combination involving us; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

**Future sales of shares of our common stock by stockholders could depress the price of our common stock.**

Based on shares outstanding as of March 31, 2014, upon the completion of this offering, we will have 28,938,899 shares of our common stock outstanding. Of these shares, the shares sold in this offering will be freely tradable. The holders of substantially all of our shares of common stock have signed lock-up agreements under which they have agreed not to sell, transfer or dispose of, directly or indirectly, any shares of our common stock or any securities into or exercisable or exchangeable for shares of our common stock without the prior written consent of Jefferies and Cowen and Company for a period of 180 days, subject to a possible extension under certain circumstances, after the date of this prospectus. After the expiration of the lock-up period, these shares may be sold in the public market, subject to prior registration or qualification for an exemption from registration, including, in the case of shares held by affiliates, compliance with the volume restrictions of Rule 144. To the extent that any of these stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the contractual lock-ups and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline significantly.

In addition, the 4,250,501 shares of our common stock reserved for issuance under our equity incentive plans, which includes 2,694,647 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2014, will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the price of our common stock could decline substantially.

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

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

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

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

a staggered board of directors;

authorizing the board to issue, without stockholder approval, preferred stock with rights senior to those of our common stock;

authorizing the board to amend our bylaws and to fill board vacancies until the next annual meeting of the stockholders;

prohibiting stockholder action by written consent;

limiting the liability of, and providing indemnification to, our directors and officers;



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eliminating the ability of our stockholders to call special meetings; and

requiring advance notification of stockholder nominations and proposals.

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

These and other provisions in our restated certificate of incorporation and our amended and restated bylaws to be effective in connection with the offering under Delaware law could discourage potential takeover attempts, reduce the price that investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions. See "Description of Capital Stock - Preferred Stock" and "Description of Capital Stock - Anti-Takeover Provisions."

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

As of December 31, 2013, we had \$263.6 million of federal and \$229.4 million of state net operating loss carryforwards available to offset future taxable income. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code has previously occurred or will occur as a result of this offering. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

In addition to historical information, this prospectus, including the sections titled "Prospectus summary," "Risk factors," Management's discussion and analysis of financial condition and results of operations" and "Business," contains forward-looking statements. In some cases, we may 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 Abaloparatide-SC, Abaloparatide-TD, 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.



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The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements. These important factors include our financial performance, our ability to attract and retain customers, our development activities and those other 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.

Before you decide to invest in our common stock, you should carefully consider these risk factors, together with the other information contained in this prospectus, including our financial statements and the related notes and the information set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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**USE OF PROCEEDS**

We estimate that our net proceeds from this offering will be approximately \$46.8 million, assuming an initial public offering price of \$8.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that our net proceeds from this offering will be approximately \$54.0 million. Each \$1.00 increase or decrease in the assumed initial public offering price of \$8.00 per share would result in an approximately \$6.0 million increase or decrease in our net proceeds from this offering, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of one million shares in the number of shares to be offered by us would increase or decrease our net proceeds from this offering by approximately \$7.4 million, assuming that the public offering price is \$8.00 per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We expect to use the net proceeds of this offering together with our existing resources as follows:

approximately \$43.0 million to complete development, submit an NDA and MAA and to obtain regulatory approval of Abaloparatide-SC;

approximately \$3.0 million to continue collaborative development work with 3M and prepare/initiate the next phase of clinical studies for Abaloparatide-TD; and

the remainder to initiate a Phase 1 development of RAD1901 for the treatment of BCBM, to begin establishing sales and marketing capabilities to commercialize our product candidates and for working capital and general corporate purposes, including for monthly interest payments on our new credit facility and the costs associated with being a public company. For additional information related to our credit facility, including the interest rate and maturity, see "Management Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Financings New Credit Facility."

Our expected use of net proceeds from this offering represents our intentions based upon our present plans and business conditions, which could change in the future as our plans and business conditions evolve.

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

Our ability to pay cash dividends is restricted pursuant to the terms of our credit facility. See "Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Financings."

Table of Contents**CAPITALIZATION**

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of March 31, 2014, as follows:

on an actual basis;

on a pro forma basis to give effect to (1) the automatic conversion of all outstanding shares of our convertible preferred stock into 19,465,131 shares of common stock in connection with this offering, (2) the issuance of 2,588,104 shares of common stock to the holders of our series B, B-2, A-1, A-2, and A-3 convertible preferred stock in connection with this offering in satisfaction of accumulated dividends as of March 31, 2014 and (3) the filing of our restated certificate of incorporation, which will occur concurrently with the closing of this offering; and

on a pro forma as adjusted basis to give further effect to our issuance and sale of 6,500,000 shares of our common stock in this offering at an assumed public offering price of \$8.00 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information provided in the table below does not give effect to additional borrowings of approximately \$21.0 million under our new credit facility, entered into on May 30, 2014, or the repayment of the \$9.3 million outstanding under our credit facility with General Electric Capital Corporation and Oxford Finance LLC. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Financings—New Credit Facility".

You should read this information in conjunction with "Summary Financial Data," "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," our financial statements and related notes, all included elsewhere in this prospectus.

	<b>AS OF MARCH 31, 2014</b>		
	<b>ACTUAL</b>	<b>PRO FORMA</b>	<b>PRO FORMA AS ADJUSTED(1)</b>
	<b>(In thousands, except share and per share data)</b>		
Cash, cash equivalents and marketable securities	\$ 29,558	\$ 29,558	\$ 76,323
Convertible preferred stock, par value \$.0001 per share: 4,571,443 shares authorized, 3,907,741 shares outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma, as adjusted.		294,032	\$
<b>Stockholders' (deficit) equity:</b>			
Common stock, par value \$.0001 per share: 100,000,000 shares authorized, 385,664 shares issued and outstanding, actual; 200,000,000 shares authorized, 22,438,899 shares issued and outstanding, pro forma; 200,000,000 shares authorized, 28,938,899 shares issued and outstanding, pro forma as adjusted			2                      3
Preferred stock, par value \$.0001 per share: no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma, as adjusted			
Additional paid-in capital		294,030	340,794
Accumulated other comprehensive loss			
Accumulated deficit	(296,247)	(296,247)	(296,247)

Total stockholders' (deficit) equity	(296,247)	(2,215)	44,550
Total capitalization	\$ (2,215)	\$ (2,215)	\$ 44,550

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(1)

Each \$1.00 increase or decrease in the assumed public offering price of \$8.00 per share would increase or decrease each of the pro forma as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$6.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of one million shares in the number of shares to be offered by us would increase or decrease each of the pro forma as adjusted cash, cash equivalents and marketable securities, total stockholders' equity and total capitalization by approximately \$7.4 million, assuming that the public offering price is \$8.00 per share, the midpoint of the price range set forth on the cover page of this prospectus and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering.

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The table above does not include the following potentially dilutive shares of common stock outstanding:

2,694,647 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$7.28 per share as of March 31, 2014;

1,555,854 shares of our common stock reserved for future issuance under our 2011 equity incentive plan as of March 31, 2014, which includes options to purchase 576,743 shares of our common stock that we have granted effective upon and subject to the effectiveness of the registration statement of which this prospectus forms a part;

78,760 shares of common stock issuable upon the exercise of outstanding warrants to purchase shares of our series B-2 convertible preferred stock and the automatic conversion of such shares in connection with this offering, at an exercise price equal to the initial public offering price in this offering, as described in more detail below in the section entitled " Series B-2 Convertible Preferred Stock";

1,330,995 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$14.16 per share as of March 31, 2014; and

245,784 shares of our common stock issuable to the holders of our series B, B-2, A-1, A-2 and A-3 convertible preferred stock in connection with this offering in satisfaction of dividends accruing from April 1, 2014 to May 31, 2014, plus additional shares of our common stock issuable to such holders in satisfaction of dividends accruing after May 31, 2014 to the date of the closing of this offering, as described in more detail in the section of this prospectus entitled "Capitalization Preferred Stock Dividends".

***Series B-2 Convertible Preferred Stock***

On February 14, 2014, we entered into a Series B-2 Convertible Preferred Stock and Warrant Purchase Agreement, or the series B-2 purchase agreement. During February and March 2014, we consummated closings under the series B-2 purchase agreement, whereby, in exchange for aggregate gross proceeds to us of approximately \$27.5 million, we issued an aggregate of 448,060 shares of series B-2 convertible preferred stock and warrants to purchase up to a total of 491,293 shares of our common stock with an exercise price of \$14.004 per share.

The series B-2 convertible preferred stock will automatically convert into shares of our common stock upon the closing of this offering at a conversion rate determined by dividing the initial purchase price of \$61.42 per share by the lower of (1) \$14.004 per share and (2) the initial public offering price in this offering. For purposes of this prospectus, we have assumed the conversion price of the series B-2 convertible preferred stock will be \$8.00 per share and that the series B-2 convertible preferred stock will convert into 3,440,200 shares of common stock upon the closing of this offering. If the initial public offering price in this offering is less or greater than \$8.00 per share (and less than \$14.004 per share), you can estimate the number of shares of common stock that will be issuable upon conversion of the series B-2 convertible preferred stock by dividing \$61.42 by the initial public offering price and then multiplying that quotient by 448,060. For example, if the initial public offering price was \$7.00 per share, the number of shares of common stock that we will issue upon conversion of the series B-2 convertible preferred stock will increase by 491,206 shares.

In connection with our new credit facility, we issued the lenders warrants to purchase an aggregate of up to 10,258 shares of our series B-2 convertible preferred stock at an exercise price of \$61.42 per share. Upon the closing of this offering at the assumed initial public offering price of \$8.00 per share and the automatic conversion of our series B-2 convertible preferred stock into common stock, these warrants will be exercisable for up to 78,760 shares of common stock. If the initial public offering price in this offering is less than or greater than \$8.00 per share (and less than \$14.004 per share), you can estimate the number of shares of common stock that will be issuable upon exercise of the these warrants by dividing \$61.42 by the initial public offering price in this offering and then multiplying that quotient by 10,258. For example, if the initial public offering price was \$7.00 per share, the number of shares of common stock issuable upon exercise of the warrants will increase by 11,247.

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Holders of the series B-2 convertible preferred stock are also entitled to received accrued dividends, which are described below under the caption " Preferred Stock Dividends."

***Preferred Stock Dividends***

Each share of our series B, B-2, A-1, A-2 and A-3 preferred stock is entitled to receive a per share dividend at the rate of 8% of the original purchase price of such series per annum, compounding annually, and accruing on a daily basis, whether or not declared. These dividends are payable, at the discretion of our board of directors, in cash or shares of our common stock calculated by dividing the aggregate accumulated accrued dividend amount by the applicable conversion price for such series of convertible preferred stock. Our board of directors has determined to pay such accrued dividends in the form of shares of common stock. The aggregate number of shares of common stock issuable upon conversion of the series B, B-2, A-1, A-2 and A-3 convertible preferred stock that was outstanding as of March 31, 2014 is 2,588,104. An additional 245,784 shares of our common stock in the aggregate are issuable upon conversion to holders of our series B, B-2, A-1, A-2 and A-3 convertible preferred stock in satisfaction of dividends accrued from April 1, 2014 to May 31, 2014. Approximately 3,409 additional shares of common stock will be issuable upon conversion to holders of our series B, A-1, A-2 and A-3 convertible preferred stock in satisfaction of dividends accrued for each day after May 31, 2014 through the date of the listing of our common stock on the NASDAQ Global Market and approximately 755 additional shares of common stock will be issuable upon conversion to holders of our series B-2 convertible preferred stock in satisfaction of dividends accrued for each day after May 31, 2014 through the date of the closing of this offering.

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**DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of March 31, 2014 was \$(296.2) million or \$(768.15) per share of common stock, based on 385,664 shares of common stock outstanding as of March 31, 2014. Historical net tangible book value per share is determined by dividing our total tangible assets less total liabilities and redeemable preferred stock by the actual number of shares of common stock outstanding.

Our pro forma net tangible book value (deficit) as of March 31, 2014 was \$(2.2) million, or \$(0.10) per share of common stock, based on 22,438,899 shares of common stock outstanding after giving effect to (1) the automatic conversion of all of our outstanding convertible preferred stock into 19,465,131 shares of common stock in connection with this offering and (2) the assumed issuance of 2,588,104 shares of common stock in connection with this offering in satisfaction of accumulated dividends on our series B, B-2, A-1, A-2 and A-3 convertible preferred stock through March 31, 2014. Pro forma net tangible book value per share is determined by dividing our total tangible assets less total liabilities and redeemable preferred stock by the pro forma number of shares of common stock outstanding at March 31, 2014 before giving effect to our sale of shares of common stock in this offering.

After giving further effect to our issuance and sale of 6,500,000 shares of our common stock in this offering at an assumed initial public offering price of \$8.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma net tangible book value as of March 31, 2014 would have been \$44.6 million, or \$1.54 per share. This represents an immediate increase in pro forma net tangible book value per share of \$1.64 to existing stockholders and immediate dilution of \$6.46 in pro forma net tangible book value per share to new investors purchasing common stock in this offering.

The pro forma and pro forma as adjusted net tangible book value does not give effect to additional borrowings of approximately \$21.0 million under our new credit facility entered into on May 30, 2014, or the repayment of the \$9.3 million outstanding under our credit facility with General Electric Capital Corporation and Oxford Financial LLC. See "Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Financings New Credit Facility".

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Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis.

Assumed initial public offering price per share	\$8.00
Historical net tangible book value (deficit) per share as of March 31, 2014	\$(768.15)
Pro forma increase per share attributable to conversion of convertible preferred stock and issuance of shares of common stock in satisfaction of accumulated dividends on series B, B-2, A-1, A-2 and A-3 convertible preferred stock	768.05
Pro forma net tangible book value per share as of March 31, 2014, before this offering	(0.10)
Increase in pro forma net tangible book value per share attributable to investors in this offering	1.64
Pro forma as adjusted net tangible book value per share as of March 31, 2014, after this offering	1.54
Dilution per share to new investors in this offering	6.46

Each \$1.00 increase or decrease in the assumed initial public offering price of \$8.00 per share would increase or decrease our pro forma net tangible book value by approximately \$6.0 million, our pro forma net tangible book value per share by approximately \$0.21 and dilution per share to new investors by approximately \$0.21, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase of one million in the number of shares offered by us would increase the pro forma as adjusted net tangible book value by approximately \$7.4 million, or \$0.20 per share, and would decrease the dilution per share to new investors in this offering by \$0.20 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses. Similarly, a decrease of one million shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value by approximately \$7.4 million, or \$0.21 per share, and would increase the dilution per share to new investors in this offering by \$0.21 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial price to the public and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase additional shares in full or if any additional shares are issued in connection with outstanding options or warrants, you will experience further dilution.

The following table summarizes, on a pro forma as adjusted basis described above, the total number of shares purchased from us, the total consideration paid, or to be paid, and the average price per share paid, or to be paid, by existing stockholders and by new investors in this offering at an assumed initial public



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offering price of \$8.00 per share before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	<b>SHARES PURCHASED</b>		<b>TOTAL CONSIDERATION</b>		<b>AVERAGE PRICE PER SHARE</b>
	<b>NUMBER</b>	<b>PERCENT</b>	<b>AMOUNT</b>	<b>PERCENT</b>	
Existing stockholders	22,438,899	78%	\$ 242,642,521	82%	\$ 10.81
New investors	6,500,000	22%	52,000,000	18%	\$ 8.00
<b>Total</b>	<b>28,938,899</b>	<b>100%</b>	<b>\$ 294,642,521</b>	<b>100%</b>	<b>\$ 10.18</b>

Each \$1.00 increase or decrease in the assumed public offering price of \$8.00 per share would increase or decrease the total consideration paid by new investors by \$6.5 million and increase or decrease the percentage of total consideration paid by new investors by approximately 1%, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

If the underwriters exercise their over-allotment option in full, the following will occur:

the percentage of shares of our common stock held by existing stockholders will decrease to approximately 75% of the total number of shares of our common stock outstanding after this offering; and

the number of shares of our common stock held by new investors will increase to 7,475,000, or approximately 25% of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations exclude the following potentially dilutive shares of common stock:

2,694,647 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$7.28 per share as of March 31, 2014;

1,555,854 shares of our common stock reserved for future issuance under our 2011 equity incentive plan as of March 31, 2014, which includes options to purchase 576,748 shares of our common stock that we have granted effective upon and subject to the effectiveness of the registration statement of which this prospectus forms a part;

78,760 shares of common stock issuable upon the exercise of outstanding warrants to purchase shares of our series B-2 convertible preferred stock and the automatic conversion of such shares in connection with this offering, at an exercise price equal to the initial public offering price in this offering, as described in more detail in the section of this prospectus entitled "Capitalization Series B-2 Convertible Preferred Stock";

1,330,995 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$14.16 per share as of March 31, 2014; and

245,784 shares of our common stock issuable to the holders of our series B, B-2, A-1, A-2 and A-3 convertible preferred stock in connection with this offering in satisfaction of dividends accruing from April 1, 2014 to May 31, 2014, plus additional shares of our common stock issuable to such holders in satisfaction of dividends accruing after May 31, 2014, as

described in more detail in the section of this prospectus entitled "Capitalization Preferred Stock Dividends".

Table of Contents**SELECTED FINANCIAL DATA**

You should read the following selected historical financial data in conjunction with "Management's discussion and analysis of financial condition and results of operations" and the financial statements and related notes, all included elsewhere in this prospectus.

We derived the statements of operations data for the years ended December 31, 2013, 2012 and 2011 and the balance sheets data as of December 31, 2013 and 2012 from our audited financial statements included elsewhere in this prospectus. We derived the statement of operations data for the three months ended March 31, 2014 and 2013 and the balance sheet data as of March 31, 2014 from our unaudited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future, and our interim results are not necessarily indicative of our full year results.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS DATA	YEAR ENDED DECEMBER 31,			THREE MONTHS ENDED MARCH 31,	
	2013	2012	2011	2014	2013
	(in thousands, except share and per share amounts)			(unaudited)	
Operating expenses:					
Research and development	\$ 60,536	\$ 54,961	\$ 36,179	\$ 9,717	\$ 17,113
General and administrative	6,829	9,469	5,330	2,139	1,811
Income from operations	(67,365)	(64,430)	(41,509)	(11,856)	(18,724)
Other income (expense):					
Interest income (expense), net	9,085	(2,095)	(236)	(2,233)	11,111
Net (expense) income, net	(2,410)	(2,603)	(731)	(399)	2,387
Loss	(60,690)	(69,128)	(42,476)	(14,488)	(8,337)
Other comprehensive loss, net of tax:					
Realized (loss) gain from available-for-sale securities		(5)	8		
Other comprehensive loss	\$ (60,690)	\$ (69,133)	\$ (42,468)	\$ (14,488)	\$ (8,337)
Net earnings attributable to common stockholders	\$ (78,161)	\$ (83,120)	\$ 113	\$ (19,457)	\$ (11,346)
Net earnings per share - basic	\$ (203.91)	\$ (225.71)	\$ 0.51	\$ (50.45)	\$ (30.00)
Net earnings per share - diluted	\$ (203.91)	\$ (225.71)	\$ 0.06	\$ (50.45)	\$ (30.00)
Weighted average shares - basic	383,310	368,261	219,254	385,664	380,000
Weighted average shares - diluted	383,310	368,261	1,774,935	385,664	380,000
Normalized loss attributable to common stockholders - basic and diluted(1)	\$ (60,690)			\$ (19,457)	
Normalized loss per share - basic(1) (unaudited)	\$ (3.97)			\$ (1.00)	
Normalized loss per share - diluted(1) (unaudited)	\$ (3.97)			\$ (1.00)	

Weighted-average common shares used in computing pro forma earnings per share (unaudited)	15,277,598	19,445,393
Weighted-average common shares used in computing pro forma earnings per share (unaudited)	15,277,598	19,445,393

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(1)

For a description of the calculation of basic and diluted pro forma loss attributable to common stockholders and basic and diluted pro forma loss per share, see note 2 to our audited financial statements and note 2 to our unaudited financial statements, each of which are included elsewhere in this prospectus.

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<b>BALANCE SHEET DATA</b>	<b>AS OF DECEMBER 31,</b>		<b>AS OF</b>
	<b>2013</b>	<b>2012</b>	<b>MARCH</b>
	<b>31,</b>		
	<b>2014</b>		
	<b>(in thousands)</b>		
Cash, cash equivalents and marketable securities	\$ 12,303	\$ 22,653	\$ 29,558
Working capital	(22,675)	8,026	2,275
Total assets	12,758	25,300	31,906
Total liabilities	37,257	55,312	34,121
Total convertible preferred stock	252,802	170,649	294,032
Total liabilities, convertible preferred stock and stockholders' deficit	12,758	25,300	31,906

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion of our financial condition and results of operations in conjunction with "Summary financial data," "Selected financial data" and the financial statements and related notes, all included elsewhere in this prospectus. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. You should read "Risk factors" for a discussion of important factors that could cause or contribute to these differences.*

**OVERVIEW**

We are a science-driven biopharmaceutical company focused on developing novel differentiated therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases. Our lead product candidate is abaloparatide (BA058), a bone anabolic for the treatment of osteoporosis delivered via subcutaneous injection, which we refer to as Abaloparatide-SC. We are currently in Phase 3 development of Abaloparatide-SC and expect to announce top-line data from this study in late 2014. If the results are positive, we plan to submit a new drug application, or NDA, in the United States, and a marketing authorization application, or MAA, in Europe, in mid-2015. We hold worldwide commercialization rights to Abaloparatide-SC, other than in Japan, and with a favorable regulatory outcome, we anticipate our first commercial sales of Abaloparatide-SC will take place in 2016. We are leveraging our investment in Abaloparatide-SC to develop Abaloparatide-TD. We expect this line extension will provide improved patient convenience by enabling administration of abaloparatide through a short-wear-time transdermal patch. We have recently completed a successful Phase 2 proof of concept study of Abaloparatide-TD.

Our current clinical product portfolio also includes a novel oral agent, RAD1901, a selective estrogen receptor down-regulator/degrader, or SERD. We are developing RAD1901 at higher doses for the treatment of breast cancer brain metastases, or BCBM, and intend to advance its development with the initiation of two Phase 1 clinical trials – a maximum tolerated dose study that has commenced patient screening, and a Phase 1b clinical trial in BCBM, which is expected to commence in late-2014. At low doses, RAD1901 acts as a selective estrogen-receptor modulator, or SERM. Low-dose RAD1901 has shown efficacy for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study.

***Abaloparatide***

Abaloparatide is a novel synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a bone anabolic treatment for osteoporosis. Osteoporosis is a disease that affects nearly 10 million people in the United States, with an additional approximately 43 million people at increased risk for the disease. It is characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. Anabolic agents, like Forteo (teriparatide), are used to increase bone mineral density, or BMD, and to reduce the risk of fracture. We believe abaloparatide has the potential to increase BMD and bone quality to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis. Based upon various published studies, including studies published by Marc C. Hochberg, MD, MPH (2002) and John A. Kanis (2014), we believe that increases in BMD are predictive of reduction in fracture risk. We are developing two formulations of abaloparatide:

*Abaloparatide-SC* is an injectable subcutaneous formulation of abaloparatide. In August 2009, we announced positive Phase 2 data that showed Abaloparatide-SC produced faster and greater BMD increases at the spine and the hip with substantially less hypercalcemia than Forteo (teriparatide), which is the only approved subcutaneous injectable anabolic agent for the treatment of osteoporosis in the United States. A subsequent Phase 2 clinical trial announced in January 2014 also confirmed the results of our first clinical trial by demonstrating that Abaloparatide-SC produces BMD increases from baseline in the spine and hip that are comparable to our earlier Phase 2 clinical trial. In April 2011, we commenced a Phase 3 clinical trial of Abaloparatide-SC. Enrollment was completed in March 2013, and we expect to announce top-line data at the end of the fourth quarter of 2014. Assuming a favorable outcome, we plan to use the results from this Phase 3 clinical trial to support a

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new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, and believe we could obtain approval of the NDA in 2016.

*Abaloparatide-TD* is a line extension of Abaloparatide SC in the form of a convenient, short-wear-time (approximately five minutes) transdermal patch. In a recent Phase 2 clinical trial, Abaloparatide-TD demonstrated a statistically significant mean percent increase from baseline in BMD as compared to placebo at the lumbar spine and at the hip. These results demonstrated a clear proof of concept by achieving a dose dependent increase in BMD. Following additional formulation development work, we intend to advance an optimized Abaloparatide-TD product in additional clinical studies and to a Phase 3 bridging study and to subsequently submit for approval. We hold worldwide commercialization rights to Abaloparatide-TD technology.

In April 2011, we began the dosing of subjects in a pivotal Phase 3 clinical study managed by Nordic Bioscience Clinical Development VII A/S, or Nordic, at certain clinical sites operated by the Center for Clinical and Basic Research, a leading global CRO with extensive experience in global osteoporosis registration studies. We designed this Phase 3 study to enroll a total of 2,400 patients to be randomized equally to receive daily doses of one of the following: 80 micrograms ( $\mu\text{g}$ ) of abaloparatide, a matching placebo, or the approved dose of 20  $\mu\text{g}$  of Forteo for 18 months. The study will also include a 6-month extension period in order to obtain 24-months of fracture data, as requested by the FDA. We plan to submit the New Drug Application, or NDA, with the 24-month fracture data. We believe the study is powered to show that abaloparatide is superior to placebo for prevention of vertebral fracture. We believe the study is also powered to show that abaloparatide is superior to Forteo for greater BMD improvement at major skeletal sites and for a lower occurrence of hypercalcemia, a condition in which the calcium level in a patient's blood is above normal. We expect to report top-line 18-month fracture data from this study at the end of the fourth quarter of 2014. Upon completion of this Phase 3 trial, we intend to submit for regulatory approval in the United States and Europe in mid-2015. With standard review time and a favorable regulatory outcome, we will begin commercial sales in 2016.

On May 9, 2014, we submitted a breakthrough therapy designation request to the FDA for Abaloparatide-SC for the treatment of postmenopausal osteoporosis. Abaloparatide-SC was selected for clinical development on the basis of its demonstrated marked effects on increasing bone mass in non-clinical models. The recently completed analyses of two abaloparatide Phase 2 clinical trials have confirmed these non-clinical results, demonstrating potentially important clinical benefits relative to current anabolic therapies, including faster and greater increases in hip (non-vertebral) and spine (vertebral) BMD. We believe these results could support a breakthrough therapy designation.

***RAD1901***

RAD1901 is a SERD that we believe crosses the blood-brain barrier and that we are evaluating for the treatment of BCBM. RAD1901 has been shown to bind with good selectivity to the estrogen receptor and to have both estrogen-like and estrogen-antagonistic effects in different tissues. In many cancers, hormones, like estrogen, stimulate tumor growth and a desired therapeutic goal is to block this estrogen-dependent growth while inducing apoptosis of the cancer cells. SERDs are an emerging class of endocrine therapies that directly induce estrogen receptor, or ER, degradation, enabling them to remove the estrogen growth signal in ER-dependent tumors without allowing ligand-independent resistance to develop. There is currently only one SERD, Faslodex (fulvestrant), approved for the treatment of hormone-receptor positive metastatic breast cancer; however, for patients with brain metastases (BCBM), there are no approved targeted therapies that cross the blood-brain barrier. We believe there is a significant opportunity for RAD1901 to be the first ER- targeted therapy that crosses the blood-brain barrier to more effectively treat ER-positive BCBM and potentially reduce both intracranial and extracranial BCBM tumors. We intend to commence a Phase 1 maximum tolerated dose study in healthy volunteers to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also use 18F-fluoroestradiol positron emission tomography (PET) in this study to provide a pharmacodynamic assessment of estrogen receptor turnover following RAD1901 treatment. Patient screening for this maximum tolerated dose study is currently underway. We also intend to commence a Phase 1 clinical trial in 2014 to evaluate high-dose RAD1901 for the treatment of BCBM. In March 2014,

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we submitted to the FDA an application for orphan medicinal product designation of RAD1901 for the treatment of BCBM.

We are also developing RAD1901 at lower doses as a selective estrogen receptor modulator, or SERM, for the treatment of vasomotor symptoms. Historically, hormone replacement therapy, or HRT, with estrogen or progesterone was considered the most efficacious approach to relieving menopausal symptoms such as hot flashes. However, because of the concerns about the potential long-term risks and contraindications associated with HRT, we believe a significant need exists for new therapeutic treatment options to treat vasomotor symptoms. In a Phase 2 proof of concept study, RAD1901 at lower doses demonstrated a reduction in the frequency and severity of moderate and severe hot flashes. We believe RAD1901 is an attractive candidate for advancement into Phase 2b development as a treatment for vasomotor symptoms.

Our efforts and resources are focused primarily on developing Abaloparatide-SC, Abaloparatide-TD, RAD1901 and our other pharmaceutical product candidates, raising capital and recruiting personnel. We have no product sales to date and we will not receive any revenue from product sales unless and until we receive approval for Abaloparatide-SC from the FDA, or equivalent foreign regulatory bodies. However, developing pharmaceutical products is a lengthy and very expensive process. Accordingly, our success depends not only on the safety and efficacy of abaloparatide, but also on our ability to finance the development of these products, which will require substantial additional funding to complete development and file for marketing approval. Our ability to raise this additional financing will depend on our ability to execute on the abaloparatide development plan, manage and coordinate, on a cost-effective basis, all the required components of the NDA submission for Abaloparatide-SC and scale-up Abaloparatide-SC and Abaloparatide-TD manufacturing capacity. In addition, we currently have no sales, marketing or distribution capabilities and thus our ability to market abaloparatide may depend in part on our ability to enter into and maintain collaborative relationships, which will depend on the strength of our clinical data, our access to capital and other factors.

**Future Financing Needs**

We expect to finance the future development costs of Abaloparatide-SC, Abaloparatide-TD and RAD1901 with our existing cash and cash equivalents and marketable securities, future offerings of our common stock or preferred stock, or through other strategic financing opportunities. Our current strategy is to initiate a Phase 1B clinical study of RAD1901 for the treatment of BCBM in 2014. However, due to its early stage of development, we are not yet able to determine the possible marketing approval timeline or future development costs at this time. Our current strategy is to collaborate with third parties for the further development and commercialization of RAD140 and RAD1901 for the treatment of vasomotor symptoms. Therefore, we do not expect that we will incur substantial future costs for these programs because we expect these costs will be borne by third parties. Therefore, it is not possible to project the future development costs or possible marketing approval timeline at this time.

We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, progress on securing third-party collaborators, as well as ongoing assessments of such product candidate's commercial potential and our ability to fund this product development.

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

Abaloparatide-SC is our only product candidate in late stage development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. Obtaining approval



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of an NDA is an extensive, lengthy, expensive and uncertain process, and any approval of Abaloparatide-SC may be delayed, limited or denied for many reasons, including:

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

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

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

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

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

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

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

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

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

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

In addition, the FDA may change its approval policies or adopt new regulations. For example, on February 15, 2012, we received a letter from the FDA stating that, after internal consideration, the agency believes that a minimum of 24-months of fracture data is necessary for approval of new products for the treatment of postmenopausal osteoporosis, and our ongoing Abaloparatide-SC pivotal Phase 3 clinical study is designed to produce fracture data based on an 18-month primary endpoint. Based on our discussions with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from a 6-month extension of the abaloparatide 80 µg and placebo groups in our Phase 3 clinical study that will receive an approved alendronate (generic Fosamax) therapy for osteoporosis management. We plan to submit the NDA with the 24-month fracture data. We cannot be certain that the FDA will be supportive of this plan, will not change this approval policy again or adopt other approval policies or regulations that adversely affect any NDA that we may submit.

## **FINANCIAL OVERVIEW**

### **Research and development expenses**

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

None of the research and development expenses in relation to our product candidates are currently borne by third parties. Our lead product candidate is abaloparatide and it represents the largest portion of our research and development expenses for our product candidates. We began tracking program expenses for Abaloparatide-SC in 2005, and program expenses from inception to March 31, 2014 were approximately \$152.1 million. We began tracking program expenses for Abaloparatide-TD in 2007, and program expenses from inception to March 31, 2014 were approximately \$29.8 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to

March 31, 2014 were approximately \$15.5 million. We began tracking program expenses for RAD140 in 2008, and program expenses from

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inception to March 31, 2014 were approximately \$5.2 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs.

Costs related to facilities, depreciation, stock-based compensation and research and development support services are not directly charged to programs as they benefit multiple research programs that share resources.

We expect that future development costs related to the Abaloparatide-SC and Abaloparatide-TD programs will increase through possible marketing approval in the United States for Abaloparatide-SC in mid-2016 and for Abaloparatide TD in mid-2020. For Abaloparatide-SC, we estimate that future development costs may exceed \$63.0 million, including \$27.0 million for clinical costs, \$23.0 million for license and milestone payments and NDA submission fees, \$12.0 million for manufacturing costs and \$1.0 million for preclinical costs. For Abaloparatide-TD, we estimate that future development costs may exceed \$45.0 million, including \$35.0 million for clinical costs, \$8.0 million for manufacturing costs, and \$2.0 million for preclinical costs and NDA submission fees. As a portion of the development costs for Abaloparatide-SC are to be settled in shares of our series A-6 convertible preferred stock, the amount of future development costs will be affected by changes in the fair value of the series A-6 convertible preferred stock (see notes 11 and 13 to our audited financial statements and notes 5 and 7 to our unaudited financial statements, each of which are included elsewhere in this prospectus).

The following table sets forth our research and development expenses related to Abaloparatide-SC, Abaloparatide-TD, RAD1901 and RAD140 for the years ended December 31, 2013, 2012 and 2011 and the three months ended March 31, 2014 and 2013 (in thousands):

	YEAR ENDED			THREE MONTHS		
	DECEMBER 31,			ENDED MARCH		
	2013	2012	2011	2014	2013	
Abaloparatide-SC	\$ 45,977	\$ 44,692	\$ 27,046	\$ 8,107	\$ 12,036	
Abaloparatide-TD	11,459	6,040	6,369	185	4,423	
RAD1901		59	70			
RAD140		18	23			

**General and administrative expenses**

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, professional fees, business insurance, rent, general legal activities, including the cost of maintaining our intellectual property portfolio, and other corporate expenses. We expect our general and administrative expenses to increase as a result of higher costs associated with being a publicly company with stock listed on the NASDAQ Global Market.

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

**Interest income and interest expense**

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

Interest expense reflects interest due under our loan and security agreement, or the Credit Facility, entered into on May 23, 2011 with General Electric Capital Corporation, or GECC, as agent and lender, and Oxford Finance, as a lender. We drew \$12.5 million under an initial and second term loan during the year ended December 31, 2011 and an additional \$12.5 million under a third term loan during the year ended December 31, 2012. See "Liquidity and Capital Resources - Financings." In connection with the funding

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of the term loans, we issued warrants to purchase up to 12,280 shares of our series A-1 convertible preferred stock at an exercise price of \$81.42 per share, which exercise price, as a result of an anti-dilution adjustment effected in connection with our issuance of the Series B Shares and warrants pursuant to the Purchase Agreement, was effectively reduced, on an as-converted basis, to \$16.970 as of March 31, 2014.

**Other income (expense)**

For the years ended December 31, 2013 and 2012 and the three months ended March 31, 2014 and 2013, other income and asset (expense) primarily reflects changes in the fair value of our warrant liability and the series A-6 convertible preferred stock liability and asset from the date of the initial accrual to the reporting date as discussed in note 11 to our audited financial statements and note 5 to our unaudited financial statements, each of which are included elsewhere in this prospectus.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

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

**Accrued clinical expenses**

When preparing our financial statements, we are required to estimate our accrued clinical expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with parties depend on factors, such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. Examples of estimated accrued clinical expenses include:

fees paid to investigative sites and laboratories in connection with clinical studies;

fees paid to CROs in connection with clinical studies, if CROs are used; and

fees paid to contract manufacturers in connection with the production of clinical study materials.

When accruing clinical expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

**Research and development expenses**

We account for research and development costs by expensing such costs to operations as incurred. Research and development costs primarily consist of personnel costs, outsourced research activities, laboratory supplies and license fees.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. If expectations change such that we do not expect we will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments would be charged to expense.

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**Stock-based compensation**

We measure stock-based compensation cost at the accounting measurement date based on the fair value of the option, and recognize the expense on a straight-line basis over the requisite service period of the option, which is typically the vesting period. We estimate the fair value of each option using the Black-Scholes option pricing model that takes into account the fair value of our common stock, the exercise price, the expected life of the option, the expected volatility of our common stock, expected dividends on our common stock, and the risk-free interest rate over the expected life of the option. Due to our limited history, we use the simplified method described in the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*, to determine the expected life of the option grants. The estimate of expected volatility is based on a review of the historical volatility of similar publicly held companies in the biotechnology field over a period commensurate with the option's expected term. We have never declared or paid any cash dividends on our common stock and we do not expect to do so in the foreseeable future. Accordingly, we use an expected dividend yield of zero. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant valuation for a period commensurate with the option's expected term. These assumptions are highly subjective and changes in them could significantly impact the value of the option and hence the related compensation expense.

We apply an estimated forfeiture rate to current period expense to recognize compensation expense only for those awards expected to vest. We estimate forfeitures based upon historical data, adjusted for known trends, and will adjust the estimate of forfeitures if actual forfeitures differ or are expected to differ from such estimates. Subsequent changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and also will impact the amount of stock-based compensation expense in future periods.

Stock-based compensation expense recognized for options granted to consultants is also based upon the fair value of the options issued, as determined by the Black-Scholes option pricing model. However, the unvested portion of such option grants is re-measured at each reporting period, until such time as the option is fully vested.

We have historically granted stock options at exercise prices not less than the fair value of our common stock as determined by our board of directors. Our board of directors has historically determined, with input from management, the estimated fair value of our common stock on the date of grant based on a number of objective and subjective factors, including:

the prices at which we sold shares of convertible preferred stock;

the superior rights and preferences of securities senior to our common stock at the time of each grant;

the likelihood of achieving a liquidity event such as a public offering or sale of our company;

our historical operating and financial performance and the status of our research and product development efforts; and

the achievement of enterprise milestones, including our entering into collaboration and license agreements.

Our board of directors also considers valuations provided by management in determining the fair value of our common stock and has consistently used the most recent valuation provided by management for determining the fair value of our common stock unless a specific event occurs that necessitates an interim valuation.

The valuations are prepared based on the guidance from the Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or Practice Aid, that was developed by staff of the American Institute of Certified Public Accountants and a task force comprising representatives from the appraisal, preparer, public accounting, venture capital and academic communities and utilized the probability-weighted expected return method, or PWERM, as outlined in the Practice Aid. PWERM considers the value of preferred and common stock based upon the probability-weighted present value of expected future net cash flows, considering each of the possible future events, as well as the rights and preferences of each share class. PWERM is complex as it requires numerous assumptions relating to potential future outcomes of

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equity, hence, the use of this method can be applied: (1) when possible future outcomes can be predicted with reasonable certainty; and (2) when there is a complex capital structure (i.e., several classes of preferred and common stock).

**Fair value measurements**

We define fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions.

The fair value hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). Our financial assets and liabilities are classified within the fair value hierarchy based on the lowest level of input that is significant to the fair value measurement. The three levels of the fair value hierarchy, and its applicability to our financial assets, are described below:

*Level 1* Unadjusted quoted prices in active markets that are accessible at the measurement date of identical, unrestricted assets.

*Level 2* Quoted prices for similar assets, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data. Level 2 includes investments valued at quoted prices adjusted for legal or contractual restrictions specific to the security.

*Level 3* Pricing inputs are unobservable for the asset, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the asset. Level 3 includes private investments that are supported by little or no market activity.

As of December 31, 2013 and 2012, and March 31, 2014, we hold financial assets which are measured using Level 1, Level 2 and Level 3 inputs. Assets measured using Level 1 inputs include money market funds, which are valued using quoted market prices with no valuation adjustments applied. Assets measured using Level 2 inputs include marketable securities that consist primarily of government agency securities (direct issuance bonds, corporate bonds, etc.) and are valued using third-party pricing resources, which generally use interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing. Assets and liabilities measured using Level 3 inputs include our stock asset, stock liability, other liability and warrant liability. The stock asset represents the prepaid balance and the stock liability represents the accrued balance of the research and development expense related to the stock dividends to be issued to Nordic in shares of our series A-6 convertible preferred stock (or in shares of common stock if we list our common stock on a national exchange) which is being recognized ratably over the estimated per patient treatment period under the three work statements executed with Nordic, or the Nordic Work Statements. The other liability represents the liability to issue shares of our series A-6 convertible preferred stock for services rendered in connection with the Nordic Work Statements. The liability is calculated based upon the number of shares earned by Nordic through the performance of clinical trial services multiplied by the estimated fair value of our series A-6 convertible preferred stock at each reporting date. The fair values of the stock asset, stock liability and other liability are based upon the fair value of our series A-6 convertible preferred stock as determined using PWERM, as described above.

The warrant liability represents the liability for the warrants issued to the placement agent we engaged in connection with our series A-1 convertible preferred stock financing, to the investors in our series B convertible preferred stock financing in April and May 2013, and Series B-2 convertible preferred stock financing in February and March 2014, and to the lenders in connection with our Credit Facility. The warrant liability is calculated using the Black-Scholes option pricing method.

As of December 31, 2013, we held no Level 3 assets and Level 3 liabilities represent approximately 57% of our total assets and 20% of our total liabilities. As of March 31, 2014, Level 3 assets and Level 3 liabilities represent approximately 18% of our total assets and 17% of our total liabilities. The other liability

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balance will continue to increase until we issue the accrued shares of series A-6 preferred stock to Nordic. The stock liability balance will fluctuate with the other liability and amount of research and development expense related to stock dividend amounts being recognized ratably over the estimated per patient treatment period. Increases and decreases in the aggregate fair value of these liabilities will affect net loss as changes in fair value are recognized as other income (expense), but the changes will not significantly impact our liquidity and capital resources.

**RESULTS OF OPERATIONS**

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

**Three Months Ended March 31, 2014 and March 31, 2013 (in thousands, except percentages)**

	<b>THREE MONTHS ENDED</b>		<b>CHANGE</b>	
	<b>2014</b>	<b>2013</b>	<b>\$</b>	<b>%</b>
<b>Operating expenses:</b>				
Research and development	\$ 9,717	\$ 17,287	\$ (7,570)	(44)%
General and administrative	2,139	1,578	561	36%
Loss from operations	(11,856)	(18,865)	(7,009)	(37)%
<b>Other (expense) income:</b>				
Other (expense) income, net	(2,233)	11,256	13,489	120%
Interest (expense) income, net	(399)	(696)	(297)	(43)%
Net loss	\$ (14,488)	\$ (8,305)	\$ 6,183	74%

*Research and development expenses* For the three months ended March 31, 2014, research and development expense was \$9.7 million compared to \$17.3 million for the three months ended March 31, 2013, a decrease of \$7.6 million, or 44%. This decrease is primarily a result of a decrease in the total professional contract service costs associated with the development of Abaloparatide-SC and Abaloparatide-TD. During the three months ended March 31, 2014, we incurred professional contract service costs associated with the development of Abaloparatide-SC and Abaloparatide-TD of \$8.1 million and \$0.2 million, respectively, compared to \$12.1 million and \$4.4 million, respectively, for the three months ended March 31, 2013. The decrease in contract service costs associated with the development of Abaloparatide-SC is primarily a result of fewer patients enrolled in the Phase 3 clinical trial as of March 31, 2014, as compared to the three months ended March 31, 2013. The decrease in contract service costs associated with the development of Abaloparatide-TD is as a result of the completion of the Phase 2 clinical trial (which began dosing patients in September 2012) in September 2013. We expect that costs associated with the development of Abaloparatide-SC will continue to decrease over the course of the clinical trial as patients complete treatment. We expect that the costs associated with the development of Abaloparatide-TD will increase as we begin to advance an optimized Abaloparatide-TD product in additional clinical studies, followed by a Phase 3 bridging study. In addition, there will be variability from quarter to quarter in the costs for Abaloparatide-SC, driven primarily by the euro/dollar exchange rate and fluctuations in the value of the convertible preferred stock issuable to Nordic under the Stock Issuance Agreement, which is more fully described below under "Liquidity and Capital Resources Research and Development Agreements."

*General and administrative expenses* For the three months ended March 31, 2014, general and administrative expense was \$2.1 million compared to \$1.6 million for the three months ended March 31, 2013, an increase of \$0.5 million, or 36%. This increase was primarily the result of an increase during the three months ended March 31, 2014, in legal fees of approximately \$0.3 million, consulting support of

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approximately \$0.2 million, as well as an increase in compensation expense as a result of an increase in headcount and non-cash stock-based compensation expense.

*Other (expense) income, net* For the three months ended March 31, 2014, other expense, net of other income, was \$2.2 million, as compared to other income, net of expense during the three months ended March 31, 2013 of \$11.3 million. Other expense, net of other income, primarily reflects changes in the fair value of the stock asset, stock liability, other liability and warrant liability as discussed in notes 5 and 7 to our financial statements included in our condensed quarterly financial statements for the three months ended March 31, 2014. The \$2.2 million of other expense, net of income, for the three months ended March 31, 2014 was primarily due to an increase in the fair value of our stock liability and warrant liability as a result of an overall increase in the fair value of the underlying convertible preferred stock from December 31, 2013 to March 31, 2014. The \$11.3 million of other income, net of expense, for the three months ended March 31, 2013 was primarily due to a decrease in the fair value of our stock liability and warrant liability as a result of an overall decrease in the fair value of the underlying convertible preferred stock from December 31, 2012 to March 31, 2013.

*Interest (expense) income* For the month ended March 31, 2014, interest expense, net of interest income, was \$0.4 million compared to \$0.7 million for the three months ended March 31, 2013, a decrease of \$0.3 million, or 43%. This decrease was primarily a result of lower average debt outstanding during the three months ended March 31, 2014 as compared to the three months ended March 31, 2013.

**Years Ended December 31, 2013 and December 31, 2012 (in thousands, except percentages)**

	YEARS ENDED		CHANGE	
	DECEMBER 31, 2013	2012	\$	%
Operating expenses:				
Research and development	\$ 60,536	\$ 54,961	\$ 5,575	10%
General and administrative	6,829	9,469	(2,640)	(28)%
Loss from operations	(67,365)	(64,430)	(2,935)	5%
Other (expense) income:				
Other income (expense), net	9,085	(2,095)	11,180	(534)%
Interest (expense) income, net	(2,410)	(2,603)	193	(7)%
Net loss	\$ (60,690)	\$ (69,128)	\$ 8,438	

*Research and development expenses* For the year ended December 31, 2013, research and development expense was \$60.5 million compared to \$55.0 million for the year ended December 31, 2012, an increase of \$5.6 million, or 10%. During the year ended December 31, 2013, we incurred professional contract services associated with the development of Abaloparatide-SC and Abaloparatide-TD of \$57.4 million, compared to \$50.7 million for the year ended December 31, 2012. This increase was primarily the result of additional expenses incurred for the enrollment of patients in our Phase 3 clinical trial of Abaloparatide-SC, which began dosing of patients in April 2011 and completed enrollment in March 2013, and for the enrollment of patients in our Phase 2 clinical trial of Abaloparatide-TD, which began dosing patients in September 2012 and completed patient visits in August 2013. We expect that Abaloparatide-SC expenses will decrease over the course of the clinical study as patients complete treatment. In addition, there will be variability from quarter to quarter in the costs for Abaloparatide-SC, driven primarily by the euro/dollar exchange rate and fluctuations in the value of the convertible preferred stock issuable to Nordic under the Stock Issuance Agreement, which is more fully described below under "Liquidity and Capital Resources - Research and Development Agreements."

*General and administrative expenses* For the year ended December 31, 2013, general and administrative expense was \$6.8 million compared to \$9.5 million for the year ended December 31, 2012, a decrease of \$2.6 million, or 28%. This decrease was primarily the result of significant fees incurred during the year ended December 31, 2012 for consulting and legal costs associated with the compilation and review of our various filings with the Securities and Exchange Commission, including the filing of our first Form 10-K as a reporting company, and a one-time non-recurring consultation fee of approximately \$0.3 million, as well as a decrease in the amount of franchise tax expense recognized during the year ended December 31, 2013, as compared to the year ended December 31, 2012.



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*Other income (expense), net* For the year ended December 31, 2013, other income, net of other expense, was \$9.1 million. Other income, net of other expense, primarily reflects changes in the fair value of the stock liability and other liability as discussed in notes 11 and 13 to our financial statements included elsewhere in this prospectus. The \$9.1 million of other income, net of expense, as of December 31, 2013 was primarily due to a decrease in the fair value of our stock liability and other liability as a result of an overall decline in the fair value of the underlying convertible preferred stock from December 31, 2012 to December 31, 2013.

*Interest (expense) income, net* For the year ended December 31, 2013, interest expense, net of interest income, was \$2.4 million compared to \$2.6 million for the year ended December 31, 2012, a decrease of \$0.2 million, or 7%. This decrease was primarily a result of lower average debt outstanding during the year ended December 31, 2013 as compared to the year ended December 31, 2012.

**Years Ended December 31, 2012 and December 31, 2011 (in thousands, except percentages)**

	YEARS ENDED		CHANGE	
	DECEMBER 31, 2012	2011	\$	%
Operating expenses:				
Research and development	\$ 54,961	\$ 36,179	\$ 18,782	52%
General and administrative	9,469	5,330	4,139	78%
Loss from operations	(64,430)	(41,509)	(22,921)	55%
Other (expense) income:				
Other (expense) income, net	(2,095)	(236)	(1,859)	788%
Interest (expense) income, net	(2,603)	(731)	(1,872)	256%
Net loss	\$ (69,128)	\$ (42,476)	\$ (26,652)	

*Research and development expenses* For the year ended December 31, 2012, research and development expense was \$55.0 million compared to \$36.2 million for the year ended December 31, 2011, an increase of \$18.8 million, or 52%. This increase was primarily the result of increased professional contract services associated with the development of Abaloparatide-SC and Abaloparatide-TD. For the year ended December 31, 2012, we incurred professional contract services associated with the development of Abaloparatide-SC and Abaloparatide-TD of \$50.7 million, compared to \$33.4 million for the year ended December 31, 2011. This increase was primarily the result of expenses incurred for continuing enrollment of patients in our Phase 3 study of Abaloparatide-SC, which began with the dosing of patients in April 2011.

*General and administrative expenses* For the year ended December 31, 2012, general and administrative expense was \$9.5 million compared to \$5.3 million for the year ended December 31, 2011, an increase of \$4.1 million or 78%. The increase was primarily the result of increased employee related costs, including an increase in stock-based compensation expense and salary expense as a result of an increase in employee headcount, as well as an increase in legal and accounting fees and the costs associated with being a public company.

*Other (expense) income, net* For the year ended December 31, 2012, other expense, net of other income, was \$2.1 million. Other expense, net of other income, primarily reflects changes in the fair value of the stock liability and other liability from the date of the initial accrual to the reporting date as discussed in notes 11 and 13 to our financial statements included elsewhere in this prospectus.

*Interest (expense) income, net* For the year ended December 31, 2012, interest expense, net of interest income, was \$2.6 million compared to \$0.7 million for the year ended December 31, 2011. Interest expense reflects interest due on our Credit Facility.

Table of Contents**LIQUIDITY AND CAPITAL RESOURCES**

From inception to March 31, 2014, we have incurred an accumulated deficit of \$296.2 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and expenses supporting those activities. We have financed our operations since inception primarily through the private sale of preferred stock as well as the receipt of \$5.0 million in fees associated with an option agreement. We have also borrowed \$25.0 million under our Credit Facility in three term loans. Our total cash, cash equivalents and marketable securities balance as of March 31, 2014 is \$29.6 million. We believe that our existing resources will be sufficient to fund our planned operations into the third quarter of 2014. However, we believe that the proceeds from this offering, together with our existing resources, will be sufficient to fund our planned operations into the third quarter of 2015. We have based this estimate on assumptions that may prove to be wrong, and we could use up our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical trials. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any product candidates from the FDA and other regulatory authorities.

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

	YEARS ENDED DECEMBER 31,			THREE MONTHS ENDED MARCH 31,	
	2013	2012	2011	2014	2013
Net cash (used in) provided by:					
Operating activities	\$ (45,017)	\$ (43,158)	\$ (35,896)	\$ (7,206)	\$ (7,279)
Investing activities	3,971	27,435	(23,800)		4,000
Financing activities	34,696	9,248	74,242	24,461	(1,969)
Net (decrease) increase in cash and cash equivalents	\$ (6,350)	\$ (6,475)	\$ 14,546	\$ 17,255	\$ (5,248)

**Cash Flows from Operating Activities**

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

Net cash used in operating activities for the three months ended March 31, 2013 was \$7.3 million, which was primarily the result of a net loss of \$8.3 million and \$7.2 million net non-cash adjustments to reconcile net loss to net cash used in operations, partially offset by changes in working capital of \$8.2 million. The \$8.3 million net loss is primarily due to expenses incurred in connection with our ongoing Phase 3 clinical trial of Abaloparatide-SC and our Phase 2 clinical study of Abaloparatide-TD, which commenced during the third quarter of 2012. The \$7.2 million net non-cash adjustments to reconcile net loss to net cash used in operations, includes an \$11.3 million reduction to the fair value of our other current assets, warrant liability and other liability as a result of a decline in the fair value of underlying convertible preferred stock from December 31, 2012 to March 31, 2013, and was partially offset by \$3.6 million of research and development expenses settled in stock.

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Net cash used in operating activities for the year ended December 31, 2013 was \$45.0 million, which was primarily the result of a net loss of \$60.7 million, partially offset by net changes in working capital of \$9.7 million and \$6.0 million net non-cash adjustments to reconcile net loss to net cash used in operations. The \$60.7 million net loss was primarily due to expenses incurred in connection with our ongoing Phase 3 clinical study of Abaloparatide-SC and our Phase 2 clinical study of Abaloparatide-TD, which finished dosing patients during the three months ended September 30, 2013. The \$6.0 million net non-cash adjustments to reconcile net loss to net cash used in operations included \$13.1 million of research and development expenses settled in stock and stock-based compensation expense of \$1.5 million, and was partially offset by a \$9.1 million reduction in the fair value of our warrant liability, stock liability and other liability as a result of a decline in the fair value of the underlying convertible preferred stock from December 31, 2012 to December 31, 2013.

Net cash used in operating activities for the year ended December 31, 2012 was \$43.2 million, which was primarily the result of a net loss of \$69.1 million, partially offset by changes in working capital of \$6.4 million and \$19.5 million of non-cash adjustments to reconcile net loss to net cash used in operations, including \$15.1 million of research and development expenses settled in stock. The \$69.1 million net loss and \$15.1 million of research and development expenses settled in stock are primarily due to expenses incurred in connection with our ongoing Phase 3 clinical study of Abaloparatide-SC and our Phase 2 clinical study of Abaloparatide-TD, which commenced during the third quarter of 2012.

**Cash Flows from Investing Activities**

There was no net cash provided by or used in investing activities for the three months ended March 31, 2014. Net cash provided by investing activities for the three months ended March 31, 2013 was \$4.0 million. The net cash provided by investing activities during the three months ended March 31, 2013 was a result of \$4.0 million in net proceeds received from the sale or maturity of marketable securities.

Net cash provided by investing activities for the year ended December 31, 2013 was \$4.0 million, as compared to net cash provided by investing activities of \$27.4 million for the year ended December 31, 2012.

The net cash provided by investing activities during the year ended December 31, 2013 was primarily a result of \$21.0 million net proceeds received from the sale or maturity of marketable securities, partially offset by \$17.1 million in purchases of marketable securities. The net cash provided by investing activities during the year ended December 31, 2012 was primarily a result of a \$46.5 million in net proceeds from the sale or maturity of marketable securities, partially offset by \$19.0 million in purchases of marketable securities.

Our investing cash flows will be impacted by the timing of purchases and sales of marketable securities. All of our marketable securities have contractual maturities of less than one year. Due to the short-term nature of our marketable securities, we would not expect our operational results or cash flows to be significantly affected by a change in market interest rates due to the short-term duration of our investments.

On January 7, 2014, we entered into a letter agreement with Vetter Pharma International GMBH, or Vetter, that authorized Vetter to begin purchasing and installing dedicated equipment that will be utilized in the formulation and filling of Abaloparatide-SC. In accordance with the letter agreement, the total capital expenditures are not to exceed €0.6 million (\$0.9 million) without our prior written consent. We expect that all equipment will be purchased and installed in 2014 and funded by our existing cash and cash equivalents.

**Cash Flows from Financing Activities**

Net cash provided by financing activities for the three months ended March 31, 2014 was \$24.5 million, as compared to \$2.0 million net cash used in financing activities for the three months ended March 31, 2013.

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

Net cash used in financing activities for the year three months March 31, 2013 consisted of \$2.0 million of payments under our Credit Facility.

Net cash provided by financing activities for the year ended December 31, 2013 was \$34.7 million, as compared to \$9.2 million of net cash provided by financing activities for the year ended December 31, 2012.

Net cash provided by financing activities for year ended December 31, 2013 consisted of \$42.9 million of net proceeds from the issuance of our series B convertible preferred stock in April and May of 2013, partially offset by payments under our Credit Facility of \$8.2 million.

Net cash provided by financing activities for the year ended December 31, 2012 consists of \$12.5 million of proceeds from our Credit Facility and \$0.3 million of net proceeds from stock option exercises, offset by \$3.5 million of payments on our Credit Facility.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing and potential collaboration agreements. Through March 31, 2014, almost all of our financing has been through private placements of preferred stock and borrowings under our Credit Facility. We can give no assurances that any additional capital that we are able to obtain, if any, will be sufficient to meet our needs. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies. We may also need additional funds for possible future strategic acquisitions of businesses, products or technologies complementary to our business. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition and results of operations. Additional equity financing may be dilutive to the holders of our common stock and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

**Financings**

Through March 31, 2014, we have received aggregate net cash proceeds of \$238.2 million from the sale of shares of our preferred stock as follows:

ISSUE	YEAR	NO. SHARES	NET PROCEEDS (IN THOUSANDS)
Series B redeemable convertible preferred stock <sup>(1)</sup>	2003, 2004, 2005	1,599,997	\$ 23,775
Series C redeemable convertible preferred stock <sup>(1)</sup>	2006, 2007, 2008	10,146,629	82,096
Series A-1 convertible preferred stock <sup>(1)</sup>	2011	9,223,041	61,591
Series A-5 convertible preferred stock <sup>(1)</sup>	2011	64,430	525
Series B convertible preferred stock	2013	701,235	42,870
Series B-2 convertible preferred stock	2014	448,060	27,368
<b>Total</b>		<b>22,183,392</b>	<b>\$ 238,225</b>

(1)

Share amounts stated in pre-Merger shares, which converted into the rights to one-tenth of one share pursuant to the Merger.

*Existing credit facility.* On May 23, 2011, we entered into our credit facility with GECC, as agent and a lender, and Oxford Finance LLC, as a lender, consisting of three term loans, pursuant to which we may draw an aggregate of \$25.0 million. We drew \$6.3 million under the initial term loan on May 23, 2011. The initial term loan is repayable over a term of 42 months, including a six-month interest-only period, and



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bears interest at 10.16% per year. We drew \$6.3 million under the second term loan on November 21, 2011. The second term loan is repayable over a term of 36 months, including an approximately six-month interest-only period, and bears interest at 10.0% per year. On May 29, 2012, we drew \$12.5 million under the third term loan. The third term loan is repayable over a term of 30 months, including an approximated six-month interest-only period, and bears interest at 10.0% per year. On each of May 23, 2011, November 21, 2011 and May 29, 2012, we issued warrants to GECC and Oxford Finance LLC for the purchase of up to a total 12,280 shares of series A-1 preferred stock. The warrants each have a term of 10 years. The terms of the warrants provide that the exercise price may be adjusted in the event we issue shares of the Series A-1 at a price lower than \$81.42 per share. As a result of an anti-dilution adjustment effected in connection with the issuance of the new series B convertible preferred stock in May 2013, the exercise price of the warrants has been effectively reduced, on an as-converted basis, to \$16.970 as of March 31, 2014. On May 30, 2014, we repaid all amounts owed by us under this credit facility using proceeds from our new term loan. See "New Credit Facility" below.

*Series B preferred stock financing.* On April 23, 2013, we entered into a Series B Convertible Preferred Stock and Warrant Purchase Agreement, or the Purchase Agreement, and consummated a first closing under the Purchase Agreement, whereby in exchange for aggregate proceeds of approximately \$43.0 million, we issued 700,098 shares of our series B convertible preferred stock, or Series B, which are convertible into an aggregate of 3,070,626 shares of our common stock and warrants to purchase up to a total of 767,651 shares of our common stock at an exercise price of \$14.004 per share. On May 10, 2013, we consummated a second closing under the Purchase Agreement, whereby in exchange for aggregate proceeds of approximately \$0.1 million, we issued 1,137 shares of Series B and warrants to purchase up to a total of 1,246 shares of our common stock.

The shares of our Series B are convertible, in whole or in part, at the option of the holder at any time into shares of common stock, on an approximately 4.386-for-one basis at an initial effective conversion price of \$14.004 per share. Holders of shares of Series B are entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrue on a daily basis commencing on the date of issuance of the shares of Series B. Dividends are payable, as accrued, upon liquidation, event of sale, and conversion to common stock, including upon mandatory conversion of the Series B upon the Company's common stock becoming listed for trading on a national stock exchange. The holders of shares of Series B are also entitled to dividends declared or paid on any shares of common stock.

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

Each share of Series B has the right to that number of votes per share as is equal to the number shares of common stock into which such share of Series B is then convertible.

The warrants issuable pursuant to the Purchase Agreement are exercisable at any time prior to the fifth anniversary of their issuance.

The issuance of the shares of Series B pursuant to the Purchase Agreement and accompanying warrants under the Purchase Agreement resulted in an adjustment to the conversion price of the Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series A-3 convertible preferred stock, or the Anti-Dilution Adjustment. As a result of the Anti-Dilution Adjustment, the effective conversion price of each share of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and

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Series A-3 convertible preferred stock was reduced from \$18.564 to \$17.390 as of December 31, 2013. Accordingly, each share of Series A-1, Series A-2 and Series A-3 is convertible into 4.682 shares of our common stock as of December 31, 2013.

*Series B-2 preferred stock financing.* On February 14, 2014, we entered into the a Series B-2 Convertible Preferred Stock and Warrant Purchase Agreement, pursuant to which we may raise up to approximately \$40.2 million through the issuance of (1) up to 655,000 shares of series B-2 convertible preferred stock, or Series B-2, and (2) warrants to acquire up to 718,201 shares of its common stock at an exercise price of \$14.004 per share.

Shares of our Series B-2 are convertible, in whole or in part, at the option of the holder at any time into shares of common stock, on an approximately 4.386-for-one basis at an initial effective conversion price of \$14.004 per share. Holders of shares of Series B-2 are entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrue on a daily basis commencing on the date of issuance of the shares of Series B-2. Dividends are payable, as accrued, upon liquidation, event of sale, and conversion to common stock, including upon mandatory conversion of the Series B-2 upon the Company's common stock becoming listed for trading on a national stock exchange. The holders of shares of Series B-2 are also entitled to dividends declared or paid on any shares of common stock.

Shares of Series B-2 rank senior in payment to any other dividends payable on any and all series of preferred stock and upon liquidation, or an event of sale, each share of Series B-2 shall rank equally with each other share of Series B-2 and New Series B, senior to all shares of Series A-1, Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6 and senior to all shares of common stock. In the event of a liquidation, dissolution, or winding-up of the Company, the holders of the Series B-2 are entitled to be paid first out of the assets available for distribution, before any payment is made to the Series A-1, Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6. Payment to the holders of Series B-2 shall consist of one and a half (1.5) times the original issuance price of \$61.42, plus all accrued but unpaid dividends.

On various dates in February and March 2014, we consummated closings under the Series B-2 Purchase Agreement, whereby, in exchange for aggregate gross proceeds to us of approximately \$27.5 million, we issued an aggregate of 448,060 Series B-2 Shares and warrants to purchase up to a total of 491,293 shares of our common stock.

Each share of Series B-2 has the right to that number of votes per share as is equal to the number shares of common stock into which such share of Series B-2 is then convertible.

The warrants issuable pursuant to the Purchase Agreement are exercisable for a period of five years from issuance.

The issuances of the Series B-2 and accompanying warrants under the Purchase Agreement resulted in an additional adjustment to the Conversion Price of the Series A-1, Series A-2 and Series A-3. As a result of such adjustment, the effective conversion price of each share of Series A-1, Series A-2 and Series A-3 was reduced from \$17.390 to \$16.970. Accordingly, each share of Series A-1, Series A-2 and Series A-3 is currently convertible into approximately 4.798 shares of common stock.

*New credit facility.* On May 30, 2014, we entered into a Loan and Security Agreement, or the new credit facility, with Solar Capital Ltd., or Solar, as collateral agent and a lender, and Oxford Finance LLC, or Oxford, as a lender, pursuant to which Solar and Oxford agreed to make available to us \$30.0 million in the aggregate subject to certain conditions to funding. An initial term loan was made on May 30, 2014 in an aggregate principal amount equal to \$21.0 million, or the initial term loan. We are required to make interest-only payments through June 1, 2015, and beginning on July 1, 2015, we are required to make payments of principal and accrued interest in equal monthly installments over a term of 36 months. If we consummate any one or more public or private stock offerings, equity raises or strategic partner arrangements resulting in the receipt of at least \$65.0 million in aggregate net cash proceeds on or prior to May 31, 2015, we will be permitted to make interest-only payments through December 1, 2015 rather than July 1, 2015, and beginning on January 1, 2016, we would be required to make payments of principal and

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accrued interest in equal monthly installments over a term of 30 months. In addition to the initial term loan, we may request an additional term loan in an aggregate principal amount of \$9.0 million, or the second term loan, after the completion of our initial public offering if the net cash proceeds are at least \$65.0 million subject to certain customary conditions to funding. We do not expect the net cash proceeds from our initial public offering to be at least \$65.0 million. Therefore, we do not expect to request the second term loan. Both the initial term loan and the second term loan bear interest per annum at 9.85% plus one-month LIBOR (customarily defined). All principal and accrued interest on the initial term loan and, if funded, the second term loan, are due on June 1, 2018.

We used approximately \$9.3 million of the initial term loan to repay all the amounts owed by us under our existing credit facility with General Electric Capital Corporation and Oxford Finance LLC.

As security for our obligations under the new credit facility, we granted a security interest in substantially all of our existing and after-acquired assets except for our intellectual property and certain other customary exclusions.

On May 30, 2014, pursuant to the Loan and Security Agreement with Solar and Oxford, we issued to Solar and Oxford warrants to purchase an aggregate of up to 10,258 shares of our series B-2 convertible preferred stock at an exercise price equal to \$61.42 per share. Upon the closing of this offering at the assumed initial public offering price of \$8.00 per share and the automatic conversion of our series B-2 convertible preferred stock into common stock, these warrants will be exercisable for up to 78,760 shares of common stock. These warrants are immediately exercisable for cash or by net exercise and will expire five years from their issuance. If the initial public offering price in this offering is less than or greater than \$8.00 per share, the number of shares of common stock issuable upon exercise of these warrants will increase or decrease, respectively. For additional information regarding these warrants, see "Capitalization Series B-2 Convertible Preferred Stock".

**Research and Development Agreements**

*Abaloparatide-SC Phase 3 Clinical Trial* On March 29, 2011, we and Nordic entered into a Clinical Trial Services Agreement, a Work Statement NB-1, or the Work Statement NB-1, under such Clinical Trial Services Agreement and a related Stock Issuance Agreement, as amended to date, or the Stock Issuance Agreement. Pursuant to the Work Statement NB-1, Nordic is managing the Phase 3 clinical trial, or the Phase 3 Clinical Trial, of Abaloparatide-SC and is being compensated for such services in a combination of cash and shares of stock.

In December 2011, we entered into an amendment to the Work Statement NB-1, or the First Amendment. Pursuant to the original terms of the Work Statement NB-1, the study was to be conducted in 10 countries at a specified number of sites within each country. The terms of the First Amendment (1) provided for two additional countries (the United States and India) in which the trial would be conducted, (2) specified a certain number of sites within each such additional country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect the addition of such countries and sites within the study's parameters. Payments to be made by us to Nordic under the First Amendment are denominated in both euros and U.S. dollars and total up to €717,700 (\$988,775) and \$289,663, respectively, for the 15 additional study sites in India contemplated by the First Amendment and up to €1.2 million (\$1.7 million) and \$143,369, respectively, for the five additional study sites in the United States contemplated by the First Amendment.

In June 2012, we entered into a second amendment to the Work Statement NB-1, or the Second Amendment. Pursuant to the original terms of the Work Statement NB-1, as amended by the First Amendment, the study was to be conducted in 12 countries at a specified number of sites within each country. The terms of the Second Amendment (1) increased the overall number of sites by adding sites in Europe, Brazil and Argentina and removing other sites, (2) specified a certain number of sites within each country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect additional services to be provided at existing sites and the addition of the new study sites



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within the study's parameters. The Second Amendment also provided that cash payments to Nordic under the Clinical Trial Services Agreement as well as the payment of shares of stock under the related Stock Issuance Agreement each be reduced by an amount of €11,941 (\$16,451) per subject for any subjects enrolled in India or the United States. Such reductions are applied in pro rata monthly installments. Payments to be made by us to Nordic under the Second Amendment in connection with the additional services provided at existing sites and the conduct of the study at the new study sites are denominated in both euros and U.S. dollars and total of up to €3.7 million (\$5.1 million) and \$205,540, respectively.

In March 2014, we entered into a fourth amendment to the Work Statement NB-1, or the Fourth Amendment. Pursuant to the terms of the Fourth Amendment, we agreed to pay to Nordic an additional performance incentive, or a Performance Incentive Payment, of \$500,000 for every 50 patients that, subsequent to March 28, 2014, complete all end-of-study procedures, up to a maximum aggregate amount of additional payments equal to \$5.0 million. Pursuant to the Work Statement NB-1, as amended by the Fourth Amendment, any Performance Incentive Payment would be paid in cash in the event an underwritten initial public offering of shares of our common stock, or an IPO, is consummated prior to May 31, 2014. On May 19, 2014, we entered into a fifth amendment to the Work Statement NB-1, which amended the date from May 31, 2014 to June 30, 2014. Should an IPO not be consummated by us prior to June 30, 2014, any Performance Incentive Payments will be paid instead through the issuance to Nordic of shares of our capital stock under the same model for equity-based compensation that is contemplated by our existing outstanding work statements under the Clinical Trial Services Agreement.

Pursuant to the Work Statement NB-1, we are required to make certain per patient payments denominated in both euros and U.S. dollars for each patient enrolled in the Phase 3 Clinical Trial followed by monthly payments for the duration of the study and final payments in two equal euro-denominated installments and two equal U.S. dollar-denominated installments. Changes to the Clinical Trial schedule may alter the timing, but not the aggregate amounts of the payments.

The Work Statement NB-1, as amended on December 9, 2011, June 18, 2012 and March 28, 2014, provides for a total of up to approximately €41.2 million (\$56.7 million) of euro-denominated payments and a total of up to approximately \$3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus aggregate Performance Incentive Payments of up to \$5.0 million. These payments may be adjusted based upon actual sites opened, work performed or number of patients enrolled.

Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase the equivalent of €371,864 of series A-5 convertible preferred stock at \$8.142 per share, and 64,430 shares of series A-5 convertible preferred stock were sold to Nordic on May 17, 2011 for proceeds of \$525,154. These shares were exchanged in a merger of the former operating company with a subsidiary of ours in May 2011 (see note 3 to our audited financial statements included elsewhere in this prospectus) for an aggregate of 6,443 shares of our series A-5 convertible preferred stock.

The Stock Issuance Agreement provides that Nordic is entitled to receive quarterly stock dividends, payable in shares of series A-6 convertible preferred stock or shares of common stock if our preferred stock has been converted in accordance with its amended certificate of incorporation, having an aggregate value, under the Work Statement NB-1 of up to €36.8 million (\$50.7 million), or the Nordic Accruing Dividend. In the event Nordic sells the shares of series A-5 convertible preferred stock or in the event the shares of series A-5 convertible preferred stock are converted into common stock in accordance with our amended certificate of incorporation, this right to receive the Nordic Accruing Dividend will terminate, but a right to receive an equivalent number of shares of series A-6 convertible preferred stock or common stock, as applicable, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

The Nordic Accruing Dividend related to the Phase 3 Clinical Trial is determined based upon the estimated period that will be required to complete the Phase 3 Clinical Trial. On the last business day of each calendar quarter (each, an "Accrual Date"), beginning with the quarter ended June 30, 2011, the Company has a liability, under the Work Statement NB-1 to issue shares of Series A-6 (or common stock, after the conversion of the Company's preferred stock into common stock) to Nordic that is referred to as the

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Applicable Quarterly Amount and is equal to €36.8 million (\$50.7 million) (subject to adjustment in accordance with the applicable provisions of the Second Amendment relating to consideration payable for patients enrolled in India and the U.S.) minus the aggregate value of any prior Nordic Accruing Dividend accrued divided by the number of calendar quarters it will take to complete the Phase 3 Clinical Trial. To calculate the aggregate number of shares due to Nordic in each calendar quarter, the Company converts the portion of €36.8 million (\$50.7 million) to accrue in such calendar quarter into U.S. dollars using the simple average of the exchange rate for buying U.S. dollars with euros for all Mondays in such calendar quarter. We then calculate the aggregate number of shares to accrue in such calendar quarter by dividing the U.S. dollar equivalent of the Applicable Quarterly Amount, by the greater of (1) the fair market value of our common stock as of the applicable Accrual Date or (2) \$81.42 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic are to be issued when declared or paid by our Board of Directors, who are required to do so upon Nordic's request, or upon an event of sale. As of December 31, 2013, 438,124 shares of Series A-6 were due to Nordic under Work Statement NB-1, as amended. In December 2013, Nordic requested that all shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-1 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 438,124 shares accrued under Work Statement NB-1 on December 31, 2013.

On March 28, 2014, we entered into Amendment No. 2 to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011, or the Second Stock Issuance Agreement Amendment, with Nordic. The Second Stock Issuance Agreement Amendment required that our board of directors declare, as soon as reasonably practical, a stock dividend of 29 shares of our Series A-6 for each share of our outstanding Series A-5, all of which are held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in relation to Work Statement NB-1 and Work Statement NB-3, excluding any Performance Incentive Payments payable in stock. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment provided further that in the event an IPO occurs prior to May 31, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3 for all periods of time after 2014, excluding any Performance Incentive Payments, will be changed from the right to receive stock to the right to receive a total cash payment from us of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, we entered into Amendment No. 3 to the Amended and Restated Stock Issuance Agreement, which amended the date from May 31, 2014 to June 30, 2014. The Amended and Restated Stock Issuance Agreement, as amended, also stipulates that all consideration to be paid to Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an IPO be payable in cash.

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

We recognize research and development expense for the amounts due to Nordic under the Work Statement NB-1 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 3 Clinical Trial, or a twenty-month period. We recognize research and development expense for the amounts due to Nordic under the Fourth Amendment on a per patient basis when the End-of-Study visit and all other required procedures are completed. We recorded \$31.6 million, \$30.8 million, and \$5.1 million of research and development expense during the years ended December 31, 2013, 2012, and 2011, respectively, and \$4.5 million and \$9.1 million of research and development expense during the three months ended March 31, 2014 and 2013, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Trial. During the year ended December 31, 2011, we also recorded approximately \$11.0 million of research and development expense associated with the costs incurred for preparatory and other start-up costs to initiate the Phase 3 Clinical Trial.

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As of March 31, 2014, we had (1) an asset of \$0.3 million reflected in prepaid expenses and other current assets on the balance sheet resulting from services provided by Nordic, which are payable in the form of a stock dividend and (2) a liability of \$12.5 million that is reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

*Abaloparatide-SC Phase 3 Clinical Extension Study* In February 2013, we entered into the Work Statement NB-3 under the Clinical Trial Services Agreement and the related Stock Issuance Agreement. Pursuant to the Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the 18-month Abaloparatide-SC Phase 3 Clinical Trial, or the Extension Study, and will be compensated for such services in a combination of cash and shares of stock. Under the terms of a Letter of Intent that we entered into with Nordic on October 22, 2012 setting forth the parties' obligations to negotiate in good faith to enter into Work Statement NB-3, we were required to make an initial payment of €806,468 (\$1.1 million).

In March 2014, we entered into an amendment to the Work Statement NB-3, or the NB-3 Amendment. The NB-3 Amendment was effective as of February 28, 2014 and provides that Nordic will perform a Period 2 extension study, or the Second Extension, to evaluate an additional eighteen months of standard-of-care osteoporosis management following the Period 1 extension of six months upon completion of the Phase 3 clinical study of our Abaloparatide-SC product. Payments in cash to be made by us to Nordic under the NB-3 Amendment are denominated in both euros and U.S. dollars and total up to approximately €3.0 million (\$4.1 million) and \$527,740, respectively. In addition, we agreed to issue to Nordic shares of our series A-6 convertible preferred stock having a value of up to the sum of approximately €3.0 million (\$4.1 million) and \$527,740 as additional payment for the services to be provided under the NB-3 Amendment, with the issuance of such shares to be made pursuant to the terms of an Amendment No. 2, entered into by us with Nordic on March 28, 2014, to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011.

Payments in cash to be made to Nordic under the Work Statement NB-3, as amended by the NB-3 Amendment are denominated in both euros and U.S. dollars and total up to €7.5 million (\$10.3 million) and \$1.1 million, respectively. In addition, we will issue to Nordic shares of our series A-6 convertible preferred stock having a value of up to €7.5 million (\$10.3 million) and \$0.8 million, as additional payment for services to be provided under the Work Statement NB-3 and the Services Agreement.

The Stock Issuance Agreement provides that, beginning with the quarter ended March 31, 2013, Nordic is entitled to receive quarterly stock dividends in connection with services performed under the Work Statement NB-3, payable in shares of series A-6 convertible preferred stock, or shares of common stock if our preferred stock has been automatically converted into common stock in accordance with our amended certificate of incorporation, having an aggregate value of up to €7.5 million (\$10.3 million) and \$0.8 million. In the event Nordic sells the shares of series A-5 convertible preferred stock or in the event the shares of series A-5 convertible preferred stock are converted into common stock in accordance with our amended certificate of incorporation, this right to receive the Nordic Accruing Dividend will terminate, but a right to receive an equivalent number of shares of series A-6 convertible preferred stock or common stock, as applicable, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

The Nordic Accruing Dividend related to the Extension Study is determined based upon the estimated period that will be required to complete the Extension Study. On each Accrual Date, beginning with the quarter ended March 31, 2013, the Company will recognize a liability to issue shares of series A-6 convertible preferred stock to Nordic with an Applicable Quarterly Amount value equal to €7.5 million (\$10.3 million) and \$0.8 million minus the aggregate value of any previously accrued Nordic Accruing Dividend related to the Extension Study divided by the number of calendar quarters it will take to complete the Extension Study. We calculate the aggregate number of shares of series A-6 convertible preferred stock to accrue in such calendar quarter by dividing such Applicable Quarterly Amount, by the greater of (1) the fair market value of our common stock as of the applicable Accrual Date or (2) \$81.42 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic are to be issued when

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declared or paid by our Board of Directors, who are required to do so upon Nordic's request, or upon an event of sale. As of December 31, 2013, 25,772 shares of Series A-6 were due to Nordic under Work Statement NB-3. In December 2013, Nordic requested that all shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-3 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 25,772 shares accrued under Work Statement NB-3 on December 31, 2013.

On March 28, 2014, we entered into Amendment No. 2 to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011, or the Second Stock Issuance Agreement Amendment, with Nordic. The Second Stock Issuance Agreement Amendment required that our board of directors declare, as soon as reasonably practical, a stock dividend of 29 shares of our Series A-6 for each share of our outstanding Series A-5, all of which are held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in relation to Work Statement NB-1 and Work Statement NB-3, excluding any Performance Incentive Payments payable in stock. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment provided further that in the event an IPO occurs prior to May 31, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3 for all periods of time after 2014, excluding any Performance Incentive Payments, will be changed from the right to receive stock to the right to receive a total cash payment from us of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, we entered into Amendment No. 3 to the Amended and Restated Stock Issuance Agreement, which amended the date from May 31, 2014 to June 30, 2014. The Amended and Restated Stock Issuance Agreement, as amended, also stipulates that all consideration to be paid to Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an IPO be payable in cash.

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

On December 6, 2013, we entered into a Letter of Intent, or the Letter of Intent, with Nordic, which provided that we and Nordic would continue to negotiate the definitive terms of the NB-3 Amendment. Pursuant to the Letter of Intent, we were required to make an initial payment of €222,573 (\$0.3 million) and agreed to commence payment of the cash compensation due in consideration of the services being provided by Nordic under the NB-3 Amendment. The Letter of Intent terminated in accordance with its terms on February 28, 2014 (pursuant to an extension mutually agreed to by the Company and Nordic).

We recognize research and development expense for the amounts due to Nordic under the Work Statement NB-3 and Amendment ratably over the estimated per patient treatment periods beginning upon enrollment or over a nine-month and nineteen-month period, respectively. We recorded \$4.5 million of research and development expense during the year ended December 31, 2013, and \$2.5 million and \$0.5 million of research and development expense during the three months ended March 31, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Extension Study and Second Extension.

As of March 31, 2014, we had (1) an asset of \$0.9 million reflected in prepaid expenses and other current assets on the balance sheet resulting from services provided by Nordic, which are payable in the form of a stock dividend and (2) a liability of \$1.3 million that is reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

*Abaloparatide-TD Phase 2 Clinical Trial* On July 26, 2012, we entered into a Letter of Intent, or the Phase 2 Letter of Intent, with Nordic, which provides that we and Nordic will, subject to compliance by us with certain requirements of our Certificate of Incorporation and applicable securities laws, negotiate in good faith to enter into (1) a Work Statement NB-2, or the Work Statement NB-2, a draft of which is

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attached to the Phase 2 Letter of Intent, and (2) an amendment to the Amended and Restated Stock Issuance Agreement.

In February 2013, we executed the final Work Statement NB-2 under the Clinical Trial Services Agreement and the related Stock Issuance Agreement. Pursuant to the Work Statement NB-2, Nordic will provide clinical trial services relating to the Phase 2 Clinical Trial and will be compensated for such services in a combination of cash and shares of stock. Payments in cash to be made by us to Nordic under Work Statement NB-2 are denominated in both euros and U.S. dollars and total up to €3.6 million (\$5.0 million) and \$0.3 million, respectively. In addition, we will issue to Nordic shares of our series A-6 preferred stock having a value of up to \$2.9 million, as additional payment for services to be provided under the Work Statement NB-2 and the Clinical Trial Services Agreement.

The Stock Issuance Agreement provides that Nordic is entitled to receive quarterly stock dividends in connection with services performed under Work Statement NB-2, payable in shares of series A-6 convertible preferred stock, or shares of common stock if our preferred stock has been automatically converted in accordance with its amended certificate of incorporation. In the event Nordic sells the shares of series A-5 convertible preferred stock or in the event the shares of series A-5 convertible preferred stock are converted into common stock in accordance with our amended certificate of incorporation, this right to receive the Nordic Accruing Dividend will terminate, but a right to receive an equivalent number of shares of series A-6 convertible preferred stock or common stock, as applicable, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

The Nordic Accruing Dividend related to the Phase 2 Clinical Trial is determined based upon the estimated period that will be required to complete the Phase 2 Clinical Trial. On each Accrual Date, beginning with the quarter ended December 31, 2012, we will recognize a liability to issue shares of Series A-6 to Nordic with an Applicable Quarterly Amount and is equal to up to \$2.9 million minus the aggregate value of any prior Nordic Accruing Dividend related to the Phase 2 Clinical Study divided by the number of calendar quarters it will take to complete the Phase 2 Clinical Study. We calculate the aggregate number of shares of Series A-6 to accrue in such calendar quarter by dividing such Applicable Quarterly Amount, by the greater of (1) the fair market value of our common stock as of the applicable Accrual Date or (2) \$81.42 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic are to be issued when declared or paid by our Board of Directors, who are required to do so upon Nordic's request, or upon an event of sale. As of December 31, 2013, 32,215 shares of Series A-6 were due to Nordic under Work Statement NB-2. In December 2013, Nordic requested that all shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-2 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 32,215 shares accrued under Work Statement NB-2 on December 31, 2013, which constituted all shares of Series A-6 due under Work Statement NB-2.

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

We recognize research and development expense for the amounts due to Nordic under the Work Statement NB-2 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 2 Clinical Trial, or a nine-month period. We recorded \$4.1 million and \$1.4 million of research and development expense during the years ended December 31, 2013 and 2012 and nil and \$1.7 million in research and development expense during the three months ended March 31, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Phase 2 Clinical Trial. Additionally, we recorded approximately \$0.9 million of research and development expense associated with the costs incurred for preparatory and other start-up costs to initiate the Phase 2 Clinical Trial during the year ended December 31, 2012. As of March 31, 2014, all obligations due to Nordic under Work Statement NB-2 had been paid.

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We are also responsible for certain pass-through costs in connection with the Phase 3 Clinical Trial, Extension Study and Phase 2 Clinical Trial. Pass-through costs are expensed as incurred or upon delivery. We recognized research and development expense of \$3.9 million, \$6.0 million, and \$5.0 million for pass through costs during years ended December 31, 2013, 2012, and 2011, respectively, and \$0.3 million and \$1.1 million during the three months ended March 31, 2014 and 2013, respectively.

We estimate that our future cash obligations to Nordic in relation to Work Statement NB-1, Work Statement NB-2 and Work Statement NB-3, as amended, will approximate the following as of December 31, 2013 (in thousands):

	TOTAL(1)		LESS THAN 1 YEAR		1-3 YEARS		MORE THAN	
	EURO	USD	EURO	USD	EURO	USD	4-5 YEARS	5 YEARS
	DENOMINATED	DENOMINATED	DENOMINATED	DENOMINATED	DENOMINATED	DENOMINATED	DENOMINATED	DENOMINATED
	EURO	USD PAYMENTS	EURO	USD PAYMENTS	EURO	USD PAYMENTS	EURO	USD PAYMENTS
Work Statement NB-1	€ 13,492	\$ 18,591	€ 1,418	\$ 1,418	€ 0	\$ 0		
Work Statement NB-2	416	573	28	28	416	573	28	
Work Statement NB-3	5,051	6,960	1,384	1,907	3,667	5,053		
Performance Incentive Payments			5,000		5,000			
<b>Total Payments</b>	<b>€ 18,959</b>	<b>\$ 26,124</b>	<b>€ 6,446</b>	<b>\$ 6,446</b>	<b>€ 3,667</b>	<b>\$ 5,053</b>		

(1)

In accordance with Amendment No. 3 to the Stock Issuance Agreement, if an initial public offering occurs prior to June 30, 2014, any future payments of stock owed to Nordic under Work Statement NB-1 and Work Statement NB-3 will be changed from the right to receive stock to the right to receive a total cash payment of \$4.3 million, payable in ten equal monthly installments beginning on March 31, 2015. This amount is not reflected in the table.

The amounts above exclude pass-through costs and, in accordance with the respective work statements, may be adjusted from time to time and at the end of the study to reflect actual study activities completed by the study subjects. The future obligations under Work Statement NB-3 are based upon our current estimate of patient enrollment rates, which are based upon historical enrollment rates and estimated drop outs. These amounts may not be representative of the actual future enrollment rates which would have an impact on the amount and timing of our future cash payments to Nordic.

**License agreement obligations**

*Abaloparatide.* In September 2005, we exclusively licensed the worldwide rights (except for Japan) to abaloparatide and analogs from Ipsen, including US Patent No. 5,969,095, (effective filing date March 29, 1996, statutory term expires March 29, 2016) entitled "Analogues of Parathyroid Hormone" that claims abaloparatide and US Patent No. 6,544,949 (effective filing date March 29, 1996, statutory term expires March 29, 2016) entitled "Analogues of Parathyroid Hormone" that claims methods of treating osteoporosis using abaloparatide and pharmaceutical compositions comprising abaloparatide, and the corresponding foreign patents and continuing patent applications. In addition, we have rights to joint intellectual property related to abaloparatide, including rights to the jointly derived intellectual property contained in US Patent No. 7,803,770 (effective filing date October 3, 2007, statutory term expires March 26, 2028 with 175 days of patent term adjustment due to delays in patent prosecution by the USPTO) and related patents and patent applications both in the United States and worldwide (excluding Japan) that cover the method of treating osteoporosis using the Phase 3 clinical study dosage strength and form. In consideration for the rights to

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abaloparatide and in recognition of certain milestones having been met as of December 31, 2012, we have paid to Ipsen an aggregate amount of \$1.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. The range of milestone payments that could be paid under the agreement is €10.0 million to €36.0 million (\$13.8 million to \$50.0 million). Should abaloparatide become commercialized, we or our sublicensees will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product on a country by country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country. The date of the last to expire of the abaloparatide patents, barring

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any extension thereof, is expected to be March 26, 2028. In the event that we sublicense abaloparatide to a third party, we are obligated to pay a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double-digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, we will be obligated to pay to Ipsen a fixed low single-digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of our patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country. Effective May 11, 2011, Ipsen agreed to accept shares of series A-1 preferred stock in lieu of a cash milestone payment of €1.0 million. We issued 173,263 shares of series A-1 preferred stock to Ipsen on May 17, 2011 to settle the liability. These shares were exchanged in the Merger for an aggregate of 17,326 shares of series A-1 convertible preferred stock and upon the listing of our common stock on the NASDAQ Global Market will convert automatically into 83,130 shares of common stock. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

*RAD1901.* In June 2006, we exclusively licensed the worldwide rights (except for Japan) to RAD1901 from Eisai Co. Ltd., or Eisai. In particular, we have licensed US Patent No. 7,612,114 (effective filing date December 25, 2003, statutory term extended to August 18, 2026 with 967 days of patent term adjustment due to delays by the USPTO) and US Patent No. 8,399,520 (effective filing date December 25, 2003, statutory term expires December 25, 2023). In consideration for the rights to RAD1901 and in recognition of certain milestones having been met to date, we have paid to Eisai an aggregate amount of \$1.5 million. The range of milestone payments that could be paid under the agreement is \$1.0 million to \$20.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. Should RAD1901 become commercialized, we will be obligated to pay to Eisai a royalty in a variable mid-single digit range based on net sales of the product on a country by country basis for a period that expires on the later of (1) date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the product is not covered by data protection clauses, and the sales of lawful generic version of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated. The latest valid claim is expected to expire, barring any extension thereof, on August 18, 2026. The royalty rate shall then be subject to reduction and the royalty obligation will expire at such time as sales of lawful generic version of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. We were also granted the right to sublicense with prior written approval from Eisai, but subject to a right of first negotiation held by Eisai if we seek to grant sublicenses limited to particular Asian countries. If we sublicense RAD1901 to a third party, we will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees we receive from such sublicensee and royalties in a variable mid-single digit range based on net sales of the sublicensee. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

**NET OPERATING LOSS CARRYFORWARDS**

As of December 31, 2013, we had federal and state net operating loss carryforwards of approximately \$263.6 million and \$229.4 million, respectively, the use of which may be limited, as described below. If not utilized, the net operating loss carryforwards will expire at various dates through 2033.

Under Section 382 of the Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be used annually in the future to offset taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards before they expire. The closing of this offering together with private placements and other transactions that have occurred since our inception, may have triggered an ownership



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change pursuant to Section 382, which could limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset taxable income, if any. Any such limitation, whether as the result of this offering, prior private placements, sales of common stock by our existing stockholders or additional sales of common stock by us after this offering, could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal or state income tax benefit in our statement of operations.

**OFF-BALANCE SHEET ARRANGEMENTS**

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

**RECENTLY ADOPTED ACCOUNTING STANDARDS**

In July 2013, the FASB issued Accounting Standards Update No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* ("ASU 2013-11"). ASU 2013-11 clarifies guidance and eliminates diversity in practice on the presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists at the reporting date. The amendments to ASU 2013-11 are effective for interim and annual fiscal periods beginning after December 15, 2013, with early adoption permitted. We adopted ASU 2013-11 on January 1, 2014. Its adoption did not have a material impact on our results of operations, financial position, or cash flows.

In December 2013, the FASB issued Accounting Standards Update No. 2013-12, *Definition of a Public Business Entity* ("ASU 2013-12"). ASU 2013-12 amends the Master Glossary of the FASB Accounting Standards Codification to include one definition of public business entity for future use in GAAP. ASU 2013-12 does not affect existing requirements but will be used in considering the scope of new financial guidance and will identify whether the guidance does or does not apply to public business entities. We adopted ASU 2013-12 on January 1, 2014. Its adoption did not have a material impact on our results of operations, financial position or cash flows.

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**BUSINESS**

**OVERVIEW**

We are a science-driven biopharmaceutical company focused on developing novel differentiated therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases. Our lead product candidate is abaloparatide (BA058), a bone anabolic for the treatment of osteoporosis delivered via subcutaneous injection, which we refer to as Abaloparatide-SC. We are currently in Phase 3 development of Abaloparatide-SC and expect to announce top-line data from this study in late 2014. If the results are positive, we plan to submit a new drug application, or NDA, in the United States, and a marketing authorization application, or MAA, in Europe, in mid-2015. We hold worldwide commercialization rights to Abaloparatide-SC, other than in Japan, and with a favorable regulatory outcome, we anticipate our first commercial sales of Abaloparatide-SC will take place in 2016. We are leveraging our investment in Abaloparatide-SC to develop Abaloparatide-TD. We expect this line extension will provide improved patient convenience by enabling administration of abaloparatide through a short-wear-time transdermal patch. We have recently completed a successful Phase 2 proof of concept study of Abaloparatide-TD.

Our current clinical product portfolio also includes a novel oral agent, RAD1901, a selective estrogen receptor down-regulator/degrader, or SERD. We are developing RAD1901 at higher doses for the treatment of breast cancer brain metastases, or BCBM, and intend to advance its development with the initiation of two Phase 1 clinical trials – a maximum tolerated dose study that has commenced patient screening, and a Phase 1b clinical trial in BCBM, which is expected to commence in late-2014. At low doses, RAD1901 acts as a selective estrogen-receptor modulator, or SERM. Low-dose RAD1901 has shown efficacy for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study.

***Abaloparatide***

Abaloparatide is a novel synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a bone anabolic treatment for osteoporosis. Osteoporosis is a disease that affects nearly 10 million people in the United States, with an additional approximately 43 million people at increased risk for the disease. It is characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. Anabolic agents, like Forteo (teriparatide), are used to increase bone mineral density, or BMD, and to reduce the risk of fracture. We believe abaloparatide has the potential to increase BMD and bone quality to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis. Based upon various published studies, including studies published by Marc C. Hochberg, MD, MPH (2002) and John A. Kanis (2014), we believe that increases in BMD are predictive of reduction in fracture risk. We are developing two formulations of abaloparatide:

*Abaloparatide-SC* is an injectable subcutaneous formulation of abaloparatide. In August 2009, we announced positive Phase 2 data that showed Abaloparatide-SC produced faster and greater BMD increases at the spine and the hip with substantially less hypercalcemia than Forteo (teriparatide), which is the only approved subcutaneous injectable anabolic agent for the treatment of osteoporosis in the United States. A subsequent Phase 2 clinical trial announced in January 2014 also confirmed the results of our first clinical trial by demonstrating that Abaloparatide-SC produces BMD increases from baseline in the spine and hip that are comparable to our earlier Phase 2 trial. In April 2011, we commenced a Phase 3 clinical trial of Abaloparatide-SC. Enrollment was completed in March 2013, and we expect to announce top-line data at the end of the fourth quarter of 2014. Assuming a favorable outcome, we plan to use the results from this Phase 3 clinical trial to support a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, and believe we could obtain approval of the NDA in 2016.

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*Abaloparatide-TD* is a line extension of Abaloparatide SC in the form of a convenient, short-wear-time (approximately five minutes) transdermal patch. In a recent Phase 2 clinical trial, Abaloparatide-TD demonstrated a statistically significant mean percent increase from baseline in BMD as compared to placebo at the lumbar spine and at the hip. These results demonstrated a clear proof of concept by achieving a dose dependent increase in BMD. Following additional formulation development work, we intend to advance an optimized Abaloparatide-TD product in additional clinical studies and to a Phase 3 bridging study and to subsequently submit for approval. We hold worldwide commercialization rights to Abaloparatide-TD technology.

On May 9, 2014, we submitted a breakthrough therapy designation request to the FDA for Abaloparatide-SC for the treatment of postmenopausal osteoporosis. Abaloparatide-SC was selected for clinical development on the basis of its demonstrated marked effects on increasing bone mass in non-clinical models. The recently completed analyses of two abaloparatide Phase 2 clinical trials have confirmed these non-clinical results, demonstrating potentially important clinical benefits relative to current anabolic therapies, including faster and greater increases in hip (non-vertebral) and spine (vertebral) BMD. We believe these results could support a breakthrough therapy designation.

***RAD1901***

RAD1901 is a SERD that we believe crosses the blood-brain barrier and that we are evaluating for the treatment of BCBM. RAD1901 has been shown to bind with good selectivity to the estrogen receptor and to have both estrogen-like and estrogen-antagonistic effects in different tissues. In many cancers, hormones, like estrogen, stimulate tumor growth and a desired therapeutic goal is to block this estrogen-dependent growth while inducing apoptosis of the cancer cells. SERDs are an emerging class of endocrine therapies that directly induce estrogen-receptor, or ER, degradation, enabling them to remove the estrogen growth signal in ER-dependent tumors without allowing ligand-independent resistance to develop. There is currently only one SERD, Faslodex (fulvestrant), approved for the treatment of hormone-receptor positive metastatic breast cancer; however, for patients with brain metastases (BCBM), there are no approved targeted therapies that cross the blood-brain barrier. We believe there is a significant opportunity for RAD1901 to be the first ER-targeted therapy that crosses the blood-brain barrier to more effectively treat ER-positive BCBM and potentially reduce both intracranial and extracranial BCBM tumors. We intend to commence a Phase 1 maximum tolerated dose study in healthy volunteers to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also use 18F-fluoroestradiol positron emission tomography (PET) in this study to provide a pharmacodynamic assessment of estrogen receptor turnover following RAD1901 treatment. We also intend to commence a Phase 1 clinical trial in 2014 to evaluate high-dose RAD1901 for the treatment of BCBM. Patient screening for this maximum tolerated dose study is currently underway. In March 2014, we submitted to the FDA an application for orphan medicinal product designation of RAD1901 for the treatment of BCBM.

We are also developing RAD1901 at lower doses as a selective estrogen receptor modulator, or SERM, for the treatment of vasomotor symptoms. Historically, hormone replacement therapy, or HRT, with estrogen or progesterone was considered the most efficacious approach to relieving menopausal symptoms such as hot flashes. However, because of the concerns about the potential long-term risks and contraindications associated with HRT, we believe a significant need exists for new therapeutic treatment options to treat vasomotor symptoms. In a Phase 2 proof of concept study, RAD1901 at lower doses demonstrated a reduction in the frequency and severity of moderate and severe hot flashes. We believe RAD1901 is an attractive candidate for advancement into Phase 2b development as a treatment for vasomotor symptoms.

Additional information regarding our clinical trials, their designs and the results of previously completed clinical trials is described in the section of this prospectus entitled " Our Product Candidates." The U.S. National Institutes of Health also provides a database of human clinical trials, that includes our Phase 2 or later clinical trials, which can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The information contained in, or that can be accessed through, this website is not part of, and is not incorporated into, this prospectus and should not be considered part of this prospectus.

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**OUR OPPORTUNITY**

*Osteoporosis*

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. 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. 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 prevalence of osteoporosis is growing and, according to the National Osteoporosis Foundation, or 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 and aromatase inhibitors that are increasingly used for breast cancer and the hormone therapies used for prostate cancer.

The NOF has estimated that 10 million people in the United States, composed of eight million women and two million men, already have osteoporosis, and another approximately 43 million have low bone mass placing them at increased risk for osteoporosis. In addition, the NOF has estimated that osteoporosis is responsible for more than two million fractures in the United States each year resulting in an estimated \$19 billion in costs annually. The NOF expects that the number of fractures in the United States due to osteoporosis will rise to three million by 2025, resulting in an estimated \$25.3 billion in costs each year. Worldwide, osteoporosis affects an estimated 200 million women according to the International Osteoporosis Foundation, or IOF, and causes more than 8.9 million fractures annually, which is equivalent to an osteoporotic fracture occurring approximately every three seconds. The IOF has estimated that 1.6 million hip fractures occur worldwide each year, and by 2050 this number could reach between 4.5 million and 6.3 million. The IOF estimates that in Europe alone, the annual cost of osteoporotic fractures could surpass €76 billion by 2050.

There are two main types of osteoporosis drugs currently available in the United States, anti-resorptive agents and anabolic agents. Anti-resorptive agents act to prevent further bone loss by inhibiting the breakdown of bone, whereas anabolic agents stimulate bone formation to build new, high-quality bone. According to industry sources, sales of these drugs in the United States, Japan and the five major markets in Europe exceeded \$6 billion in 2011. We believe there is a large unmet need in the market for osteoporosis treatment because existing therapies have shortcomings in efficacy, tolerability and convenience. For example, one current standard of care, bisphosphonates, an anti-resorptive agent, has been associated with infrequent but serious adverse events, such as osteonecrosis of the jaw and atypical fractures, especially of long bones. These side effects, although uncommon, have created increasing concern with physicians and patients. Many physicians are seeking alternatives to bisphosphonates. The two primary alternatives to bisphosphonates that are approved for the treatment of osteoporosis, Lilly's Forteo and Amgen's Prolia, had reported sales of approximately \$1.2 billion and \$700 million, respectively, in 2013. Forteo, a 34 amino acid recombinant peptide of human parathyroid hormone, is the only anabolic drug approved in the United States for the treatment of osteoporosis. We believe there is a significant opportunity for an anabolic agent that is able to increase BMD to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis with added advantages in convenience and safety.

*Our Solution Abaloparatide*

Abaloparatide is a novel synthetic peptide analog of PTHrP that we are developing as a bone anabolic treatment for osteoporosis. PTHrP, unlike parathyroid hormone, is critical in the formation of the skeleton, is involved in the regulation of bone formation and is 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. We believe that abaloparatide is the most advanced PTHrP analog in clinical development for the treatment of

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osteoporosis and that it can provide the following advantages over other current standard of care treatments for osteoporosis:

improved efficacy greater bone build at hip and spine;

faster benefit for building bone;

shorter treatment duration;

less hypercalcemia;

no additional safety risks; and

no refrigeration required in use.

*Abaloparatide-SC.* In August 2009, we announced positive Phase 2 data that showed Abaloparatide-SC produced faster and greater BMD increases at the spine and the hip with substantially less hypercalcemia than Forteo, the only approved anabolic agent for the treatment of osteoporosis in the United States. Specifically, our study demonstrated that total hip BMD showed a more than five-fold benefit of Abaloparatide-SC at a dose of 80µg over Forteo after 24 weeks. Abaloparatide-SC at 80µg increased mean lumbar spine BMD by 6.7% at 24 weeks, compared to 5.5% with Forteo, and by 12.9% at 48 weeks, compared to 8.6% with Forteo. A subsequent Phase 2 clinical trial announced in January 2014 also confirmed the results of the first clinical trial by demonstrating that Abaloparatide-SC produces increases in BMD from baseline in the spine and hip that are comparable to the earlier Phase 2 trial. In April 2011, we began dosing patients in a pivotal, multinational Phase 3 clinical trial designed to show that Abaloparatide-SC prevents new vertebral fracture compared to placebo. We completed enrollment in this Phase 3 clinical study in March 2013 and expect to report top-line 18-month fracture data at the end of the fourth quarter of 2014. If the data from this Phase 3 clinical trial are positive, we plan to submit the NDA and the MAA for Abaloparatide-SC in mid-2015. We expect commercial launch to follow in 2016 in the United States, if and when the FDA approves the NDA for Abaloparatide-SC, and in the EU if and when an MAA for Abaloparatide-SC is approved.

*Abaloparatide-TD.* Abaloparatide-TD is a convenient, short-wear-time transdermal patch formulation of abaloparatide with Phase 2 clinical results suggesting efficacy, safety and tolerability in the treatment of osteoporosis. In January 2014, we reported positive results from a Phase 2 clinical trial of Abaloparatide-TD which showed at each dose there was a statistically significant mean percent increase from baseline in BMD, as compared to placebo, at the lumbar spine. Additionally, at the 100 µg and 150 µg doses, there was a statistically significant mean percent increase from baseline in BMD, as compared to placebo, at the hip. In addition, there was a consistent dose effect observed with increasing doses of Abaloparatide-TD, with a statistically significant dosing trend seen for changes in both spine and total hip BMD. As a result, we believe that by offering an alternative to daily injections, Abaloparatide-TD, if approved, could further improve patient outcomes by increasing patient acceptance.

We currently plan to optimize Abaloparatide-TD to achieve efficacy comparable to that of Abaloparatide-SC. If Abaloparatide-SC is approved by the FDA, we believe that we will only need to conduct a single non-inferiority Phase 3 clinical trial comparing the change in lumbar spine BMD at 12 months for patients dosed with Abaloparatide-TD to patients dosed with Abaloparatide-SC to show that the effect of Abaloparatide-TD treatment is comparable to that of Abaloparatide-SC. If our clinical trials of Abaloparatide-SC and Abaloparatide-TD are successful, we expect to seek marketing approval of Abaloparatide-TD as a line extension of Abaloparatide-SC. The FDA approval of Abaloparatide-TD, and the timing of any such approval, is dependent upon the approval of Abaloparatide-SC.

***Metastatic Breast Cancer***

According to the World Health Organization, breast cancer is the second most common cancer in the world and the most prevalent cancer in women, accounting for 16% of all female cancers. The major cause of death from breast cancer is metastases, most commonly to the bone, liver, lung and brain. About 5% of patients have distant metastases at the time of diagnoses, and these patients have a 5-year survival rate of only 24%, compared with a greater than 98% survival rate for patients with only local disease. Importantly, even patients without metastases at diagnosis are at risk for developing metastases over time.



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Approximately, 70% of breast cancers express the estrogen receptor, or ER, and depend on estrogen signaling for growth and survival. There are three main classes of therapies for ER-positive tumors available: aromatase inhibitors, or AIs; SERMs; and SERDs. AIs, which block the generation of estrogen, and SERMs, which selectively inhibit an ER's ability to bind estrogen, both block ER-dependent signaling but leave functional ERs present on breast cancer cells. For this reason, although these classes of drugs are effective as adjuvants for breast cancer, patients' tumors often acquire resistance to them by developing the ability to signal through the ER in a ligand-independent manner. SERDs, in contrast, are an emerging class of endocrine therapies that directly induce ER degradation. Therefore, these agents should be able to treat ER-dependent tumors without allowing ligand-independent resistance to develop, and they should also be able to act on AI- and SERM-resistant ER-positive tumors. Symptomatic BCBM occur in 10% to 16% of patients with metastatic breast cancer and are associated with particularly high morbidity and mortality. Current standard of care involves a combination of whole-brain radiotherapy, surgery or stereotactic radiosurgery, depending on the clinical context. These treatments are often only marginally effective, and are themselves associated with significant morbidity and mortality.

There is currently only one SERD approved for the treatment of ER-positive metastatic breast cancer, but there are no approved targeted therapies that cross the blood-brain barrier and can treat patients with ER-positive BCBM. We believe a significant opportunity exists for a SERD that can cross the blood-brain barrier to more effectively treat ER-positive BCBM and potentially delay or eliminate the need for radiation or surgery.

*Our Solution RAD1901*

We are developing RAD1901 as a high-dose SERD in an oral formulation in Phase 1 clinical development for the treatment of BCBM. RAD1901 has been shown to bind with good selectivity to the estrogen hormone receptor and to have both estrogen-like and estrogen-antagonist effects in different tissues. In cell culture, RAD1901 does not stimulate replication of breast cancer cells, and antagonizes the stimulating effects of estrogen on cell proliferation. Furthermore, in breast cancer cell lines a dose dependent down regulation of ER, has been observed, a process we have shown to involve proteosomal mediated degradation pathway. In a model of breast cancer in which human breast cancer cells are implanted in mice and allowed to establish tumors in response to estrogen treatment, we have shown that treatment with RAD1901 results in decreased tumor growth. Studies with RAD1901 have established the pharmacokinetic profile, including demonstration of good oral bioavailability and the ability of RAD1901 to cross the blood-brain barrier, with therapeutic levels detectable in the brain. We believe that RAD1901 could offer the following advantages over other current standard of care treatments for BCBM:

ability to penetrate the blood-brain barrier;

oral administration; and

treatment of hormone-resistant breast cancers.

We intend to advance the development of RAD1901 with the initiation of two Phase 1 clinical trials – a maximum tolerated dose study that has commenced patient screening, and a Phase 1b clinical trial in BCBM, which is expected to commence in late-2014.

*Vasomotor symptoms*

Vasomotor symptoms, such as hot flashes and night sweats, are common during menopause, with up to 85% of women experiencing them during the menopause transition, for a median duration of four years. In 2010, approximately 11.5 million women in the United States were in the 45 to 49 year age range upon entering perimenopause/menopause. In addition, most women receiving systemic therapy for breast cancer suffer hot flashes, often with more severe or prolonged symptoms than women experiencing natural menopause. These symptoms can disrupt sleep and interfere with quality of life. An estimated two million women go through menopause every year in the United States, 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

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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.

*Our Solution RAD1901*

We are developing RAD1901 as a low dose SERM in an oral formulation for the treatment of vasomotor symptoms. We conducted a Phase 2 proof of concept study in 100 healthy perimenopausal women using four doses of RAD1901 10 mg, 25 mg, 50 mg and 100 mg and placebo. While a classic dose-response effect was not demonstrated, at the 10 mg dose level RAD1901 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 hot flashes at either the two-, three- or four-week time-points. A similar reduction in composite score frequency  $\times$  severity of hot flashes was identified at all time-points, with a statistically significant difference from placebo achieved at the two-, three- or four-week time-points.

We anticipate our next clinical study will be a Phase 2b study conducted in approximately 200 perimenopausal women experiencing a high frequency of hot flashes at baseline. The main study endpoints would be an assessment of the change in the frequency and severity of moderate and severe hot flashes.

**OUR STRATEGY**

Our goal is to become a leading provider of therapeutics for osteoporosis and other serious endocrine-mediated diseases. To achieve this goal we plan to:

**Advance the development and obtain regulatory approval of Abaloparatide-SC.** We are evaluating Abaloparatide-SC in an ongoing Phase 3 clinical trial for the treatment of osteoporosis and expect to report top-line 18-month fracture data at the end of the fourth quarter of 2014. If the results are positive, we plan to submit an NDA for Abaloparatide-SC in the United States, and an MAA in the European Union, in mid-2015.

**Extend the lifecycle of abaloparatide through the continued development of Abaloparatide-TD.** We are developing Abaloparatide-TD as a short-wear-time transdermal patch and we anticipate, pending a favorable regulatory outcome, commercial launch two to three years after the first commercial sale of Abaloparatide-SC. If Abaloparatide-SC is approved by the FDA, we believe that we will only need to conduct a single non-inferiority Phase 3 clinical trial comparing the change in BMD for patients dosed with Abaloparatide-TD as compared to patients dosed with Abaloparatide-SC. If our clinical trials of Abaloparatide-SC and Abaloparatide-TD are successful, we expect to seek marketing approval of Abaloparatide-TD as a line extension of Abaloparatide-SC.

**Establish internal sales and marketing capabilities to commercialize our product candidates in the United States.** We currently plan to commercialize any of our approved product candidates by developing an internal sales force focused on specialists in core strategic markets in the United States. We believe that we can effectively target those markets using a sales force of approximately 150 representatives and that by doing so we can achieve a greater return on our product investment than if we license our products to third parties for sale. We plan to expand the use of our products to primary care physicians through selective co-promotion partnerships. Our management team has experience commercializing products in these core strategic markets, and understands the relevant sales, marketing and reimbursement requirements.

**Selectively pursue collaborations to commercialize our product candidates outside the United States.** We intend to seek to enter into one or more collaborations for the commercialization of our approved product candidates in strategic markets in Europe and in other countries worldwide.



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**Continue to expand our product portfolio.** We plan to leverage our drug development expertise to discover and develop additional product candidates focused on serious endocrine-related diseases and conditions, including the development of RAD1901 as a potential treatment for ER-positive BCBM. We may also consider opportunistically expanding our product portfolio through in-licensing, acquisitions or partnerships.

**OUR PRODUCT CANDIDATES**

The following table identifies the product candidates in our current product portfolio, their proposed indication and stage of development:

**Abaloparatide**

*Overview*

Abaloparatide is a novel synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a bone anabolic treatment for osteoporosis. PTHrP, unlike PTH, is critical in the formation of the skeleton, is involved in the regulation of bone formation and is 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 (a protein of 139 to 173 amino acids) is different from PTH (a protein of 84 amino acids) in its structure and role. In 2009, the medical journal, Nature Chemical Biology, published the results of a study indicating that PTH (which primarily regulates calcium homeostasis and bone resorption) and PTHrP activate the same parathyroid hormone receptor, or PTHR1, but produce divergent effects in bone due to differences in receptor conformation selectivity, receptor localization and downstream cell signaling. Forteo is a 34 amino acid recombinant peptide of human parathyroid hormone. We believe that abaloparatide is the most advanced PTHrP analog in clinical development for the treatment of osteoporosis. We acquired and maintain exclusive worldwide rights, excluding Japan, to certain patents, data and technical information related to abaloparatide through a license agreement with an affiliate of Ipsen Pharma SAS, or Ipsen.

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We are developing abaloparatide for the prevention of fractures in postmenopausal women at risk of fracture from severe osteoporosis. Recognizing both the therapeutic potential of abaloparatide in this indication as well as the drawbacks inherent in self-injection therapies in this population, we are also developing Abaloparatide-TD for transdermal administration of the product using a microneedle technology from 3M. We plan to develop and register Abaloparatide-SC as our lead product, with Abaloparatide-TD as a line extension that provides greater patient convenience. We believe the ability of Abaloparatide-TD to capitalize on the more extensive fracture study data of Abaloparatide-SC will allow the patch product to be accelerated through later-phase development without requiring its own fracture study.

*Abaloparatide-SC*

We are developing Abaloparatide-SC as a once daily sub-cutaneous injection of abaloparatide for the treatment of osteoporosis. We have completed two Phase 2 clinical trials of Abaloparatide-SC. We announced results from our first Phase 2 clinical trial in August 2009, which showed that Abaloparatide-SC produced faster and greater BMD increases at the spine and the hip with substantially less hypercalcemia than Forteo, the only approved anabolic agent for the treatment of osteoporosis in the United States. Specifically, our study demonstrated that total hip BMD showed a more than five-fold benefit of Abaloparatide-SC at a dose of 80µg over Forteo after 24 weeks. Abaloparatide-SC at 80µg increased mean lumbar spine BMD by 6.7% at 24 weeks, compared to 5.5% with Forteo, and by 12.9% at 48 weeks, compared to 8.6% with Forteo. Abaloparatide-SC at 80µg increased mean femoral neck BMD by 3.1% at 24 weeks, compared to 1.1% with Forteo, and 0.8% with a placebo, and by 4.1% at 48 weeks, compared to 2.2% with Forteo. At 24 weeks, 66% of Abaloparatide-SC treated patients had increases in BMD at the lumbar spine, total hip and femoral neck, compared with 29% of placebo treated patients (p=0.0015) and 40% of Forteo treated patients (p=0.0250). In January 2014, we reported positive data from a second Phase 2 clinical trial of abaloparatide. Consistent with our Phase 2 clinical trial of Abaloparatide-SC completed in 2009, our second clinical trial demonstrated that patients who received a 80 µg dose of Abaloparatide-SC experienced increases in BMD from baseline in the lumbar spine (5.8% increase from baseline), total hip (2.7% increase from baseline) and femoral neck (2.7% increase from baseline and 3.1% increase net placebo). In addition to the BMD results, these study results add to the safety data from the prior Phase 2 clinical study with Abaloparatide-SC, which demonstrated that abaloparatide is generally safe and well tolerated.

In April 2011, we commenced our ongoing Phase 3 clinical trial of Abaloparatide-SC, which completed enrollment in March 2013 with 2,463 subjects. The trial was designed to enroll 2,400 subjects that would be randomized equally to receive daily doses of one of the following: 80 µg of abaloparatide, a matching placebo, or the approved dose of 20 µg of Forteo for 18 months. The trial is designed to test our belief that abaloparatide is superior to placebo for the prevention of vertebral fracture and to Forteo for greater BMD improvement at major skeletal sites and for a lower occurrence of hypercalcemia. We believe the trial will also show that BMD gains for abaloparatide patients will occur earlier than for Forteo patients. In 2012 we participated in a Type A meeting with the Division of Reproductive and Urologic Products of the FDA and discussed the Abaloparatide-SC single pivotal placebo-controlled, comparative Phase 3 fracture study. The FDA indicated that it wanted us to provide additional feedback on the design of our ongoing Phase 3 clinical trial so that the data would be adequate for submission of an NDA for the treatment of osteoporosis. Following this meeting, we amended our protocol to incorporate changes in response to our discussions with the FDA, which included the addition of a 6-month extension study during which patients will receive an approved alendronate therapy in order to obtain 24-month fracture data. The FDA determination of the approvability of any NDA is made based on their independent assessment of the totality of the data submitted. Based on our discussions with the FDA, we believe that a successful, single pivotal placebo-controlled, comparative Phase 3 fracture study will be sufficient to support approval of Abaloparatide-SC for the treatment of osteoporosis in the United States. We believe that the use of a single pivotal placebo-controlled comparative Phase 3 fracture study is consistent with the approach taken with Forteo and Prolia, which were each approved by the FDA for the treatment of osteoporosis in the United States on the basis of a single pivotal placebo-controlled Phase 3 fracture study.

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Before we submit an NDA to the FDA for Abaloparatide-SC as a treatment for osteoporosis, we must complete our pivotal Phase 3 clinical trial based upon 18-month fracture data, a carcinogenicity study in rats, and bone quality studies in rats and monkeys. We also may need to complete several additional studies including, a thorough QT Phase 1 study, a Phase 1 pharmacokinetic, or PK, study in renal patients, a Phase 1 absolute bioavailability PK study and several drug interaction studies. Assuming we do not encounter any unforeseen delays during the course of developing Abaloparatide-SC, we expect to present top-line 18-month fracture data at the end of the fourth quarter of 2014. If the data from this Phase 3 clinical trial are positive, and we have completed the other necessary trials, we plan to submit the NDA for Abaloparatide-SC in mid-2015. We expect commercial launch to follow in the United States, if and when the FDA approves the NDA for Abaloparatide-SC.

We understand that Phase 3 clinical trials with similar size, design and endpoints as our Phase 3 clinical trial have been sufficient to support registration with the European Medicines Agency, or the EMA, for other bone anabolic drugs used to treat women with osteoporosis in the European Union, or the EU. In December 2012, we met with the Swedish Medical Products Agency, or the MPA, to review the design and the overall progress of the Phase 3 clinical trial. The MPA confirmed that the program, based on the current single pivotal trial design, could support the submission and potential approval of an MAA in the EU, depending on the results of the Phase 3 clinical trial.

***Abaloparatide-TD***

We are developing Abaloparatide-TD as a line extension of Abaloparatide-SC in a short-wear-time transdermal patch formulation. In January 2014, we reported positive data from our Phase 2 clinical trial of Abaloparatide-TD. The results demonstrated that for each Abaloparatide-TD dose there was a statistically significant mean percent increase from baseline in BMD at the lumbar spine, as compared to placebo. For the 100 µg and 150 µg Abaloparatide-TD doses, there was also a statistically significant mean percent increase from baseline in BMD at the hip, as compared to placebo. The highest Abaloparatide-TD dose of 150 µg produced increases in BMD from baseline in the lumbar spine and total hip of +2.9% and +1.5%, respectively, compared to changes in the placebo group of +0.04% and -0.02%, respectively. In addition, there was a consistent dose effect seen with increasing doses of Abaloparatide-TD, with a statistically significant dosing trend seen for changes in both spine and total hip BMD. Further, the overall tolerability and safety profile was acceptable, there were no clinically significant signs of anti-abaloparatide antibodies, and patient ratings of patch adhesion and local skin response to the transdermal patch technology were also acceptable.

In order to further enhance BMD efficacy, we currently plan to modify the pharmacokinetic profile of Abaloparatide-TD to more closely resemble that of Abaloparatide-SC. If Abaloparatide-SC is already approved by the FDA, we believe that we will only need to conduct a single non-inferiority Phase 3 clinical trial comparing the change in lumbar spine BMD at 12 months for patients dosed with Abaloparatide-TD to patients dosed with Abaloparatide-SC to confirm that the effect of Abaloparatide-TD treatment is comparable to that of Abaloparatide-SC. If our clinical trials of Abaloparatide-SC and Abaloparatide-TD are successful, we expect to seek marketing approval of Abaloparatide-TD as a line extension of Abaloparatide-SC. The FDA approval of Abaloparatide-TD, and the timing of any such approval, is dependent upon the approval of Abaloparatide-SC.

***Clinical Development***

*Pivotal Phase 3 Clinical Trial of Abaloparatide-SC*

In April 2011, we commenced our ongoing Phase 3 trial, which completed enrollment in March 2013. The trial completed enrollment with 2,463 patients at 28 medical centers in 10 countries in the United States, Europe, Latin America and Asia. Patients in the trial are randomized equally to receive daily doses of one of the following for 18 months: 80 µg of abaloparatide; a matching placebo or the approved dose of 20 µg of Forteo.

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On February 15, 2012, we received a letter from the FDA stating that, after internal consideration, the agency believes that a minimum of 24-month fracture data are necessary for approval of new products for the treatment of postmenopausal osteoporosis. Our ongoing Abaloparatide-SC pivotal Phase 3 clinical study is designed to produce fracture data based on an 18-month primary endpoint. The FDA's letter solicited a meeting to review the status of our Phase 3 clinical study and discuss options for fulfilling the FDA's new request for 24-month fracture data in the context of the ongoing Phase 3 study. We subsequently met with the FDA on March 21, 2012 to discuss satisfying the 24-month data request while preserving the current 18-month primary endpoint. Based upon our discussion with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from a 6-month extension of the abaloparatide 80 µg and placebo groups in our Phase 3 study that will receive an approved alendronate (generic Fosamax) therapy for osteoporosis management. We intend to submit the NDA with the 24-month fracture data.

*Study population* The study enrolled otherwise healthy ambulatory women aged 50 to 85 (inclusive) who had been postmenopausal for at least five years, met the study entry criteria and had provided written informed consent. Osteoporosis is defined as when a patient's t-score is less than or equal to -2.5, meaning that the patient has a BMD that is two and a one-half standard deviations below the mean BMD of an ethnically matched thirty year old man or woman, as applicable. The women enrolled in the study have a BMD t-score  $\leq -2.5$  and  $> -5.0$  at the lumbar spine or hip (femoral neck) by dual-energy X-ray absorptiometry, or 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 five years. Postmenopausal women older than 65 who met the above fracture criteria but had a t-score of  $\leq -2.0$  and  $> -5.0$  could also be enrolled. Women older than 65 who did not meet the fracture criteria could also be enrolled if their t-score was  $\leq -3.0$  and  $> -5.0$ . All patients were to be in good general health as determined by medical history, physical examination (including vital signs) and clinical laboratory testing. We believe this study population contains a patient population reflective of the type of severe osteoporosis patients that specialists will treat in their practices.

*Study design*

The 2,463 eligible patients were randomized equally to receive one of the following for 18 months:

abaloparatide at a dose of 80 µg;

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a matching placebo; or

Forteo at a dose of 20 µg.

The study drug was blinded to patients and medical personnel until the randomization process was completed. Treatment with abaloparatide 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. Therefore, its identity cannot be blinded to treating physicians and patients once use begins. Study medication will be self-administered daily by subcutaneous injection for a maximum of 18 months. 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 endpoints* The primary efficacy endpoint will be the number of patients treated with Abaloparatide-SC that show 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 a superiority difference on vertebral fracture incidence between placebo patients and those who receive Abaloparatide-SC at a dose of 80 µg.

*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 from baseline to end-of-treatment. 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 and as compared to Forteo, as well as the number of hypercalcemic events in Abaloparatide-SC treated patients when compared to Forteo at end-of-treatment.

Additional secondary endpoints will include change in standing height and changes in serum bone formation markers across treatment, such as PINP, osteocalcin and bone-specific alkaline phosphatase.

*Extension study design.*

Each of the abaloparatide 80 µg and placebo groups in our Phase 3 study will be eligible to continue in an extension study and will receive an approved alendronate (generic Fosamax) therapy for osteoporosis management. A key endpoint of the extension study will be the reduction in new vertebral fractures at up to 24 months in all randomized patients, including abaloparatide-treated and placebo-treated patients who are treated with alendronate at the end of treatment.

*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 (four 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.

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Bone biopsy of the iliac crest will be performed in a subset of patients receiving abaloparatide at a dose of 80 µg and placebo for assessment of bone quality and quantitative bone histomorphometry which is the quantitative 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 approximately 100 patients in each treatment group by renal computed tomography, or CT, scan.

Overall study safety is being monitored by an independent DSMB.

*Abaloparatide-SC Phase 2 Clinical Trial*

We conducted a randomized, placebo-controlled, parallel group dose-finding Phase 2 study (Study BA058-05-002) in the United States, Argentina, India and the United Kingdom. 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. The purpose of the study was to evaluate the safety and efficacy of daily injections of Abaloparatide-SC in women with osteoporosis. Postmenopausal women between the ages of 55 and 85 (inclusive) who had a BMD t-score  $\leq -2.5$  at the lumbar spine or hip (femoral neck) by DXA or a BMD t-score  $\leq -2$  and a prior low trauma fracture or an additional risk factor were candidates for this study. The study evaluated the effects of Abaloparatide-SC at multiple doses (placebo, 20 µg, 40 µg 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. 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 24 weeks and 48 weeks. Abaloparatide-SC and 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 subcutaneous injection. Four weeks prior to start of treatment, patients began taking calcium and vitamin D supplements that continued throughout the study.

*Initial 24 weeks of treatment* The following tables depict the percent change in total BMD-spine and BMD-hip at 12 and 24 weeks for each of arm of the trial.

In the ITT population, the mean percent change from baseline at week 12 in lumbar spine BMD (active treatment – placebo) for Abaloparatide-SC 40 µg and 80 µg groups were statistically significant ( $p = 0.0013$  and  $p < 0.001$ , respectively). The difference was not statistically significant in the Abaloparatide-SC 20 µg group, in the placebo group or in the Forteo group ( $p = 0.055$ ). At week 24, the mean percent change from baseline continued to increase and was statistically significantly proportional to dose ( $p < 0.001$ ) as shown in Figure A below. Again, the mean gain in total spine BMD was statistically significant for Abaloparatide-SC 40 µg ( $p < 0.001$ ) and 80 µg ( $p < 0.001$ ) groups. The mean BMD gain at week 24 was also statistically significant for the Forteo group ( $p < 0.001$ ). The difference was not statistically significant in the Abaloparatide-SC 20 µg group or in the placebo group. The response of lumbar spine BMD to Abaloparatide-SC was dose dependent, and the 80 µg Abaloparatide-SC dose produced a larger percentage increase in BMD at the lumbar spine than the approved 20 µg Forteo dose.

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*Figure A Mean Standard Error of the Mean (SEM) Percent Change from Baseline at weeks 12 and 24 in Total Spine BMD (ITT Population, N =221)*

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

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

Abaloparatide-SC also induced a dose-dependent rise in major markers of bone anabolic activity, including P1NP, bone specific alkaline phosphatase, or BSAP, and osteocalcin. The response to Forteo was somewhat greater for anabolic markers and 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, suggesting a close of the anabolic window and attenuation in the anabolic benefit of continued Forteo administration. While elevated over baseline, the Abaloparatide-SC patient group maintained lower levels of resorption markers (CTX) throughout the study period as compared to Forteo. We believe abaloparatide may demonstrate a lengthening of the anabolic window as compared to Forteo.

Abaloparatide-SC 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 serious adverse events, or SAE's. Adverse events were reported by 74% of patients in the first six 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. Treatment-related treatment emergent adverse events were reported in approximately 30% of patients, with similar incidence across all treatment groups. Seven subjects discontinued due to adverse events: one in the abaloparatide 20 µg group, one in the abaloparatide 40 µg group, three in the abaloparatide 80 µg group and two in the Forteo group. Eight patients (four percent) experienced at least one SAE and the incidence of such events was similar across treatment groups. Five SAEs, unrelated to treatment, were reported in three 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 (greater than or equal to 10.5 milligrams per deciliter, or mg/dL) were observed in 40% of the Forteo group while also observed in four percent, 12%, 19% and 18% of the placebo, Abaloparatide-SC at doses of 20 µg, 40 µg and 80 µg groups, respectively. Most elevations were noted at the four-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 seven patients, including 0%, 5%, 2%, 2% and 7% of patients in the placebo, Abaloparatide-SC 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.

Sixteen patients had low titer antibodies against abaloparatide after 24 weeks of treatment. Of these, five were in the abaloparatide 20 µg group, six were in the abaloparatide 40 µg group and five were in the abaloparatide 80 µg group. There were no associated safety events or attenuation of treatment efficacy. One antibody- positive patient in the Abaloparatide-SC 40 µg group was found to have possible evidence of neutralizing activity using an in vitro assay at 24 weeks without evidence of attenuation of drug efficacy; the patient achieved a 9.3% gain in total 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 Abaloparatide-SC 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 spine BMD, femoral neck BMD and total hip BMD observed in the Abaloparatide-SC 80 µg group, as shown in Figure C below. By week 48, mean percent changes in spine BMD were 0.7%, 5.1%, 9.8% and 12.9% for the placebo, Abaloparatide-SC 20 µg, Abaloparatide-SC 40 µg and Abaloparatide-SC 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 Abaloparatide-SC 80 µg group gained 4.1% compared to the mean of the Forteo group at 2.2%. The total gain in hip BMD was 0.7%, 2.0%, 2.1% and 2.7% for the placebo, Abaloparatide-SC 20 µg, Abaloparatide-SC 40 µg and Abaloparatide-SC 80 µg groups, respectively, compared to 1.3% for the Forteo group.

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*Figure C Mean (SEM) Percent Change from Baseline at weeks 12, 24 and 48 in Total Spine BMD (Extension Population N=55)*

No treatment-related SAEs or deaths were reported during this time period. Two patients discontinued treatment, one for bilateral femoral hernias (Abaloparatide-SC 80 µg) and one for moderate syncope (Abaloparatide-SC 40 µg). Study-related adverse events 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 during the second 24 weeks of study treatment.

*Non-Head-to-Head Comparison of Abaloparatide-SC and Amgen Anti-sclerostin Antibody Phase 2 Study Results*

Our Abaloparatide-SC Phase 2 clinical study used substantially similar patient inclusion and exclusion criteria as a study completed by Amgen of the use of a human anti-sclerostin antibody, romosozumab or AMG 785, for the treatment of osteoporosis. A comparison of the 6-month and 12-month spine BMD results of the AMG 785 study at the 210 mg once-monthly subcutaneous dosing regimen, including both patients treated with AMG 785 and a control group of patients treated with Forteo, and our Abaloparatide-SC study at the 80 mcg single daily subcutaneous dose are set forth in the following table. While we believe the comparison is useful in evaluating the results of our Phase 2 clinical study of Abaloparatide-SC, the Abaloparatide-SC and AMG 785 studies were separate trials conducted at different sites, and we have not conducted a head-to-head comparison of the drugs in a single clinical trial. Results of an actual head-to-head comparison study may differ significantly from those set forth in the following table. In addition, because the Abaloparatide-SC and AMG 785 studies were separate studies and because the

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Abaloparatide-SC Phase 2 clinical study involved a lesser number of patients, differences between the results of the two studies may not be statistically or clinically meaningful.

Product	Abaloparatide-SC		AMG 785 Phase 2(2)	
	Phase 2(1)			
Dose	80 mcg	Forteo	210 mg	Forteo
Dosing frequency	Daily	Forteo	Monthly	Daily
No. of Injections per dose	1	Forteo	3	1
Type of Injection	Self	Forteo	Physician	Self
Spine Mean Percent BMD Change from Baseline 24 weeks/6 months	+6.7%	+5.5%	+8.2%	+4.8%
Spine Mean Percent BMD Change from Baseline 48 weeks/12 months	+12.9%	+8.6%	+11.3%	+7.1%
Femoral Neck Mean Percent BMD Change from Baseline 48 weeks/12 months	+4.1%	+2.2%	+3.7%	+1.1%

(1) Abaloparatide-SC Study n=221 (24 weeks) and n=55 (48 weeks), 5 arms

(2) AMG 785 Study n=419 (12 months), 9 arms

*Abaloparatide-SC Phase 1 Clinical Trials*

We have completed three Phase 1 clinical trials of Abaloparatide-SC. Together with our Phase 2 clinical trials and ongoing Phase 3 clinical trial, over 1,300 patients have received the drug. The results of our Phase 1 clinical trials suggest that Abaloparatide-SC is safe and well tolerated at doses of up to 100 µg administered once daily. These studies also demonstrated that abaloparatide was 100% bioavailable, meaning it was absorbed completely, when administered subcutaneously, and that it was rapidly cleared from the circulation.

*Abaloparatide-TD Phase 2 Clinical Trials*

We conducted a randomized, double-blind, placebo-controlled, Phase 2 clinical trial of abaloparatide administered via a coated transdermal microarray delivery system in healthy postmenopausal women with osteoporosis. This study was conducted in nine centers in the United States, Denmark, Poland and Estonia. The primary objective of this study was to determine the clinical safety and efficacy of Abaloparatide-TD as assessed by changes in BMD when compared to a transdermal placebo and Abaloparatide-SC. Postmenopausal women between the ages of 55 and 85 (inclusive) who had a BMD t-score ≤-2.5 at the lumbar spine or hip (femoral neck) by DXA or a BMD t-score ≤-2 and a prior low trauma fracture or an additional risk factor were candidates for this study. Abaloparatide-TD was administered via a spring-loaded applicator and Abaloparatide-SC was administered by a multi-use pen injector into which a multi-dose glass cartridge was inserted. Four weeks prior to the start of treatment, subjects began taking calcium and vitamin D supplements which were continued throughout the study. The study drug was to be administered once daily for a total of six months.

A total of 372 subjects were screened and 250 were randomized to treatment in one of five treatment regimens: transdermal placebo, Abaloparatide-TD at doses of 50 µg, 100 µg, and 150 µg or Abaloparatide-SC at a dose of 80 µg. Two hundred and forty-nine subjects were included in the safety population and 231 subjects were included in the modified intent-to-treat, or mITT, population.

In the mITT population, the mean percent change from baseline in total spine BMD after six months of treatment increased with Abaloparatide-TD dose (0.04%, 1.87%, 2.33% and 2.95% in the placebo, Abaloparatide 50 µg, 100 µg and 150 µg groups, respectively). The test for a dose response was statistically significant (<0.0001). The mean differences (active treatment - placebo) of the percent change from baseline in total spine BMD at six months were 1.83%, 2.29% and 2.91% in the Abaloparatide-TD 50 µg, 100 µg, and 150 µg groups, respectively. The results for all Abaloparatide-TD

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dose groups were statistically significantly better than placebo ( $p=0.0066$ ,  $0.0005$ , and  $<0.0001$ , respectively).

*Figure D Mean (SEM) Percent Change from Baseline at Six Months in Total Spine BMD*

Similar to the findings in the spine, the mean percent change from baseline in total hip BMD after six months of treatment also increased with Abaloparatide-TD dose ( $-0.02\%$  and  $0.97\%$ ,  $1.32\%$  and  $1.49\%$  in the placebo, abaloparatide  $50\ \mu\text{g}$ ,  $100\ \mu\text{g}$  and  $150\ \mu\text{g}$  groups. The mean differences (active treatment - placebo) of the percent change from baseline in total hip BMD at six months were  $0.99\%$ ,  $1.33\%$  and  $1.51\%$  in the abaloparatide  $50\ \mu\text{g}$ ,  $100\ \mu\text{g}$ , and  $150\ \mu\text{g}$  groups, respectively; the results for the  $100\ \mu\text{g}$  and  $150\ \mu\text{g}$  Abaloparatide-TD dose groups were statistically significantly better than placebo ( $p=0.0056$  and  $0.0018$ , respectively).

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*Figure E Mean (SEM) Percent Change from Baseline at Six Months in Total Analyzable Hip BMD*

Analysis of adverse events was performed on treatment-emergent adverse events, or TEAEs. There were no apparent differences between the TEAE profiles across the five treatment groups. Overall, nasopharyngitis, headache, and influenza were the most frequently reported TEAEs. There were 9 serious TEAEs reported, one in the placebo group, two in the 100 µg group, two in the 150 µg group and four in the Abaloparatide-SC group. No subjects died during the course of this study. All of the events were consistent with medical events in women with postmenopausal osteoporosis, and none of the events were considered to be related to treatment with study medication.

Assessment of local tolerance consisted of daily self-evaluation by the subject of any dermal reaction for two months during the course of the study using scales that ranged from 0 to 3 or 6, with 0 indicating no effect. In general, the types of symptoms reported were similar across the treatment groups, with dermal response and swelling being the effects most frequently reported. In an initial analysis, detectable antibodies against abaloparatide were noted in a subset of patients. However, these antibodies were of low titer, and there was no evidence of an effect on safety or attenuation of treatment efficacy.

*Abaloparatide-TD Phase 1 Clinical Trials*

We have completed three Phase 1 clinical trials that collectively evaluated the safety, PK, time course of delivery and dose ranging. Abaloparatide-TD was characterized by a rapid release of abaloparatide with a faster time to reach peak concentration as well as more rapid elimination in plasma compared to Abaloparatide-SC. Peak transdermal drug levels were consistent with Abaloparatide-SC. An optimal wear time of five minutes or less was identified as well as effective sites of application. Abaloparatide-TD showed an increase in the bone-formation marker PINP in serum after seven days of exposure, consistent with bone-building activity, and was shown to be safe and well tolerated in all doses studied.

*Preclinical Pharmacology of Abaloparatide*

We have completed several preclinical studies of abaloparatide, and the following has been shown:

Abaloparatide is a potent selective agonist of the human PTH type 1 receptor (PTHr1), with binding selectivity for the RG vs R0 receptor conformation compared to PTH(1-34) and greater selectivity than PTHrP(1-34);



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

Abaloparatide-SC stimulates the formation of normal, well-organized bone and restores BMD in ovariectomized (OVX), osteopenic rats and primates. Mechanical testing of bones from OVX rats after treatment with Abaloparatide-SC revealed a significant increase in femur and vertebral bone strength. Similar studies in rats with Abaloparatide-TD show comparable restoration of bone;

Abaloparatide-SC was generally well tolerated over a wide range of doses in two species, rats and primates, for up to six months and nine months, respectively; and

Safety pharmacology studies demonstrated no respiratory, gastroenterologic, hematologic, renal or central nervous system effects.

A two-year subcutaneous injection carcinogenicity study of abaloparatide in Fischer 344 albino rats was conducted to assess the carcinogenic potential of abaloparatide. The study was conducted according to the provisions set forth in Guidance ICH-S1A, ICH-S1B, and ICH-S1C(R2), and the design was accepted by the FDA on July 15, 2009. This study evaluated three abaloparatide dose levels. The doses were selected based upon findings and tolerance in completed long-term rat toxicology studies and the anticipated tolerance over a two-year dosing period. Furthermore, the doses represent an exposure multiple over maximum clinical doses. The study included a cohort of rats being dosed with a daily subcutaneous injection of PTH(1-34) as a positive control, as it was anticipated that osteosarcomas would be observed with this treatment, as previously published for both rhPTH(1-34) and rhPTH(1-84) in similar 2-year rat carcinogenicity studies. The positive control served to provide confirmation of the sensitivity of the model. An audited draft of histopathology data revealed osteosarcomas in our carcinogenicity study in both the abaloparatide and PTH(1-34) treated groups, with similar frequency between abaloparatide and PTH(1-34) when comparing comparable exposure multiples to the human therapeutic dose.

We are also conducting one preclinical bone quality study in OVX rats with 12 months of daily Abaloparatide-SC dosing and a second preclinical bone quality study in adult OVX monkeys for 16 months. The primary objective of these studies is to determine the long-term treatment effects of Abaloparatide-SC on bone quality. Effects on bone mass, both cortical bone and cancellous bone, will be assessed by BMD and peripheral quantitative computed tomography, and bone strength will be determined by biomechanical testing. The mechanisms by which abaloparatide affects bone will be assessed by evaluation of biomarkers of bone turnover and histomorphometric indices of bone turnover. Preliminary data from the 12-month rat study has shown marked, dose dependent increases in BMD following abaloparatide treatment, increases in bone formation markers, but not bone resorption, and an increase in bone strength.

Preliminary results from the 16-month monkey OVX study have also shown significant BMD gains, together with increases in bone strength at vertebral and non-vertebral sites. In this study, ovariectomy and a 9-month bone depletion period resulted in a marked osteopenia demonstrated by decreased BMD and decreased bone strength. Daily administration of abaloparatide resulted in marked bone anabolic effects. Spine and femoral neck BMD was comparable to, or above, pre-ovariectomy levels after 4 months of treatment, with further increases at 12 months, which were sustained at 16 months. Total tibia metaphysis BMD was also increased at all doses. These BMD gains were associated with increases in bone formation markers. As expected for osteopenic animals, decreases in bone mass were associated with decreased bone strength parameters for lumbar vertebral cores and vertebral bodies in compression. Abaloparatide treatment resulted in complete reversal of ovariectomy-induced strength loss at the spine with increased yield load for the vertebral core and at the vertebral body. At an important non-vertebral site, the femoral neck, peak load shear was decreased in control animals, relative to sham, while this loss was reversed with abaloparatide treatment. This study demonstrated that abaloparatide treatment rapidly builds high-quality new bone in osteopenic monkeys, with sustained gains over time, and improved bone strength at clinically relevant sites.

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**RAD1901**

In June 2006, we exclusively licensed the worldwide rights (except for Japan) to RAD1901 from Eisai. We are developing RAD1901 as a SERD in Phase 1 clinical development for the treatment of BCM. We are also developing RAD1901, which at lower doses acts as a SERM, in an oral formulation as a treatment for vasomotor symptoms, commonly known as hot flashes or hot flushes. We currently intend to advance the development of RAD1901 for the treatment of ER-positive BCM with the initiation of two Phase 1 studies in 2014 – a maximum tolerated dose study that has commenced patient screening, and a Phase 1b clinical trial in BCM, which is expected to commence in late 2014. We currently intend to seek potential collaborations with third parties in order to advance the development of RAD1901 for the treatment of vasomotor symptoms. We anticipate the next clinical study would be a Phase 2b study conducted in approximately 200 perimenopausal women experiencing a high frequency of hot flashes at baseline. The main study endpoints would be an assessment of the change in the frequency and severity of moderate and severe hot flashes.

***Pharmacologic Characteristics***

RAD1901 has been shown to bind with good selectivity to the ER alpha, or ER $\alpha$ , and to have both estrogen-like and estrogen antagonist effects in different tissues. RAD1901 has also been shown to have estrogen-like behavioral effects in an animal model of partner preference and to reduce vasomotor signs in an animal model of menopausal hot flashes. In bone, RAD1901 protects against gonadectomy-induced bone loss. RAD1901 does not stimulate the endometrium, as shown in short and long term animal models, where changes in uterine weight, uterine epithelial thickness and C3 gene expression are measured, all of which are sensitive indicators. In studies in which an estrogen is used to stimulate the endometrium, RAD1901 antagonizes this estrogen-mediated stimulation of the endometrium. In cell culture, RAD1901 does not stimulate replication of breast cancer cells, and antagonizes the stimulating effects of estrogen on cell proliferation. Furthermore, in breast cancer cell lines a dose dependent down regulation of ER $\alpha$  is observed, a process we have shown to involve proteosomal mediated degradation pathway. In a model of breast cancer, in which human breast cancer cells are implanted in mice and allowed to establish tumors in response to estrogen treatment, we have shown that treatment with RAD1901 results in decreased tumor growth.

Pharmacokinetic studies with RAD1901 have established the PK profile including demonstration of good oral bioavailability and the ability of RAD1901 to cross the blood-brain barrier, with pharmacological levels detectable in the brain. We believe that RAD1901 is a promising agent for development in the treatment both vasomotor symptoms and a range of estrogen-driven cancers.

***Clinical Development Program***

***Phase 2 Study – Vasomotor Symptoms***

A Phase 2 proof of concept study was conducted in 100 healthy perimenopausal women using four doses of RAD1901 (10 mg, 25 mg, 50 mg 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 two-, three- or four-week time-points. A similar reduction in composite score (frequency  $\times$  severity of hot flashes) was identified at all time-points, with a statistically significant difference from placebo achieved at the two-, three- or four-week time-points. Numerical reductions in mean severity and mean daily severity were observed, but did not reach statistical significance. We believe RAD1901 is an attractive candidate for advancement to Phase 3 development as a treatment for vasomotor symptoms.

No SAEs 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 headaches. Three severe adverse events occurred, one in a



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placebo patient, none of which were considered treatment related. Two patients discontinued treatment due to an adverse event, neither in relation to the 10 mg dose.

*Phase 1 Study Vasomotor Symptoms*

We have conducted Phase 1 safety, PK and bioavailability studies of RAD1901 in 80 healthy postmenopausal women over a range of doses. 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 at all dose levels tested. All study-related adverse events were of mild intensity, with some increase in frequency at the higher doses in the multiple dose group, most commonly gastrointestinal symptoms and headaches. There were no SAEs observed.

**RAD140**

RAD140 is a nonsteroidal selective androgen receptor modulator, or SARM, 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, we believe 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, and also in the treatment of breast cancer.

We may choose to advance the RAD140 program internally or to collaborate with third parties for its further development and commercialization. Therefore, the date of any FDA approval of RAD140, if ever, cannot be predicted at this time. As a result of the uncertainties around the development strategy for RAD140, we are unable to determine the duration and costs to complete current or future clinical stages of our RAD140 product candidate.

**Manufacturing**

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. The active pharmaceutical ingredient, or API, of abaloparatide is manufactured on a contract basis by Lonza Group Ltd., or Lonza, using a solid phase peptide synthesis assembly process, and purification by high pressure liquid chromatography. Abaloparatide-SC 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. Abaloparatide-TD is manufactured by 3M based on their patented microneedle technology to administer drugs through the skin, as an alternative to subcutaneous injection. The API of RAD1901 is manufactured for us on a contract basis by Irix Pharmaceuticals, Inc.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our contract manufacturing organizations manufacture our product candidates under current Good Manufacturing Practice (cGMP) conditions. cGMP is a regulatory standard for the production of pharmaceuticals that will be used in humans.

**Intellectual Property**

As of March 31, 2014, we owned six issued United States patents, as well as twelve pending U.S. patent applications and 44 pending foreign patent applications in Europe and 15 other jurisdictions, and 13 granted foreign patents. As of March 31, 2014, we had licenses to nine U.S. patents as well as numerous foreign counterparts to many of these patents and patent applications.

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates and compositions, their methods of use and processes for their manufacture and any other inventions that are commercially important to the

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development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will significantly depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology and inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop and maintain our proprietary position.

***Abaloparatide***

We acquired and maintain exclusive worldwide rights, excluding Japan, to certain patents, data and technical information related to abaloparatide through a license agreement with an affiliate of Ipsen. Composition of matter of abaloparatide is claimed in the United States (U.S. Patent No. 5,969,095), Europe, Australia, Canada, China, Hong Kong, South Korea, New Zealand, Poland, Russia, Singapore, Mexico, Hungary, and Taiwan. These cases have a normal patent expiration date of 2016 absent any U.S. patent term extension under the Hatch-Waxman Act. The Phase 3 clinical dosage of abaloparatide by the subcutaneous route for use in treating osteoporosis is covered by Patent No. 7,803,770 until 2028 (statutory term extended with 175 days of patent term adjustment due to delays in patent prosecution by the United States Patent and Trademark Office, or USPTO) in the United States (absent any patent term extension under the Hatch-Waxman Act). The intended therapeutic formulation for Abaloparatide-SC is covered by Patent No. 8,148,333 until 2027 (statutory term extended with 36 days of patent term adjustment due to delays in patent prosecution by the USPTO) in the United States (absent any patent term extension under the Hatch-Waxman Act). Related cases granted in China, Australia, Singapore, Japan, Mexico, New Zealand, Russia and Ukraine, and currently pending in Europe, China, Australia, Canada, Brazil, Singapore, South Korea, India, Israel, Norway and Hong Kong will have a normal un-extended patent expiration date of 2027. Patent applications which cover various aspects of abaloparatide for microneedle application are pending in the United States, Australia, Brazil, Canada, China, Europe, Israel, India, Japan, Korea, Mexico, New Zealand, Russia, Singapore, and Ukraine. Any claims that might issue from these applications will have a normal expiration date no earlier than 2032. Three provisional patent applications which cover combinations of abaloparatide with various bone-directed therapeutics were filed in the US in January 2014. Regular applications claiming priority to these provisional applications are expected to be made in 2015, and any claims that might issue from those applications would have a normal expiry date no earlier than 2035.

***RAD1901***

We exclusively license the worldwide rights, except for Japan, to RAD1901 from Eisai. US Patent No. 7,612,114 (statutory term extended to 2026 with 967 days of patent term adjustment absent any Hatch-Waxman patent term extension) and US Patent No. 8,399,520 (statutory term expires 2023) cover RAD1901 as a composition of matter as well as the use of RAD1901 for treatment of estrogen-dependent breast cancer. Corresponding cases issued in Australia and Canada and pending in India and Europe will have a normal expiration date in 2023. Patent applications covering methods of using RAD1901 for the treatment of vasomotor symptoms are pending in the United States (published as US 2010/0105733A1) and Canada, and granted in Europe; any issued claims will have a normal expiration in 2027. Patent applications covering a dosage form have been filed in the United States, Europe, Canada and Mexico, and any claims that might issue from these applications will have a normal expiration date no earlier than 2031.

***RAD140***

The composition of matter of, and methods of using, RAD140 is covered by US Patent No. 8,067,448 (effective filing date February 19, 2009, and a statutory term extended to September 25, 2029, with 281 days of patent term adjustment due to delays by the USPTO) and U.S. Patent No. 8,268,872 (effective filing date February 19, 2009 with term understood to be extended with 232 days of patent term adjustments). Related patents have been granted in Australia, Japan and Mexico and additional patent

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applications are pending in the United States and numerous additional countries worldwide. Any patents issued from these filings will have a normal expiration in 2029 absent any extensions.

There can be no assurance that an issued patent will remain valid and enforceable in a court of law through the entire patent term. Should the validity of a patent be challenged, the legal process associated with defending the patent can be costly and time consuming. Issued patents can be subject to oppositions, interferences and other third party challenges that can result in the revocation of the patent or that can limit patent claims such that patent coverage lacks sufficient breadth to protect subject matter that is commercially relevant. Competitors may be able to circumvent our patents. Development and commercialization of pharmaceutical products can be subject to substantial delays and it is possible that at the time of commercialization any patent covering the product has expired or will be in force for only a short period of time following commercialization. We cannot predict with any certainty if any third party U.S. or foreign patent rights, or other proprietary rights, will be deemed infringed by the use of our technology. Nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. Should we need to defend ourselves and our partners against any such claims, substantial costs may be incurred. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability to develop or commercialize some or all of our products in the U.S. and abroad, and could result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from a third party. There can be no assurance that we can obtain a license on a reasonable basis should we deem it necessary to obtain rights to an alternative technology that meets our needs. The failure to obtain a license may have a material adverse effect on our business, results of operations and financial condition.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that we can meaningfully protect our trade secrets on a continuing basis. Others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets.

It is our policy to require our employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from us to execute confidentiality agreements upon the commencement of employment or consulting relationships. These agreements provide that all confidential information developed or made known to these individuals during the course of the individual's relationship with the company is to be kept confidential and is not to be disclosed to third parties except in specific circumstances. The agreements provide that all inventions conceived by an employee shall be the property of the company. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Our success will depend in part on our ability to obtain and maintain patent protection, preserve trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others, both in the U.S. and other territories worldwide.

**Competition**

The development and commercialization of new products to treat the targeted indications of our product candidates is highly competitive, and our products, if approved, will face considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies, including Amgen, UCB, Merck & Co, Novartis, Lilly, Genentech, Warner Chilcott, Asahi Kasei and Zosano, that are seeking to develop products for similar indications. Many of our competitors have substantially more resources than we do, including financial, manufacturing, marketing, research and drug development resources. 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.

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Within the osteoporosis market, Lilly launched Forteo in December 2002 as the first-to-market anabolic or bone-building agent for the treatment of osteoporosis. In April 2012, UCB and Amgen started a Phase 3 clinical trial program for their anti-sclerostin antibody for the treatment of osteoporosis. We are also aware that Zosano is developing a transdermal form of PTH(1-34) that would compete with Abaloparatide-TD.

RAD1901 for the treatment of BCBM will face competition from SERDs, CNS-penetrant anti-cancer agents and from chemotherapy derivatives. RAD1901 will also face competition from other therapeutics in development for the treatment of hot flashes. We cannot assure you that our current product candidates, if approved, will be able to compete effectively against these, or any other competing therapeutics that may become available on the market.

**COLLABORATIONS AND LICENSE AGREEMENTS**

**Nordic Bioscience**

*Abaloparatide-SC Phase 3 Clinical Trial* We entered into a letter of intent with Nordic Bioscience Clinical Development VII A/S, or Nordic, on September 3, 2010, pursuant to which we funded preparatory work by Nordic in respect of a Phase 3 clinical study of Abaloparatide-SC, which is being conducted at centers operated by the Center for Clinical and Basic Research, or CCBR, as well as other medical centers. CCBR is a leading global clinical research organization, or CRO, with extensive experience in global osteoporosis registration studies. 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 \$1.5 million of preparatory work by Nordic during 2010 and funded an additional \$750,000 of preparatory work by Nordic during 2011. On March 29, 2011, we and Nordic entered into a Clinical Trial Services Agreement, a Work Statement NB-1, or the Work Statement NB-1, under such Clinical Trial Services Agreement and a related Stock Issuance Agreement. Pursuant to the Work Statement NB-1, Nordic is managing the Phase 3 clinical trial, or the Phase 3 Clinical Trial, of Abaloparatide-SC and Nordic will be compensated for such services in a combination of cash and shares of stock.

The Clinical Trial Services Agreement has a five-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 diligently proceeds to cure. Termination of any Work Statement does not result in termination of the Clinical Trial 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 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: (1) the negligence or intentional misconduct of such party, its employees, agents or representatives in performing its obligations under the Clinical Trial Services Agreement or any Work Statement; and (2) 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 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.

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The Clinical Trial Services Agreement contains other customary clauses and terms as are common in similar agreements in the industry.

In December 2011, we entered into an amendment to the Work Statement NB-1, or the First Amendment. Pursuant to the original terms of the Work Statement NB-1, the study was to be conducted in 10 countries at a specified number of sites within each country. The terms of the First Amendment (1) provided for two additional countries (the United States and India) in which the trial will be conducted, (2) specified a certain number of sites within each such additional country for the conduct of the study and (3) amended various terms and provisions of the Work Statement NB-1 to reflect the addition of such countries and sites within the study's parameters. Payments to be made by us to Nordic under the First Amendment in connection with the conduct of the study in such additional countries are denominated in both euros and U.S. dollars and total up to both €717,700 (\$988,775) and \$289,663, respectively, for the 15 additional study sites in India contemplated by the First Amendment and up to both €1.2 million (\$1.7 million) and \$143,369, respectively, for the five additional study sites in the United States contemplated by the First Amendment.

In June 2012, we entered into a second amendment to the Work Statement NB-1, or the Second Amendment. Pursuant to the original terms of the Work Statement NB-1, as amended by the First Amendment, the study was to be conducted in 12 countries at a specified number of sites within each country. The terms of the Second Amendment (1) increased the overall number of sites by adding sites in Europe, Brazil and Argentina and removing other sites, (2) specified a certain number of sites within each country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect additional services provided at existing sites and the addition of the new study sites within the study's parameters. The Second Amendment also provided that cash payments to Nordic under the Clinical Trial Services Agreement as well as the payment of shares of stock under the related Stock Issuance Agreement each be reduced by an amount of €11,941 (\$16,451) per subject for any subjects enrolled in India or the United States. Such reductions are applied in pro rata monthly installments. Payments to be made by us to Nordic under the Second Amendment in connection with the extra services provided at existing sites and the conduct of the study at the new study sites are denominated in both euros and U.S. dollars and total €3.7 million (\$5.1 million) and \$205,540, respectively.

In March 2014, we entered into a fourth amendment to the Work Statement NB-1, or the Fourth Amendment. Pursuant to the terms of the Fourth Amendment, we agreed to pay to Nordic an additional performance incentive, or a Performance Incentive Payment, of \$500,000 for every 50 patients that, subsequent to March 28, 2014, complete all end-of-study procedures, up to a maximum aggregate amount of additional payments equal to \$5.0 million. Pursuant to the Work Statement NB-1, as amended by the Fourth Amendment, any Performance Incentive Payment would be paid in cash in the event an underwritten initial public offering of shares of our common stock, or an IPO, is consummated prior to May 31, 2014. On May 19, 2014, we entered into a fifth amendment to the Work Statement NB-1, which amended the date from May 31, 2014 to June 30, 2014. Should an IPO not be consummated by us prior to June 30, 2014, any Performance Incentive Payments will be paid instead through the issuance to Nordic of shares of our capital stock under the same model for equity-based compensation that is contemplated by our existing outstanding work statements under the Clinical Trial Services Agreement.

The Work Statement NB-1, as amended on December 9, 2011, June 18, 2012 and March 28, 2014, provides for a total of up to approximately €41.2 million (\$56.7 million) of euro-denominated payments and a total of up to approximately \$3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus aggregate Performance Incentive Payments of up to \$5.0 million. These payments may be adjusted based upon actual sites opened, work performed or number of patients enrolled.

Pursuant to the Work Statement NB-1, we are required to make certain per patient payments denominated in both euros and U.S. dollars for each patient enrolled in the Phase 3 Clinical Trial followed by monthly payments for the duration of the study and final payments in two equal euro-denominated installments and

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two equal U.S. dollar-denominated installments. Changes to the Clinical Study schedule may alter the timing, but not the aggregate amounts of the payments.

Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase the equivalent of €371,864 of Series A-5 Convertible Preferred Stock at \$8.142 per share, and 64,430 shares of Series A-5 Convertible Preferred Stock were sold to Nordic on May 17, 2011 for proceeds of \$525,154. These shares were exchanged in the Merger for an aggregate of 6,443 shares of our Series A-5. Convertible Preferred Stock, or Series A-5.

The Stock Issuance Agreement provides that Nordic is entitled to receive quarterly stock dividends, payable in shares of our Series A-6 Convertible Preferred Stock, or Series A-6, or shares of common stock if our preferred stock has been converted in accordance with its amended certificate of incorporation, having an aggregate value, under the Work Statement NB-1 of up to €36.8 million (\$50.7 million) (the "Nordic Accruing Dividend"). In the event Nordic sells the shares of Series A-5 or in the event the shares of Series A-5 are converted into common stock in accordance with our amended certificate of incorporation, this right to receive the Nordic Accruing Dividend will terminate, but a right to receive an equivalent number of shares of Series A-6 or common stock, as applicable, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

The Nordic Accruing Dividend related to the Phase 3 Clinical Trial is determined based upon the estimated period that will be required to complete the Phase 3 Clinical Trial. On the last business day of each calendar quarter (each, an "Accrual Date"), beginning with the quarter ended June 30, 2011, the Company has a liability, under the Work Statement NB-1 to issue shares of Series A-6 (or common stock, after the conversion of the Company's preferred stock into common stock) to Nordic that is referred to as the "Applicable Quarterly Amount" and is equal to €36.8 million (\$50.7 million) (subject to adjustment in accordance with the applicable provisions of the Second Amendment relating to consideration payable for patients enrolled in India and the U.S.) minus the aggregate value of any prior Nordic Accruing Dividend accrued divided by the number of calendar quarters it will take to complete the Phase 3 Clinical Trial. To calculate the aggregate number of shares due to Nordic in each calendar quarter, we convert the portion of €36.8 million (\$50.7 million) to accrue in such calendar quarter into U.S. dollars using the simple average of the exchange rate for buying U.S. dollars with euros for all Mondays in such calendar quarter. We then calculate the aggregate number of shares to accrue in such calendar quarter by dividing the U.S. dollar equivalent of the Applicable Quarterly Amount, by the greater of (1) the fair market value of our common stock as of the applicable Accrual Date or (2) \$81.42 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic are to be issued when declared or paid by our Board of Directors, who are required to do so upon Nordic's request, or upon an event of sale. As of December 31, 2013, 438,124 shares of Series A-6 were due to Nordic under Work Statement NB-1, as amended. In December 2013, Nordic requested that all shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-1 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 438,124 shares accrued under Work Statement NB-1 on December 31, 2013.

On March 28, 2014, we entered into Amendment No. 2 to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011, or the Second Stock Issuance Agreement Amendment, with Nordic. The Second Stock Issuance Agreement Amendment required that our board of directors declare, as soon as reasonably practical, a stock dividend of 29 shares of our Series A-6 for each share of our outstanding Series A-5, all of which are held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in relation to Work Statement NB-1 and Work Statement NB-3, excluding any Performance Incentive Payments payable in stock. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment provided further that in the event an IPO occurs prior to May 31, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3 for all periods of time after 2014, excluding any Performance

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Incentive Payments, will be changed from the right to receive stock to the right to receive a total cash payment from us of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, we entered into Amendment No. 3 to the Amended and Restated Stock Issuance Agreement, which amended the date from May 31, 2014 to June 30, 2014. The Amended and Restated Issuance Agreement, as amended, also stipulates that all consideration to be paid to Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an IPO be payable in cash.

*Abaloparatide-SC Phase 3 Clinical Extension Study* In February 2013, we entered into a Work Statement NB-3 (the "Work Statement NB-3") under the Clinical Trial Services Agreement and the related Stock Issuance Agreement. Pursuant to Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the 18-month Abaloparatide-SC Phase 3 Clinical Trial, or the Extension Study, and will be compensated for such services in a combination of cash and shares of stock. Under the terms of a Letter of Intent that we entered into with Nordic on October 22, 2012 setting forth the parties' obligations to negotiate in good faith to enter into Work Statement NB-3, we were required to make an initial payment of €806,468 (\$1.1 million).

In March 2014, we entered into an amendment to the Work Statement NB-3, or the NB-3 Amendment. The NB-3 Amendment was effective as of February 28, 2014 and provides that Nordic will perform a Period 2 extension study, or the Second Extension, to evaluate an additional eighteen months of standard-of-care osteoporosis management following the Period 1 extension of six months upon completion of the Phase 3 clinical study of our Abaloparatide-SC product. Payments in cash to be made by us to Nordic under the NB-3 Amendment are denominated in both euros and U.S. dollars and total up to approximately €3.0 million (\$4.1 million) and \$527,740, respectively. In addition, we agreed to issue to Nordic shares of our series A-6 convertible preferred stock having a value of up to the sum of approximately €3.0 million (\$4.1 million) and \$527,740 as additional payment for the services to be provided under the NB-3 Amendment, with the issuance of such shares to be made pursuant to the terms of an Amendment No. 2, entered into by us with Nordic on March 28, 2014, to the Amended and Restated Stock Issuance Agreement entered into by the parties as of May 16, 2011, or the Second Stock Issuance Agreement Amendment.

Payments in cash to be made to Nordic under the Work Statement NB-3, as amended by the NB-3 Amendment, are denominated in both euros and U.S. dollars and total up to €7.5 million (\$10.3 million) and \$1.1 million, respectively. In addition, the Company will issue to Nordic, shares of our Series A-6 having a value of up to €7.5 million (\$10.3 million) and \$0.8 million, as additional payment for services to be provided under the Work Statement NB-3 and the Clinical Trial Services Agreement.

The Stock Issuance Agreement provides that, beginning with the quarter ended March 31, 2013, Nordic was entitled to receive quarterly stock dividends in connection with services performed under the Work Statement NB-3, payable in shares of Series A-6 or shares of common stock if our preferred stock has been automatically converted into common stock in accordance with our amended certificate of incorporation, having an aggregate value of up to €7.5 million (\$10.3 million) and \$0.8 million. In the event Nordic sells the shares of Series A-5 or in the event the shares of Series A-5 are converted into common stock in accordance with our amended certificate of incorporation, this right to receive the Nordic Accruing Dividend will terminate, but a right to receive an equivalent number of shares of Series A-6 or common stock, as applicable, will remain with Nordic as a contractual right under the Stock Issuance Agreement.

The Nordic Accruing Dividend related to the Extension Study is determined based upon the estimated period that will be required to complete the Extension Study. On each Accrual Date, beginning with the quarter ended March 31, 2013, we will recognize a liability to issue shares of Series A-6 to Nordic with an Applicable Quarterly Amount value equal to €7.5 million (\$10.3 million) and \$0.8 million minus the aggregate value of any previously accrued Nordic Accruing Dividend related to the Extension Study divided by the number of calendar quarters it will take to complete the Extension Study. We calculate the aggregate

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number of shares of Series A-6 to accrue in such calendar quarter by dividing such Applicable Quarterly Amount, by the greater of (1) the fair market value of our common stock as of the applicable Accrual Date or (2) \$81.42 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic are to be issued when declared or paid by our Board of Directors, who are required to do so upon Nordic's request, or upon an event of sale. As of December 31, 2013, 25,772 shares of Series A-6 were due to Nordic under Work Statement NB-3. In December 2013, Nordic requested that all shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-3 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 25,772 shares accrued under Work Statement NB-3 on December 31, 2013.

On March 28, 2014, we entered into the Second Stock Issuance Agreement Amendment with Nordic. The Second Stock Issuance Agreement Amendment required that our board of directors declare, as soon as reasonably practical, a stock dividend of 29 shares of our Series A-6 for each share of our outstanding Series A-5, all of which are held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in relation to Work Statement NB-1 and Work Statement NB-3, excluding any Performance Incentive Payments payable in stock. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment provided further that in the event an IPO occurs prior to May 31, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3 for all periods of time after 2014, excluding any Performance Incentive Payments, will be changed from the right to receive stock to the right to receive a total cash payment from us of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, we entered into Amendment No. 3 to the Amended and Restated Stock Issuance Agreement, which amended the date from May 31, 2014 to June 30, 2014. The Amended and Restated Stock Issuance Agreement, as amended, also stipulates that all consideration to be paid to Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an IPO be payable in cash.

On December 6, 2013, we entered into a Letter of Intent, or the Letter of Intent, with Nordic, which provided that we and Nordic would continue to negotiate the definitive terms of the NB-3 Amendment. Pursuant to the Letter of Intent, we were required to make an initial payment of €222,573 (\$0.3 million) and agreed to commence payment of the cash compensation due in consideration of the services being provided by Nordic under the NB-3 Amendment. The Letter of Intent terminated in accordance with its terms on February 28, 2014 (pursuant to an extension mutually agreed to by us and Nordic).

*Abaloparotide-TD Phase 2 Clinical Trial* On July 26, 2012, we entered into a Letter of Intent (the "Letter of Intent") with Nordic, which provides that the Company and Nordic will, subject to compliance by the Company with certain requirements of our amended certificate of incorporation and applicable securities laws, negotiate in good faith to enter into (1) a Work Statement NB-2 (the "Work Statement NB-2"), a draft of which is attached to the Letter of Intent, and (2) an amendment to the Amended and Restated Stock Issuance Agreement.

In February 2013, we executed the final Work Statement NB-2 under the Clinical Trial Services Agreement and the related Stock Issuance Agreement. Pursuant to the Work Statement NB-2, Nordic will provide clinical trial services relating to the Phase 2 Clinical Trial and will be compensated for such services in a combination of cash and shares of stock. Payments in cash to be made by us to Nordic under the Work Statement NB-2 are denominated in both euros and U.S. dollars and total up to €3.6 million (\$5.0 million) and \$0.3 million, respectively. In addition, we will issue to Nordic shares of our Series A-6 stock having a value of up to \$2.9 million, as additional payment for services to be provided under the Work Statement NB-2 and the Clinical Trial Services Agreement.



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

The Nordic Accruing Dividend related to the Phase 2 Clinical Trial is determined based upon the estimated period that will be required to complete the Phase 2 Clinical Trial. On each Accrual Date, beginning with the quarter ended December 31, 2012, we will recognize a liability to issue shares of Series A-6 to Nordic with an Applicable Quarterly Amount value equal to up to \$2.9 million minus the aggregate value of any prior Nordic Accruing Dividend related to the Phase 2 Clinical Study divided by the number of calendar quarters it will take to complete the Phase 2 Clinical Study. We calculate the aggregate number of shares of Series A-6 to accrue in such calendar quarter by dividing such Applicable Quarterly Amount, by the greater of (1) the fair market value of our common stock as of the applicable Accrual Date or (2) \$81.42 and rounding down the resulting quotient to the nearest whole number. Such shares due to Nordic are to be issued when declared or paid by our Board of Directors, who are required to do so upon Nordic's request, or upon an event of sale. As of December 31, 2013, 32,215 shares of Series A-6 were due to Nordic under Work Statement NB-2. In December 2013 Nordic requested that all shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-2 be issued. Accordingly, our Board of Directors declared a dividend to Nordic of all 32,215 shares accrued under Work Statement NB-2 on December 31, 2013, which constituted all shares of Series A-6 due under Work Statement NB-2.

As of March 31, 2014, all obligations under Work Statement NB-2 were fulfilled.

**3M**

In December 2008, we entered into a Feasibility Agreement with 3M whereby 3M assessed the feasibility of developing an Abaloparatide-TD product and supplying the product for preclinical studies in an animal model. Upon successful 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 an Abaloparatide-TD product and manufacture clinical and toxicology supplies of such patch product for preclinical, Phase 1 and Phase 2 studies on an exclusive basis during the term of the agreement. In December 2012, we entered into an amendment to the Development and Clinical Supplies Agreement in which 3M agreed to develop and manufacture clinical and toxicology supplies for the Phase 3 Abaloparatide-TD clinical study. In addition, 3M agreed that it will not use jointly owned intellectual property developed during and resulting from its work with Radius on Abaloparatide-TD in relation to any other PTH or PTHrP analogue or derivative. We hold exclusive worldwide rights to this use of transdermal technology.

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 \$15.2 million, in the aggregate, through March 31, 2014 in respect to services and deliverables delivered pursuant to the Feasibility Agreement and the Development and Clinical Supplies Agreement.

The Development and Clinical Supplies Agreement, as amended, provides for services through December 31, 2017, 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. 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

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claim results from 3M's breach of warranty with respect to Abaloparatide-TD 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 Abaloparatide-TD. 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, as amended in September 2007 and May 2011, under which we exclusively licensed certain Ipsen compound technology and related patents covering abaloparatide 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 revenue from the sale of products by both parties in France (subject to a mid-double digit percentage cap) and Ipsen shall bear a corresponding percentage of the costs and expenses incurred by both parties with respect to such marketing and promotion efforts in France; Ipsen shall also pay us a mid-single digit royalty on Ipsen's allocable portion of aggregate revenue from the sale of products by both parties in France. Specifically, we licensed US Patent No. 5,969,095 (effective filing date March 29, 1996, statutory term expires March 29, 2016) entitled "Analog of Parathyroid Hormone," US Patent No. 6,544,949, (effective filing date March 29, 1996, statutory term ends March 29, 2016) entitled "Analog of Parathyroid Hormone" and the corresponding foreign patents and continuing patent applications.

In addition, we have rights to joint intellectual property including rights to US Patent No. 7,803,770 (effective filing date October 3, 2007, statutory term extended to March 26, 2028 with 175 days of patent term adjustment due to delays in patent prosecution by USPTO), US Patent No. 8,148,333 (effective filing date October 3, 2007, statutory term extended to November 8, 2027 with 36 days of patent term adjustment due to delays in patent prosecution by the USPTO) and related patents and patent applications both in the United States and worldwide that cover the method of treating osteoporosis using the Phase 3 clinical dosage strength and form.

As consideration for the rights to abaloparatide licensed to us by Ipsen, we paid Ipsen a non-refundable, non-creditable initial license fee of \$250,000. The License Agreement requires us to make payments to Ipsen upon the achievement of certain development milestones in the range of \$750,000 and upon the achievement of certain development, regulatory and commercial milestones in the range of €10.0 million to €36.0 million (\$13.8 million to \$50.0 million), and we have, as of March 31, 2014, paid \$750,000 in milestone payments and issued 17,326 shares of series A-1 convertible preferred stock to Ipsen on May 17, 2011 in lieu of a €1.0 million cash payment due to Ipsen upon initiation of the first abaloparatide Phase 3 clinical study. If we or our sublicensees commercialize a product that includes the compound licensed from Ipsen or any analog thereof, we will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country.

The date of the last to expire of the abaloparatide patents, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense the rights licensed from Ipsen to a third party, we are obligated to pay Ipsen a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low

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double digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, we will be obligated to pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of our patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country. The License Agreement expires on a country by country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires, in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated.

The License Agreement may be terminated by us with prior notice to Ipsen. The License Agreement may be terminated by Ipsen upon notice to us with immediate effect, if we, in any country of the world, bring an action or proceeding seeking to have any Ipsen patent right declared invalid or unenforceable. The License Agreement can also be terminated by Ipsen if we fail to use reasonable commercial efforts to develop the licensed product for sale and commercialization in those countries within the territory where it is commercially reasonable to do so as contemplated by the License Agreement, or fail to use reasonable commercial efforts to perform our obligations under the latest revised version of the development plan approved by the joint steering committee, or fail to use reasonable commercial efforts to launch and sell one licensed product in those countries within the territory where it is commercially reasonable to do so. Either party may also terminate the License Agreement upon a material breach by the other party unless such other party cures the alleged breach within the notice period specified in the License Agreement. Ipsen may terminate the License Agreement in the event that the License Agreement is assigned or sublicensed or in the event that a third party acquires us or in the event that we acquire control over a PTH or a PTHrP compound that is in clinical development or is commercially available in the territory and that, following such assignment, sublicense, acquisition, or acquisition of control by us, such assignee, sublicensee, acquirer or we fail to meet the timetable under the latest revised version of the development plan approved by the joint steering committee under the License Agreement. Any failure to meet such timetable for purposes of such termination clause is deemed a material breach by us.

The License Agreement contains customary risk allocation clauses with each party indemnifying the other in respect of third-party claims arising out of or resulting from: (1) the gross negligence or willful misconduct of such party, its affiliates, licensees, distributors or contractors; (2) any breach by such party of its representations and warranties or any other provision of the License Agreement or any related agreement; (3) the manufacture on behalf of such party of any licensed product or compound; (4) (in the case of Ipsen) the use, development, handling or commercialization of any licensed compound, licensed product or the Ipsen formulation technology by or on behalf of Ipsen or any of its affiliates, licensees, distributors or contractors; and (5) (in our case) the making, use, development, handling or commercialization of any licensed compound or any licensed product by or on our behalf or any of our affiliates, licensees or contractors. The License Agreement contains other customary clauses and terms as are common in similar agreements in the industry. The License Agreement was amended on September 12, 2007 and May 11, 2011.

In January 2006, we entered into a Pharmaceutical Development Agreement as contemplated by the License Agreement with Ipsen. The Pharmaceutical Development Agreement, as amended in July 2007, February 2009, June 2010 and December 2011, provides for the supply of quantities of licensed product for use in certain clinical trials. Beaufour Ipsen Industrie SAS, a subsidiary of Ipsen, is responsible for the supply of Abaloparatide-SC in liquid form in a multi-dose cartridge for use in a pen delivery device. The multi-dose cartridges are manufactured for Beaufour Ipsen Industrie SAS by Vetter under a separate agreement between those parties, and abaloparatide API is manufactured by Lonza for us and is delivered to Vetter for vialing in the multi-dose cartridges. The Pharmaceutical Development Agreement expires upon the completion of the work plan entered into under the Pharmaceutical Development Agreement unless it is sooner terminated. The Pharmaceutical Development Agreement shall automatically terminate upon termination of the Ipsen license Agreement. We may terminate the Pharmaceutical Development Agreement at any time and for any reason with a specified prior notice period to Ipsen. Either party may terminate the

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Pharmaceutical Development Agreement upon a material breach by the other party with respect to the Pharmaceutical Development Agreement or the Ipsen License Agreement unless such other party cures the alleged breach within the notice period specified in the Development and Manufacturing Services Agreement. The Pharmaceutical Development Agreement contains other customary clauses and terms as are common in similar agreements in the industry.

**Eisai**

In June 2006, we exclusively licensed the worldwide (except Japan) rights to research, develop, manufacture and commercialize RAD1901 and related products from Eisai. Specifically, we licensed the patent application that subsequently issued as US Patent No. 7,612,114 (effective filing date December 25, 2003, statutory term extended to August 18, 2026 with 967 days of patent term adjustment due to delays by the USPTO) entitled "Selective Estrogen Receptor Modulator," the corresponding foreign patent applications and continuing patent applications. As consideration for the rights to RAD1901, we paid Eisai an initial license fee of \$0.5 million. In connection with the License Agreement, we have agreed to pay Eisai certain fees in the range of \$1.0 million to \$20.0 million (inclusive of the \$0.5 million initial license fee), payable upon the achievement of certain clinical and regulatory milestones.

Should a product covered by the licensed technology be commercialized, we will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the product on a country-by-country basis until the later of the last to expire of the licensed patents or the expiration of data protection clauses covering such product in such country; the royalty rate shall then be subject to reduction and the royalty obligation will expire at such time as sales of lawful generic version of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. The latest valid claim to expire, barring any extension thereof, is expected on August 18, 2026.

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

The license agreement may be terminated by us with respect to the entire territory with prior notice to Eisai if we reasonably determine that the medical/scientific, technical, regulatory or commercial profile of the licensed product does not justify continued development or marketing. The license agreement can also be terminated by Eisai on a country by country basis at any time prior to the date on which we have submitted for either an FDA NDA approval or an EMA marketing approval with respect to a licensed product, upon prior written notice to us if Eisai makes a good faith determination that we have not used commercially reasonable efforts to develop the licensed product in the territory having reference to prevailing principles and time scales associated with the development, clinical testing and government approval of products of a like nature to such licensed product, unless such default is cured within the period specified in the license agreement or if not capable of being cured within such period we commence efforts to cure and make diligent efforts to do so. Either party may also terminate the license agreement upon a material breach by the other party unless such other party cures the alleged breach within the notice period specified in the license agreement. Either party may also terminate the license agreement upon the bankruptcy or insolvency of the other party. Eisai may also terminate the license agreement with prior notice if we are acquired by, or if we transfer all of our pharmaceutical business assets (or an essential part of such assets) or more than

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50% of our voting stock to, any third-party person or organization, or otherwise come under the control of, such a person or organization, whether resulting from merger, acquisition, consolidation or otherwise in the event that Eisai reasonably determines that the person or organization assuming control of us is not able to perform the license agreement with the same degree of skill and diligence that we would use, such determination being made with reference to the following criteria with respect to the person or organization assuming control of us: (1) whether such person or organization has the financial resources to assume our obligations with respect to development and commercialization of products; (2) whether such person or organization has personnel with skill and experience adequate to assume our obligations with respect to development and commercialization of products at the stage of development and commercialization as of the date of such change; and (3) whether such person or organization expressly assumes all obligations imposed on us by the license agreement and agrees to dedicate personnel and financial resources to the development and commercialization of the licensed product that are at least as great as those provided by us. Eisai shall further have the right to terminate if the acquiring person or organization: (a) has any material and active litigations with Eisai; (b) is a certain type of pharmaceutical company; or (c) is a hostile takeover bidder against us which has not been approved by our board of directors as constituted immediately prior to such change of control.

The license agreement contains customary risk allocation clauses with each party indemnifying the other in respect of third-party claims arising out of or resulting from: (1) the negligence, reckless or intentional acts or omissions of such party, its affiliates, and licensees; (2) any breach by such party of its representations and warranties; and (3) any personal injury arising out of the labeling, packaging, package insert, other materials or promotional claims with respect to any licensed product by such party or its affiliates, licensees or distributors in the territory (in our case) or Japan (in the case of Eisai). The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

**Lonza**

In October 2007, we entered into a Development and Manufacturing Services Agreement with Lonza. We and Lonza have entered into a series of Work Orders pursuant to the Development and Manufacturing Services Agreement pursuant to which Lonza has performed pharmaceutical development and manufacturing services for our abaloparatide product. We pay Lonza for services rendered and deliverables delivered pursuant to these work orders on a fee for service basis as specified in the applicable work statement. The Development and Manufacturing Services Agreement will expire on December 31, 2015 unless it is sooner terminated, and is subject to renewal by us for successive multiple-year terms with notice to Lonza.

The Development and Manufacturing Services Agreement or any Work Order may be terminated by either party upon a material breach by the other party with respect to the Development and Manufacturing Services Agreement unless such other party cures the alleged breach within the notice period specified in the Development and Manufacturing Services Agreement. Either party may also terminate a Work Order if force majeure conditions have prevented performance by the other party for more than a specified period of time with respect to such Work Order. Termination of any Work Order for force majeure shall not result in termination of the Development and Manufacturing Services Agreement or any other Work Orders, which shall remain in force until terminated. Either party may also terminate the Development and Manufacturing Services Agreement upon the bankruptcy or insolvency of the other party. We may also terminate the Development and Manufacturing Services Agreement or any Work Order with prior notice to Lonza for convenience. We may also terminate the Development and Manufacturing Services Agreement or any Work Order if we reasonably determine that Lonza is or will be unable to perform the applicable services in accordance with the agreed upon timeframe and budget set forth in the applicable Work Order, or if Lonza fails to obtain or maintain any material governmental licenses or approvals required in connection with such services.

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The Development and Manufacturing 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 willful misconduct of such party, its affiliates and their respective officers, directors, employees and agents in performing its obligations under the Developing and Manufacturing Services Agreement; and (ii) any breach by such party of its representations and warranties under the Development and Manufacturing Services Agreement. We have agreed to indemnify Lonza in respect of third-party claims arising from or relating to the use of our product.

On December 23, 2011, we entered into Work Order No. 4, or Work Order No. 4, under that certain Development and Manufacturing Services Agreement with Lonza. Pursuant to Work Order No. 4, Lonza agreed to perform activities required for our filing of an NDA in the United States with the FDA and similar applications required by the EMA and other authorities, excluding authorities in Japan, for abaloparatide, including production of three validation batches. These activities will provide for full process qualification and all required documentation necessary for regulatory submissions of the NDA to the FDA and the NDA equivalents to such other authorities. The total compensation payable to Lonza from us for services performed under Work Order No. 4 is up to €363.5 thousand plus up to €1.1 million (\$500.8 thousand plus up to \$1.5 million), for the regulatory qualification and validation campaigns.

**Charles River Laboratories**

In March 2004, we entered into a Laboratory Services and Confidentiality Agreement with Charles River Laboratories, Inc., or CRLI, and amended this agreement on November 7, 2008. We have entered into a series of letter agreements with CRLI pursuant to this Laboratory Services and Confidentiality Agreement, covering the performance of certain testing and analytical services concerning our product candidates. We pay CRLI for services rendered and deliverables delivered pursuant to these letter agreements on a fee for service basis. We are permitted to terminate any on-going study under the Laboratory Services and Confidentiality Agreement at any time with the specified prior notice to CRLI and subject to the payment of applicable study costs and fees. Either party may terminate the Laboratory Services and Confidentiality Agreement at any time with the specified prior notice to the other party and subject to the completion of any then on-going studies and the payment by us of any fees for such studies. Either party may also terminate the Laboratory Services and Confidentiality Agreement upon a material breach by the other party unless such other party cures the alleged breach within the notice period specified in the Laboratory Services and Confidentiality Agreement.

The Laboratory Services and Confidentiality Agreement contains customary risk allocation clauses with each party indemnifying the other in respect of third-party claims arising out of or in connection with the negligence or willful misconduct of such party. We also agreed to indemnify CRLI in respect of third-party claims arising out of or in connection with the manufacture, distribution, use, sale or other disposition by us, or any of our distributors, customers, sublicensees or representatives, of any of our products or processes and/or any other substances which are produced, purified, tested or vialled by CRLI. We also agreed to indemnify CRLI against any and all liability that may be incurred as the result of any contact by us or our employees with CRLI's animals, tissues or specimens during visits to CRLI or after delivery of any samples/specimens to us. The Laboratory Services and Confidentiality Agreement contains other customary clauses and terms as are common in similar agreements in the industry.

**GOVERNMENT REGULATION**

**United States FDA process**

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA

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refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution. We expect abaloparatide, RAD1901 and RAD140 will each be subject to review by the FDA as a drug under NDA standards though we currently only have an active IND application in relation to abaloparatide in the United States. We anticipate filing an investigational new drug application for RAD1901 with the FDA in 2014, as previous studies of RAD1901 were performed outside the United States.

*Approval process.* None of our drugs may be marketed in the United States until the drug has received FDA approval. The steps required to be completed before a drug may be marketed in the United States include:

preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin and must be updated annually;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication to FDA's satisfaction;

submission to the FDA of an NDA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP regulations; and

FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application, which must become effective before human clinical trials may begin. An IND application will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND application. In such a case, the IND application sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND application will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND application.

Clinical trials necessary for product approval are typically conducted in three sequential phases, but the Phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board, or IRB, for each institution where the trials will be conducted, and each IRB must monitor the study until completion. Study subjects must provide informed consent and sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy extensive good clinical practice, or GCP, regulations and regulations for informed consent and privacy of individually identifiable information. Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness.

Phase 1 studies are usually conducted in healthy individuals and are not intended to treat disease or illness. However, Phase 1b studies are conducted in healthy volunteers or in patients diagnosed with the disease or condition for which the study drug is intended, who demonstrate some biomarker, surrogate, or possibly clinical outcome that could be considered for "proof of concept." Proof of concept in a Phase 1b





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study typically confirms the hypothesis that the current prediction of biomarker, or outcome benefit is compatible with the mechanism of action.

Phase 2 usually involves trials in a limited patient population to (1) evaluate dosage tolerance and appropriate dosage; (2) identify possible adverse effects and safety risks; and (3) evaluate preliminarily the efficacy of the drug for specific indications. Several different doses of the drug may be looked at in Phase 2 to see which dose has the desired effects. Patients are monitored for side effects and for any improvement in their illness, symptoms, or both. Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population.

A Phase 3 trial usually compares how well the study drug works compared with an inactive placebo and/or another approved medication. One group of patients may receive the new drug being tested, while another group of patients may receive the comparator drug (already approved drug for the disease being studied), or placebo.

There can be no assurance that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA or an IRB (with respect to a particular study site) may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDCA permits FDA and the IND application sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA. This process is known as a Special Protocol Assessment, or SPA. Under an SPA, the FDA agrees to not alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort and financial resources. The FDA reviews the application and may deem it to be inadequate, and companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically follows such recommendations.

*Expedited Development and Review Programs.* The FDA has various programs, including fast track, breakthrough designation, priority review and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those intended to treat serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. From time to time, we anticipate applying for expedited development and review programs that we believe meet the applicable FDA criteria, though we cannot be sure that any of our drugs will qualify for any of these programs, or even if a drug does qualify, that the review time will be reduced.

A new drug may be eligible for breakthrough therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides the opportunity for intensive guidance on an efficient drug development program

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beginning as early as Phase 1, increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, and the potential for expedited rolling review once an NDA is filed.

On May 9, 2014, we submitted an application for breakthrough therapy designation for Abaloparatide-SC; however, we cannot guarantee we will receive designation or any of its associated benefits.

*Orphan Drug Designation.* Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing. In addition, an NDA for a product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication other than the rare disease or condition for which the drug was designated.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same therapeutic agent for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. Competitors, however, may receive approval of different therapeutic agents for the same indication or obtain approval for the same therapeutic agent for a different indication. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior.

In March 2014, we submitted a request for orphan drug designation to the FDA for RAD1901 for the treatment of BCBM, but we cannot guarantee that we will obtain orphan drug designation or exclusivity. We may also seek to obtain additional orphan designations for other indications or product candidates, but the FDA may disagree with our analysis of the prevalence of a disease or condition and refuse to grant us with additional orphan designations.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and will not approve the product unless the manufacturing is in compliance with cGMP regulations. If the NDA and the manufacturing facilities are deemed acceptable by the FDA, it may issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions. Approval may also be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

*Post-approval requirements.* Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to: (1) report certain adverse reactions to the

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FDA, (2) comply with certain requirements concerning advertising and promotional labeling for their products, and (3) continue to have quality control and manufacturing procedures conform to cGMP regulations after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of ongoing compliance with cGMP regulations. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. We have used and intend to continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, including withdrawal of the product from the market.

*Hatch-Waxman Act.* Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products. In considering whether to approve such a generic drug product, the FDA requires that an Abbreviated New Drug Application, or ANDA, applicant demonstrate, among other things, that the proposed generic drug product's active ingredient is the same as that of the reference product, that any impurities in the proposed product do not affect the product's safety or effectiveness, and that its manufacturing processes and methods ensure the consistent potency and purity of its proposed product.

The Hatch-Waxman Act provides five years of data exclusivity for new chemical entities which prevents the FDA from accepting ANDAs and 505(b)(2) applications containing the protected active ingredient. We expect to be eligible for five years of data exclusivity following any FDA approval of Abaloparatide-SC.

The Hatch-Waxman Act also provides three years of exclusivity for applications containing the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of new uses of approved products, such as new indications, delivery mechanisms, dosage forms, strengths or conditions of use. For example, if Abaloparatide-SC is approved for commercialization and we are successful in performing a clinical trial of Abaloparatide-TD that provides a new basis for approval (a different delivery mechanism) it is possible that we may become eligible for an additional three-year period of data exclusivity which protects against the approval of ANDAs and 505(b)(2) applications for the protected use but will not prohibit the FDA from accepting or approving ANDAs or 505(b)(2) applications for other products containing the same active ingredient.

The Hatch-Waxman Act requires NDA applicants and NDA holders to provide certain information about patents related to the drug for listing in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). ANDA and 505(b)(2) applicants must then certify regarding each of the patents listed with the FDA for the reference product. A certification that a listed patent is invalid or will not be infringed by the marketing of the applicant's product is called a "Paragraph IV certification." If the ANDA or 505(b)(2) applicant provides such a notification of patent invalidity or non-infringement, then the FDA may accept the ANDA or 505(b)(2) application beginning four years after approval of the NDA. If an ANDA or 505(b)(2) application containing a Paragraph IV certification is submitted to the FDA and accepted as a reviewable filing by the agency, the ANDA or 505(b)(2) applicant then must provide, within 20 days, notice to the NDA holder and patent owner stating that the application has been submitted and providing the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. The NDA holder or patent owner then may file suit against the ANDA or 505(b)(2) applicant for patent infringement. If this is done within 45 days of receiving notice of the Paragraph IV certification, a one-time 30-month stay of the FDA's ability to approve the ANDA or 505(b)(2) application is triggered. The 30-month stay begins at the end of the NDA holder's data exclusivity period, or, if data exclusivity has expired, on the date that the patent holder is notified of the submission of the ANDA. The FDA may approve the proposed product before the expiration of the 30-month stay if a court

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finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

**European Union EMA process**

In the EU, medicinal products are authorized following a similar demanding process as that required in the United States and applications are based on the ICH Common Technical Document. Prior to submitting a European Marketing Authorization Application, or MAA, it is necessary to gain approval of a detailed Pediatric Investigation Plan, or PIP, with the European Medicines Agency's Pediatric Committee, or PDCO. After gaining PIP approval, medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

*Centralized procedure.* Under the centralized procedure, after the EMA issues an opinion, the European Commission issues a single marketing authorization valid across the EU, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

*National authorization procedures.* There are also two other possible routes to authorize medicinal products in several countries, which are available for products that fall outside the scope of the centralized procedure:

*Decentralized procedure.* Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of a medicinal product that has not yet been authorized in any EU country and that does not fall within the mandatory scope of the centralized procedure.

*Mutual recognition procedure.* In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Thereafter, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In light of the fact that there is no policy at the EU level governing pricing and reimbursement, the 27 EU Member States each have developed their own, often varying, approaches. In many EU Member States, pricing negotiations must take place between the holder of the marketing authorization and the competent national authorities before the product is sold in their market with the holder of the marketing authorization required to provide evidence demonstrating the pharmaco-economic superiority of its product in comparison with directly and indirectly competing products. We have reviewed our development program, proposed Phase 3 study design, and overall non-clinical and clinical data package and believe they support future regulatory approval of Abaloparatide-SC in the EU. In December 2012, we met with the Swedish Medical Products Agency, or MPA, to review the design and the overall progress of the Phase 3 study. The MPA confirmed that the program, based on the current single pivotal trial design, could support the submission and potential approval of an MAA in the EU, depending on the results of the Phase 3 study.

*Good manufacturing practices.* Like the FDA, the EMA, the competent authorities of the EU Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing of pharmaceutical and biologic products prior to approving a product. If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Once we or our partners commercialize products, we will be required to comply with cGMP, and product-specific regulations enforced by, the European Commission, the EMA and the competent authorities of EU Member States

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following product approval. Also like the FDA, the EMA, the competent authorities of the EU Member States and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our or our partners' equipment, facilities, or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations or the withdrawal of our product from the market.

*Data and Market Exclusivity.* Similar to the United States, there is a process for generic versions of innovator drug products in the EU. Abridged applications for the authorization of generic versions of drugs authorized by EMA can be submitted to the EMA through a centralized procedure referencing the innovator's data and demonstrating bioequivalence to the reference product, among other things.

New medicinal products in the EU can receive eight years of data exclusivity coupled with two years of market exclusivity, and a potential one year extension, if the marketing authorizations holder obtains an authorization for one or more new therapeutic indications that demonstrates "significant clinical benefit" in comparison with existing therapies; this system is usually referred to as "8+2+1". We expect to be eligible for at least ten years of market exclusivity following any approval of Abaloparatide-SC.

Abridged applications cannot rely on an innovator's data until after expiry of the 8 year data exclusivity term; applications for a generic product can be filed but the product cannot be marketed until the end of the market exclusivity term.

**Other international markets drug approval process**

In some international markets (e.g., China or Japan), although data generated in United States or EU trials may be submitted in support of a marketing authorization application, additional clinical trials conducted in the host territory, or studying people of the ethnicity of the host territory, may be required prior to the filing or approval of marketing applications within the country.

**Pricing and reimbursement**

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability and level of reimbursement from third-party payers such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and also the out-of-pocket obligations of member patients for such products. In addition, particularly in the United States and increasingly in other countries, we may be required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted which could potentially impact the reimbursement rates for the products we are developing and may develop in the future and also could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of products that, if successfully developed, we bring to market.

There is no legislation at the EU level governing the pricing and reimbursement of medicinal products in the EU. As a result, the competent authorities of each of the 27 EU Member States have adopted individual strategies regulating the pricing and reimbursement of medicinal products in their territory. These strategies often vary widely in nature, scope and application. However, a major element that they have in common is an increased move towards reduction in the reimbursement price of medicinal products, a reduction in the number and type of products selected for reimbursement and an increased preference for generic products

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over innovative products. These efforts have mostly been executed through these countries' existing price-control methodologies. The government of the UK announced the phase-out of its established Pharmaceutical Pricing Reimbursement Scheme approach in January 2014 and the adoption of a new value-based pricing approach. Under this approach, in a complete departure from established methodologies, reimbursement levels of each drug will be explicitly based on an assessment of value, looking at the benefits for the patient, unmet need, therapeutic innovation, and benefit to society as a whole. It is increasingly common in many EU Member States for Marketing Authorization Holders to be required to demonstrate the pharmaco-economic superiority of their products as compared to products already subject to pricing and reimbursement in specific countries. In order for drugs to be evaluated positively under such criteria, pharmaceutical companies may need to re-examine, and consider altering, a number of traditional functions relating to the selection, study, and management of drugs, whether currently marketed, under development, or being evaluated as candidates for research and/or development.

Future legislation, including the current versions being considered at the federal level in the United States and at the national level in EU Member States, or regulatory actions implementing recent or future legislation may have a significant effect on our business. Our ability to successfully commercialize products depends in part on the extent to which reimbursement for the costs of our products and related treatments will be available in the United States and worldwide from government health administration authorities, private health insurers and other organizations. Substantial uncertainty exists as to the reimbursement status of newly approved healthcare products by third-party payers.

**Sales and Marketing**

The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for the patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

We may also be subject to various federal and state laws pertaining to healthcare "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. Moreover, recent healthcare reform legislation has strengthened these laws. For example, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes, so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA permits the government to assert that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment, to third-party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational

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and monitoring requirements on companies. Similar sanctions and penalties also can be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing.

Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities.

Similar rigid restrictions are imposed on the promotion and marketing of medicinal products in the EU and other countries. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we are not directly responsible for the promotion and marketing of our products, inappropriate activity by our international distribution partners can have adverse implications for us.

**Other laws and regulatory processes**

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the United States, including laws relating to the oversight activities of the SEC and, following the listing of our capital stock on the NASDAQ Global Market, we will be subject to the regulations of the NASDAQ Global Market. In addition, the Financial Accounting Standards Board, or FASB, the SEC and other bodies that have jurisdiction over the form and content of our accounts, our financial statements and other public disclosure are constantly discussing and interpreting proposals and existing pronouncements designed to ensure that companies best display relevant and transparent information relating to their respective businesses.

Our international operations are subject to compliance with the Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We also may be implicated under the FCPA for activities by our partners, collaborators, CROs, vendors or other agents.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights or acquisitions may be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

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**EMPLOYEES**

As of March 31, 2014, we employed 11 full-time employees and two part-time employees, four of whom held Ph.D. or M.D. degrees. Eight of our employees were engaged in research and development activities and five were engaged in support administration, including business development and finance. We intend to use CROs and other third parties to perform our clinical studies and manufacturing.

**PROPERTIES**

On May 14, 2014, we entered into a lease for our executive offices with BP Bay Colony LLC for approximately 8,490 rentable square feet of space in the building located at 950 Winter Street, Waltham, Massachusetts. The estimated commencement date of the lease is August 1, 2014. The lease for our current executive offices in Cambridge, Massachusetts terminates on July 31, 2014.

**LEGAL PROCEEDINGS**

We are not currently involved in any material legal proceedings.



Table of Contents**MANAGEMENT****EXECUTIVE OFFICERS AND DIRECTORS**

The following table sets forth the name, age and position of each of our executive officers and directors as of May 31, 2014:

<b>NAME</b>	<b>AGE</b>	<b>POSITION</b>
Robert E. Ward	56	President, Chief Executive Officer and Director
B. Nicholas Harvey	53	Senior Vice President, Chief Financial Officer, Treasurer and Secretary
Gary Hattersley, Ph.D.	47	Senior Vice President, Chief Scientific Officer
John Yates, M.D.	57	Chief Medical Officer
Alan G. Harris, M.D., Ph.D.	63	Executive Medical Officer
Gregory Williams, Ph.D.	55	Chief Development Officer
Mark W. Durand	55	Chief Commercial Officer
Alan H. Auerbach <sup>(2)(3)</sup>	44	Director
Ansbert K. Gadicke, M.D. <sup>(2)(3)</sup>	56	Director
Kurt C. Graves <sup>(2)(3)</sup>	46	Chairman of the Board
Owen Hughes <sup>(1)</sup>	39	Director
Morana Jovan-Embiricos Ph.D.	47	Director
Martin Münchbach, Ph.D. <sup>(1)</sup>	43	Director
Elizabeth Stoner, M.D. <sup>(1)</sup>	64	Director

- (1) Member of the audit committee.
- (2) Member of the nominating and corporate governance committee.
- (3) Member of the compensation committee.

**Robert E. Ward** has served as our President and Chief Executive Officer and as a member of our board of directors since December 2013. Prior to joining Radius, Mr. Ward was Vice President for Strategy and External Alliances for the New Opportunities iMed of AstraZeneca ("AZ"), a biopharmaceutical company, from 2011 to 2013. In addition, he served as Co-Chair of the Joint Development Committees in AZ's drug development partnerships with Alcon and Galderma. Prior to AstraZeneca, from 2010 to 2011, Mr. Ward was the Managing Director of Harriman Biopartners, LLC, a biopharmaceutical company, and from 2006 to 2010 he was the Vice President of Corporate Development for NPS Pharmaceuticals, a pharmaceutical company. Mr. Ward received a B.A. in Biology and a B.S. in Physiological Psychology, both from the University of California, Santa Barbara; an M.S. in Management from the New Jersey Institute of Technology; and an M.A. in Immunology from The Johns Hopkins University School of Medicine. We believe Mr. Ward is qualified to serve as a member of our board of directors because of his role with us and his extensive operational knowledge of, and executive level management experience in, the global biopharmaceutical industry.

**B. Nicholas Harvey** has served as our Senior Vice President, Chief Financial Officer, Treasurer and Secretary since November 2010, and served as a member of our board of directors from November 2010 until the consummation of the Merger in May 2011. Mr. Harvey served as the Chief Financial Officer and Senior Vice President of the Former Operating Company from December 2006 until the Merger. Mr. Harvey received a Bachelor of Economics degree and a Bachelor of Laws degree with first-class honors from the Australian National University and an M.B.A. from the Harvard Business School.

**Gary Hattersley, Ph.D.**, served as our Senior Vice President of Preclinical Development from December 2011 to December 2013, and has served as Chief Scientific Officer since January 2014. He served as our Vice President of Biology from May 2011 to December 2011 and served in the same capacity at the Former



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Operating Company from April 2008 until the Merger. He also served in the Former Operating Company as Senior Director of Research from 2006 to 2008 and as Director of Disease Biology & Pharmacology from 2003 to 2006. Dr. Hattersley received a Ph.D. in Experimental Pathology from St. George's Hospital Medical School.

**John Yates, M.D.**, has served as our Chief Medical Officer since January 2014. Prior to joining Radius, from 2004 to 2007, Dr. Yates served as President of Global Research and Development for Takeda Pharmaceuticals, a pharmaceutical company. Prior to that, Dr. Yates served in roles of increasing responsibility at Merck, a pharmaceutical company, from 1990 to 2003 and was Vice President of Medical and Scientific Affairs for his latter three years with the company. Dr. Yates received M.B., Ch.B. and M.D. degrees from Sheffield University Medical School, in Sheffield, UK.

**Alan Harris, M.D., Ph.D.**, has served as our Executive Medical Officer since February 2014. Prior to joining Radius, from 2012 to 2013, Dr. Harris was the Chief Medical Officer of Morria/Celsus Biopharmaceuticals, a biopharmaceutical company. Prior to that, Dr. Harris was Consultant Chief Medical Officer of Immune Pharmaceuticals, a biopharmaceutical company, from 2011 to 2012. Before joining Immune Pharmaceuticals, Dr. Harris was Vice President of Drug Development, Regenerative Medicine and Regulatory Affairs at Neostem, Inc., a biopharmaceutical company, from 2009 to 2011. During 2008, Dr. Harris was the Senior Vice President of Research and Development and the Chief Medical Officer of NPS Pharmaceuticals, a pharmaceutical company. From 2004 to 2005, Dr. Harris was Therapeutic Head of Worldwide Medical Endocrine Care for Pfizer, Inc., a pharmaceutical company. Prior to his work at Pfizer, Dr. Harris worked for nine years at Schering Plough, a pharmaceutical company, in a number of positions related to scientific and medical affairs, including Vice President of Global Health Research and Outcomes. In 2012, Dr. Harris founded SomPharmaceuticals SA, a pharmaceutical company, where he currently serves as Chairman of the Board of Directors. Dr. Harris was an associate professor of medicine at the University of California, Los Angeles from 1992 to 1994 and has been an adjunct professor of medicine endocrinology at New York University since 2003. Dr. Harris received his medical degree from the Louis Pasteur Faculty of Medicine, University of Strasbourg, France, and his Ph.D. in endocrinology from Erasmus University, Rotterdam, The Netherlands.

**Gregory Williams, Ph.D.**, has served as our Chief Development Officer since January 2014. Prior to joining Radius, Dr. Williams was Vice President of Regulatory Affairs, Global Product and Clinical Development, and Program Management with The Medicines Company, a biopharmaceutical company, from 2006 to 2013. He was Vice President of Regulatory Affairs, Regulatory Compliance and Program Management for NPS Pharmaceuticals, a pharmaceutical company, from 2004 to 2006. Dr. Williams has a Ph.D. in Biopharmaceutics from Rutgers University and an M.B.A. from Cornell University.

**Mark W. Durand** has served as our Chief Commercial Officer since April 2014. Prior to joining Radius, from 2011 to 2014, Mr. Durand was a consultant for S&G Biopharm LLC, an independent consulting firm owned by Mr. Durand, advising emerging pharmaceutical companies with business development and financing strategies. From 2007 to 2010, Mr. Durand served as Chief Financial Officer, Senior Vice President of Finance and Business Development of Watson Pharmaceuticals, Inc. (now Activis plc), a pharmaceutical company. Prior to that, Mr. Durand served as Chief Financial Officer, Senior Vice President of Finance and Business Development of Teva Pharmaceuticals, Ltd. (Americas), a pharmaceutical company, from 2004 to 2007. Prior to joining Teva, he spent 18 years with Bristol-Myers Squibb, a pharmaceutical company. During his tenure there, Mr. Durand held a number of executive positions in finance, business development and commercial operations, including Vice President Neuroscience/Global Brand Champion Abilify, and Vice President Finance, U.S. Pharmaceutical Group. Since March 2014, Mr. Durand has served on the board of Sorrento Therapeutics, Inc., a biopharmaceutical company. Mr. Durand received a B.S. in Zoology from Duke University, an M.S. in Biological Sciences from Dartmouth and an M.B.A. in Finance and Marketing from the University of Chicago.

**Alan H. Auerbach** has served on our board of directors since May 2011 and served as a member of the board of directors of the Former Operating Company from October 2010 until the Merger. Mr. Auerbach is

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currently the Founder, Chief Executive Officer, President and Chairman of the Board of Puma Biotechnology, Inc., a company dedicated to in-licensing and developing drugs for the treatment of cancer and founded in 2010. Previously, Mr. Auerbach founded Cougar Biotechnology in May 2003 and served as the company's Chief Executive Officer, President and as a member of its board of directors until July 2009. From July 2009 until January 2010, Mr. Auerbach served as the Co-Chairman of the Integration Steering Committee at Cougar (as part of Johnson & Johnson). Mr. Auerbach received a B.S. in Biomedical Engineering from Boston University and an M.S. in Biomedical Engineering from the University of Southern California. We believe Mr. Auerbach is qualified to serve as a member of our board of directors because of his business and professional experience, including his leadership of Cougar Biotechnology in drug development, private and public financings and a successful sale of the business.

**Ansbert K. Gadicke, M.D.**, has served on our board of directors since May 2011 and served as a member of the board of directors of the Former Operating Company from November 2003 until the Merger. Dr. Gadicke has been the Co-Founder and Managing Director of MPM Capital, a venture capital firm, since August 1996. Dr. Gadicke received an M.D. from J.W. Goethe University in Frankfurt. Dr. Gadicke is a director of OSS Healthcare, Inc., Sideris Pharmaceuticals, Inc., RWHD, Inc. and Mitokyne, Inc. He served on the board of directors of Idenix Pharmaceuticals, Inc. from 1998 to 2005, BioMarin Pharmaceuticals, Inc. from 1997 to 2001, Verastem, Inc. from 2010 to 2012, Pharmasset, Inc. from 1999 to 2007 and PharmAthene, Inc. from 2004 to 2007. We believe Dr. Gadicke is qualified to serve as a member of our board of directors because of his business and professional experience, including his experience in the venture capital industry and his years of analyzing development opportunities in the life sciences sector.

**Kurt C. Graves** has served on our board of directors since May 2011 and as Chairman of our board of directors since November 2011. Mr. Graves has been the Chairman, President and Chief Executive Officer of Intarcia Therapeutics, a biotechnology company, since April 2012. Mr. Graves served as Executive Chairman of Biolex Therapeutics, a biotechnology company, from November 2010 to March 2012, and served as Executive Chairman of Intarcia Therapeutics from August 2010 to April 2012. Previously, he served as Executive Vice President, Chief Commercial Officer and Head of Strategic Development at Vertex Pharmaceuticals Inc. from July 2007 to October 2009. Prior to joining Vertex, Mr. Graves held various leadership positions at Novartis pharmaceuticals from 1999 to June 2007. He was also the first Chief Marketing Officer for the Pharmaceuticals division from September 2003 to June 2007. He currently serves as a director of Intarcia Therapeutics, Pulmatrix Therapeutics and Achillion Pharmaceuticals. He served on the board of directors of Biolex Therapeutics and Springleaf Therapeutics from 2010 to 2012. Mr. Graves received a B.S. in Biology from Hillsdale College. We believe Mr. Graves is qualified to serve as a member of our board of directors because of his extensive experience in the life sciences industry, membership on various boards of directors and his leadership and management experience.

**Owen Hughes** has served on our board of directors since April 2013. He has served as the Chief Business Officer and Head of Corporate Development at Intarcia Therapeutics, Inc. since 2013. Prior to Intarcia, he served as a Director at Brookside Capital, a hedge fund under the Bain Capital umbrella, managing public and private healthcare investments from 2008 to 2013. Mr. Hughes has served as a Senior Portfolio Manager at Pyramis Global Advisors from 2006 to 2008, co-founder and partner at Triathlon Fund Management from 2003 to 2006, an Investment Associate at Ziff Brothers Investments from 2001 to 2003; and an Assistant Vice President at Morgan Stanley/Merrill Lynch from 1998 to 2001. He earned a bachelor of arts from Dartmouth College. We believe Mr. Hughes is qualified to serve as a member of our board of directors because of his extensive business and professional experience, including his experience in the venture capital industry and years of analyzing development opportunities in the life sciences sector.

**Morana Jovan-Embiricos, Ph.D.**, has served on our board of directors since April 2013. From 2003 to 2010, Dr. Jovan-Embiricos launched and served as the Managing Partner of F2 Ventures, a biotech venture capital fund, and then launched F3 Ventures in 2010, where she serves a Managing Partner. Dr. Jovan-Embiricos was a Post-Doctoral Fellow at Harvard University. She received her Ph.D. in Biophysical Chemistry from the University of Cambridge. We believe Dr. Jovan-Embiricos is qualified to serve as a

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member of our board of directors because of her scientific background and experience in the venture capital industry.

**Martin Münchbach, Ph.D.**, has served on our board of directors since May 2011. Dr. Münchbach has managed BB Biotech Ventures II, a venture capital fund, since he launched it in 2004. Dr. Münchbach received a Ph.D. in Protein Chemistry, a M.Sc. in Biochemistry and a Master in Industrial Engineering and Management from the Swiss Federal Institute of Technology (ETH). Dr. Münchbach currently serves on the board of directors of Atlas Genetics LTD, BioVascular Inc., Opsana Therapeutics Ltd, Sonetik AG and Tioga Pharmaceuticals Inc, and he served as a director of Optimer Pharmaceuticals, Inc. from 2005 to 2008. We believe Dr. Münchbach is qualified to serve on our board of directors because of his extensive business and professional experience, including his experience in the venture capital industry, membership on various other boards of directors and scientific background.

**Elizabeth Stoner, M.D.**, has served on our board of directors since May 2011. Dr. Stoner has been a Managing Director at MPM Capital since October 2007. Dr. Stoner has been the Chief Development Officer of Rhythm Pharmaceuticals, a biotechnology company, since 2010. Prior to joining MPM Capital, Dr. Stoner served in various roles, most recently as Senior Vice President of Global Clinical Development Operations at Merck Research Laboratories, since 1985. Dr. Stoner currently serves as a director of Momenta Pharmaceuticals Inc., and she served as a director of Metabasis Therapeutics, Inc. from 2009 to 2010. Dr. Stoner received an M.D. from Albert Einstein College of Medicine, an M.S. in Chemistry from the State University of New York at Stony Brook and a B.S. in Chemistry from Ottawa University, Kansas. We believe Dr. Stoner is qualified to serve on our board of directors because of her knowledge and expertise in the development of pharmaceutical products.

**SCIENTIFIC ADVISORY BOARD**

Our management team is supported by a scientific advisory board composed of leading academic and industry scientists. Our scientific advisory board works with our management team in planning, development and execution of scientific, clinical, research and development, and business and operational initiatives and strategies. Our scientific advisory board consists of:

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John Katzenellenbogen, Ph.D. <i>Founder</i>	Swanlund Professor of Chemistry at the University of Illinois at Urbana-Champaign
C. Richard Lyttle, Ph.D. <i>Chairman of Scientific Advisory Board</i>	Previously President and CEO of Radius; senior roles at Wyeth, including VP of Discovery for Women's Health and Bone
Stavros C. Manolagas, M.D., Ph.D. <i>Founder</i>	Professor of Medicine and Director of the Division of Endocrinology and Metabolism, University of Arkansas for Medical Sciences
John T. Potts, M.D., D.Sc. <i>Founder</i>	Professor of Clinical Medicine at the Massachusetts General Hospital and Harvard Medical School; internationally recognized authority on calcium metabolism and governing hormonal mechanisms

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Our management team is also supported by Michael Rosenblatt, M.D., who participates in meetings of our scientific advisory board. Dr. Rosenblatt is one of our founders and continues to contribute his academic and industry expertise as well as his scientific advice, guidance and feedback. Dr. Rosenblatt is currently the Executive Vice President and Chief Medical Officer for Merck & Co. Prior to joining Merck, Dr. Rosenblatt was Dean of Tufts University School of Medicine and before that, he was the George R. Minot Professor of Medicine at Harvard Medical School. Dr. Rosenblatt has also served as Chief of the

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Division of Bone and Mineral Metabolism Research at Beth Israel Deaconess Medical Center, Harvard faculty dean, senior vice president for Academic Programs at CareGroup and Beth Israel Deaconess Medical Center, and Director of the Harvard-MIT Division of Health Sciences and Technology.

**BOARD COMPOSITION**

Our board of directors currently consists of eight members, all of whom were elected as directors pursuant to the board composition provisions of our current stockholders' agreement among us and our stockholders. The board composition provisions of our current stockholders' agreement will terminate upon the listing of our common stock on the NASDAQ Global Market and the effectiveness of our new stockholders' agreement, and there will be no further contractual obligations regarding the election of our directors. Our directors and officers have been appointed for one-year terms or until their respective successors are duly elected and qualified or until their earlier resignation or removal in accordance with our bylaws.

In accordance with our restated certificate of incorporation to be effective in connection with the offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election. After the consummation of this offering, our directors will be divided among the three classes as follows:

the Class I directors will be Owen Hughes, Elizabeth Stoner and Robert E. Ward, and their terms will expire at the first annual meeting of stockholders held after the consummation of this offering;

the Class II directors will be Alan H. Auerbach, Ansbert K. Gadicke and Martin Münchbach, and their terms will expire at the second annual meeting of stockholders held after the consummation of this offering; and

the Class III directors will be Kurt C. Graves and Morana Jovan-Embiricos, and their terms will expire at the third annual meeting of stockholders held after the consummation of this offering.

Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the outstanding shares of our common stock.

Our restated certificate of incorporation will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control of us.

**DIRECTOR INDEPENDENCE**

Our board of directors has determined that all of our directors, other than Mr. Ward and Dr. Jovan-Embiricos, are independent directors, as defined by applicable NASDAQ Marketplace Rules. In making such determination, the board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

**COMMITTEES OF THE BOARD OF DIRECTORS**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates under a charter that has been approved by our board. Our board of directors has determined that each of the members of the audit committee, the compensation committee and the nominating and corporate governance committee are independent as defined under the applicable rules and regulations of the SEC and the NASDAQ Marketplace Rules, including, in the case of each of the members of our audit committee, the independence requirements



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contemplated by Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

**Audit committee**

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

appoints the independent registered public accounting firm;

evaluates the independent registered public accounting firm's qualifications, independence and performance;

determines the engagement of the independent registered public accounting firm;

reviews and approves the scope of the annual audit and the audit fee;

discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;

approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;

monitors the rotation of partners of the independent registered public accounting firm on our engagement team as required by law;

reviews our financial statements and our management's discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;

reviews our critical accounting policies and estimates; and

annually reviews the audit committee charter and the committee's performance.

The current members of the audit committee are Martin Münchbach, Owen Hughes and Elizabeth Stoner. Dr. Münchbach serves as the chairman of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Stock Market. Our board of directors has determined that Dr. Münchbach is an "audit committee financial expert" as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of the NASDAQ Stock Market.

**Compensation committee**

Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. The compensation committee:



reviews and approves corporate goals and objectives relevant to compensation of our Chief Executive Officer and other executive officers;

evaluates the performance of these officers in light of those goals and objectives;

sets the compensation of these officers based on such evaluations;

approves grants of stock options and other awards under our stock plans; and

will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance of the compensation committee with its charter.

The members of the compensation committee are Ansbert K. Gadicke, Alan H. Auerbach and Kurt Graves. Dr. Gadicke serves as the chairman of the committee.

**Nominating and corporate governance committee**

The nominating and corporate governance committee is responsible for:

making recommendations to our board of directors regarding candidates for directorships and composition of our board of directors;

overseeing our corporate governance policies; and

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reporting and making recommendations to our board of directors concerning governance matters.

The members of the nominating and corporate governance committee are Kurt C. Graves, Alan H. Auerbach and Ansbert K. Gadicke. Mr. Graves serves as the chairman of the committee.

**Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon the listing of our common stock on the NASDAQ Global Market, we will post our code of business conduct and ethics on our website. We intend to disclose amendments to the code, or any waivers of its requirements, on our website as may be required by law or NASDAQ stock market listing standards.

Table of Contents**SUMMARY COMPENSATION TABLE**

The following table summarizes all compensation earned by our President and Chief Executive Officer and our two most highly compensated executive officers for the year ended December 31, 2013 (collectively, the named executive officers).

NAME AND PRINCIPAL POSITION	YEAR	NON-EQUITY INCENTIVE ALL				TOTAL
		SALARY (\$)	AWARDS (\$)(6)	OPTION (\$)(7)	PLAN (\$)(8)	
Robert E. Ward, President and Chief Executive Officer <sup>(1)</sup>	2013	18,750				18,750
C. Richard Lyttle, Former President and Chief Executive Officer <sup>(2)</sup>	2013				30,000	30,000
	2012	190,165		64,961	30,714	285,840
Andrew J. Fromkin, Former President and Chief Executive Officer <sup>(3)</sup>	2013	28,409	4,974,166		18,015	5,020,590
Michael S. Wyzga, Former President and Chief Executive Officer <sup>(4)</sup>	2013	437,500			94,704	532,204
	2012	500,000		150,000	1,032	651,032
Louis Brenner, Former Chief Medical Officer <sup>(5)</sup>	2013	330,000			240	330,240
	2012	330,000		99,000	300	429,300
B. Nicholas Harvey, Treasurer and Chief Financial Officer	2013	296,159		97,732	1,305	395,196
	2012	296,159		59,232	1,305	356,696

- (1) Mr. Ward became our President and Chief Executive Officer on December 16, 2013.
- (2) Dr. Lyttle served as our interim President and Chief Executive Officer from November 26, 2013 to December 16, 2013. Dr. Lyttle also served as our Chief Scientific Officer from December 2011 to June 2012 and has served as the Chairman of our Scientific Advisory Board since February 2012.
- (3) Mr. Fromkin served as our President and Chief Executive Officer from November 12, 2013 to November 29, 2013.
- (4) Mr. Wyzga served as our President and Chief Executive Officer from December 5, 2011 to November 11, 2013.
- (5)

Dr. Brenner served as our Senior Vice President and Chief Medical Officer from November 2011 to January 2, 2014.

- (6) The amount reported for Mr. Fromkin represents the aggregate grant date fair value of awards of stock options granted during the year computed in accordance with FASB ASC 718. For additional information, including information regarding the assumptions used when valuing the awards, refer to note 14 to our financial statements included elsewhere in this prospectus. Mr. Fromkin forfeited these awards upon his resignation on November 29, 2013.
- (7) Represents bonus amounts earned under our annual performance-based cash bonus program.
- (8) Except for Mr. Wyzga, Dr. Lyttle and Mr. Fromkin in 2013, all amounts are attributable to life insurance premiums paid by us. The 2013 amount for Mr. Wyzga includes \$860 attributable to life insurance premiums paid by us, \$2,748 for medical and dental insurance premium reimbursements made in connection with his resignation as our employee and \$91,096 in severance and accrued vacation payments made to Mr. Wyzga under the terms of his separation and release agreement. The 2013 amount for Dr. Lyttle represents fees earned due to Dr. Lyttle's service as the Chairman of our Scientific Advisory Board. The 2013 amount for Mr. Fromkin includes \$18,000 for reimbursement of legal expenses incurred in the negotiation of his employment agreement.

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**NARRATIVE DISCLOSURE TO SUMMARY COMPENSATION TABLE**

We do not currently have any formal policy for determining the compensation of executive officers. Base salaries for our named executive officers have been established through arm's-length negotiation at the time an executive was hired. The compensation committee of our board of directors annually reviews and evaluates, with input from our President and Chief Executive Officer, the need for adjustment of the base salaries of named executive officers based on changes and expected changes in the scope of an executive's responsibilities, including promotions, the individual contributions made by and performance of the executive during the prior fiscal year, the executive's performance over a period of years, overall labor market conditions, the relative ease or difficulty of replacing the executive with a well-qualified person, our overall growth and development as a company and general salary trends in our industry.

Each named executive officer is eligible to receive an annual performance-based cash bonus, in an amount up to a fixed percentage of his base salary. At the beginning of each year, our compensation committee develops, with input from our President and Chief Executive Officer, a list of goals for the year that are used as a guideline to assess the annual performance of the named executive officers. As soon as practical after the year is completed, the board reviews actual performance against the stated goals and determines subjectively what it believes to be the appropriate level of cash bonus, if any, for the named executive officers.

Each of the named executive officers in office as of January 31, 2014 is an at-will employee and eligible for discretionary bonus and equity incentive awards with certain severance rights discussed further below. The named executive officers have the following target bonus percentages:

Mr. Ward 50%

Mr. Wyzga 50%

Dr. Brenner 30%

Mr. Harvey 30%

Mr. Fromkin, Dr. Lyttle and Mr. Ward were not eligible to receive 2013 bonuses due to the short terms of employment with us during 2013.

For 2013, each named executive officer, with the exception of Mr. Fromkin, Dr. Lyttle and Mr. Ward, had the opportunity to achieve a bonus equal to the named executive officer's respective target bonus (prorated for any partial year of employment) by achievement of individual performance goals, with the compensation committee reserving the right to award amounts in excess of target bonus on a discretionary basis. The individual goals for 2013 were of different weighted importance and included completion of certain financing and public offering objectives, completion of organizational objectives and the implementation and successful execution of various elements related to the preclinical studies and clinical trials for our products, including the Phase 3 study for our Abaloparatide-SC product. The 2013 bonuses paid to the named executive officers are included in the "Non-Equity Incentive Plan Compensation" column of our Summary Compensation Table.

In November 2013, we granted an option to purchase 1,064,532 shares of our common stock to Mr. Fromkin following his commencement of employment; which option was forfeited on November, 29, 2013, upon Mr. Fromkin's resignation.

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**EMPLOYMENT, SEVERANCE AND CHANGE IN CONTROL ARRANGEMENTS**

*Robert E. Ward*

On December 16, 2013, we entered into an employment agreement with Mr. Ward, pursuant to which Mr. Ward agreed to serve as our President and Chief Executive Officer effective December 16, 2013. The agreement provides for an initial base salary of \$450,000 and the opportunity to earn an annual cash incentive award based on performance with a target value equal to 50% of Mr. Ward's annual base salary beginning in 2014. In addition, Mr. Ward will be eligible to have a one-time discretionary multiplier of up to 200% applied to his annual bonus, as determined by the Board, in the first year in which we consummate an initial public offering with gross proceeds of at least \$50 million, which we refer to as a "qualified initial public offering", or a strategic partnership, collaboration or licensing transaction relating to abaloparatide that the Board determines in its discretion constitutes a significant transaction.

Pursuant to the employment agreement, Mr. Ward is entitled to receive not later than the first meeting of our board of directors following the effective date of the employment agreement an award of a sign-on stock option for a number of shares of our common stock having an aggregate Black-Scholes value on the grant date equal to \$160,000, which will vest as to 100% of the shares subject thereto on the 60th day following the grant date, subject to Mr. Ward's continued employment on such date. This option was granted to Mr. Ward on February 16, 2014.

Mr. Ward's employment agreement also entitles him to receive not later than the first meeting of our board of directors following the effective date of the employment agreement an award of a stock option for the purchase of 793,974 shares of our common stock (the "Option"), which will vest as to 25% of the shares subject to the Option on the first anniversary of the effective date of the employment agreement, with the remaining shares vesting in substantially equal monthly installments over the following three years, subject to Mr. Ward's continued employment with us on the applicable vesting date. Notwithstanding the foregoing, in the event: (a) there is a qualified initial public offering during the first year of the employment term, (b) we submit a New Drug Application ("NDA") for abaloparatide with the Food and Drug Administration ("FDA") and the FDA accepts such application during the employment term, and/or (c) we obtain FDA approval for abaloparatide during the employment term, in each case, the Option will vest with respect to 25% of the shares subject to the Option, with such 25% portion taken pro rata from the unvested shares subject to the Option, and the remaining unvested shares will continue to vest as described in the previous sentence. In the event of a change in control during the employment term, 50% of the outstanding unvested shares subject to the Option as of the date of the change in control shall become fully vested. This option was granted to Mr. Ward on February 16, 2014.

In the event Mr. Ward's employment is terminated by us without cause or due to Mr. Ward's resignation for good reason, then subject to his executing a general release of claims, Mr. Ward will be entitled to receive:

base salary continuation payments for 12 months;

payment of continued medical care premiums for up to 12 months;

any unpaid annual bonus for the year prior to the year in which his termination occurs, based upon actual performance and payable in a lump sum;

a pro-rata portion of his bonus for the performance year in which Mr. Ward's termination occurs, based on actual performance or, if the termination occurs on or before to the date upon which performance goals for the bonus are established, on Mr. Ward's target bonus, in either case, payable in a lump sum; and

25% of the shares subject to the Option granted to Mr. Ward will accelerate and Mr. Ward will have up to nine months following the termination of his employment or, if longer, up to six months following our initial public offering, to exercise the Option.

If Mr. Ward's employment is terminated without cause or due to Mr. Ward's resignation for good reason within 24 months following a change in control, then subject to his executing a general release of claims, Mr. Ward will be entitled to receive the severance benefits described in the first three bullet points above



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(but with respect to the benefits described in bullets one and two above, for a period of 18 months rather than 12 months) and:

payment of his target annual bonus for the year in which termination occurs; and

accelerated vesting of all outstanding equity awards and up to nine months following the termination of his employment to exercise those awards.

*C. Richard Lyttle*

On February 29, 2012, we entered into a consulting agreement with Dr. Lyttle, providing for the transition of Dr. Lyttle from our Chief Scientific Officer to the Chairman of our Scientific Advisory Board as an independent contractor, effective as of June 1, 2012. The consulting agreement provides for an annual fee of \$30,000 and the continued vesting of Dr. Lyttle's outstanding options during the term of agreement.

On November 26, 2013, we entered into a letter agreement with Dr. Lyttle pursuant to which Dr. Lyttle agreed to provide additional services as our interim President and Chief Executive Officer. As compensation for Dr. Lyttle's services as interim President and Chief Executive Officer, we agreed that if we terminate Dr. Lyttle's service relationship with us following the date of the letter agreement, each of the options to purchase shares of our common stock then held by Dr. Lyttle or by The Cecil Richard Lyttle 2012 Grantor Retained Annuity Trust will become vested and exercisable in full on the date of such termination. The letter agreement does not entitle Dr. Lyttle to receive any other compensation for his service as interim President and Chief Executive Officer. Dr. Lyttle resigned as our interim President and interim Chief Executive Officer on December 16, 2013 and received no payments in connection with his resignation. Dr. Lyttle continues to serve as the Chairman of our Scientific Advisory Board.

*Andrew J. Fromkin*

On November 12, 2013, we entered into an employment agreement with Mr. Fromkin, pursuant to which Mr. Fromkin agreed to serve as our President and Chief Executive Officer effective November 12, 2013. The agreement provided for an annual base salary of \$500,000. Mr. Fromkin's employment with the Company terminated on November 29, 2013, and he was not entitled to any separation payments in connection with his termination of employment.

*Michael S. Wyzga*

On December 1, 2011, we entered into an employment letter agreement with Mr. Wyzga pursuant to which Mr. Wyzga agreed to serve as our President and Chief Executive Officer effective December 1, 2011. The agreement provided for an annual base salary of \$500,000 or such greater amount as is subsequently determined by our board of directors.

On November 11, 2013, we entered into a Separation and Release Agreement with Mr. Wyzga. In addition, in connection with Mr. Wyzga's resignation on November 11, 2013, we also entered into a letter agreement with Mr. Wyzga, pursuant to which he agreed to provide transition advisory services to us for up to six months after his resignation.

Pursuant to his separation agreement, Mr. Wyzga agreed to a general release of claims and we agreed to provide the severance payments contemplated by the terms of the Mr. Wyzga's employment agreement, which include payments totaling \$500,000 (an amount equal to Mr. Wyzga's annual base salary as of his resignation date) to be made over the 12-month period following his resignation date in accordance with our normal payroll procedures, and payment of continued medical care premiums necessary for Mr. Wyzga to continue to participate in our group medical plan during the same 12-month period. In addition, Mr. Wyzga is eligible to receive his full calendar year 2013 discretionary cash performance bonus under our bonus program based on a target bonus amount equal to 50% of his base salary, with the actual amount of any such bonus being determined on the basis of the attainment of the applicable performance metrics, as determined by our board of directors in its sole discretion. The option held by Mr. Wyzga to purchase shares of our common stock will continue to vest while Mr. Wyzga provides services to us during the advisory period (or for six months following his resignation date if we earlier terminate Mr. Wyzga's advisory services) and will remain exercisable for three months following expiration of this period.



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*Louis Brenner*

On November 9, 2011, we entered into a letter employment agreement with Dr. Brenner pursuant to which Dr. Brenner commenced employment on that date and agreed to serve as our Chief Medical Officer effective December 1, 2011. The letter agreement provided for an initial base salary of \$330,000 and the opportunity to earn an annual cash incentive award based on performance with a target value equal to 30% of Dr. Brenner's annual base salary, prorated for any partial year of employment.

Dr. Brenner resigned his employment with us on January 2, 2014. In connection with his resignation, we entered into a Separation and Release Agreement with Dr. Brenner. Pursuant to the agreement, Dr. Brenner agreed to a general release of claims and we agreed to provide the severance payments contemplated by the terms of Dr. Brenner's employment letter agreement, which included payments totaling \$247,500 (an amount equal to nine months of Dr. Brenner's annual base salary as of his resignation date) to be made over the nine-month period following his resignation date in accordance with our normal payroll procedures, and payment of continued medical care premiums necessary for Dr. Brenner to continue to participate in our group medical plan during the same nine-month period.

*B. Nicholas Harvey*

On November 15, 2006, we entered into an employment agreement with Mr. Harvey pursuant to which he agreed to serve as our Senior Vice President and Chief Financial Officer. The agreement provides for an initial base salary of \$250,000 and the opportunity to earn an annual cash incentive award based on performance with a target value equal to 30% of Mr. Harvey's annual base salary.

Mr. Harvey's agreement also provides that if his employment is terminated without cause or he resigns with good reason, he will receive six months' salary in severance payments, payable in accordance with the payroll practice then in effect, and the continuation of health insurance at no cost to him for six months and all options which would have vested in the six months following such termination shall become immediately exercisable. If our company is acquired, 50% of his then unvested options will become immediately vested and exercisable.

**RECENT CHANGES**

*Gregory Williams, Ph.D.*

On January 3, 2014, we entered into an employment letter agreement with Dr. Williams pursuant to which he serves as our Chief Development Officer for an unspecified term. The agreement entitles Dr. Williams to receive an initial annual base salary of \$325,000 and the opportunity to earn an annual cash incentive award targeted at 30% of his base salary.

In connection with his commencing employment with us, on February 16, 2014, we granted Dr. Williams an option to purchase 175,438 shares of our common stock for an exercise price per share equal to the fair market value of our stock, as determined by our board of directors, on that date. The option vests as to 25% of the underlying shares on January 6, 2015 and in twelve substantially equal quarterly installments thereafter, subject to Dr. Williams's continued employment with us through the applicable vesting date. Fifty percent of the unvested shares subject to the option will vest immediately prior to a change of control of our company.

In the event we terminate Dr. Williams's employment without cause or he resigns for good reason, both as defined in his employment letter agreement, subject to his executing a release of claims, Dr. Williams will be entitled to receive (i) a prorated annual bonus for the year in which his termination occurs if our board of directors determines to award him a bonus, (ii) nine months of base salary continuation payments and (iii) payment of medical care premiums necessary for him to continue participating in our group medical plan for the six months following his termination. If Dr. Williams's termination without cause or resignation for good reason occurs within the 12 months following a change of control, in addition to the amounts set

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forth in clauses (ii) and (iii) of the preceding sentence, he will be entitled to receive accelerated vesting of all his equity awards and a prorated portion of his target annual bonus for the year of termination.

*Mark W. Durand*

On April 1, 2014, we entered into an employment letter agreement with Mark W. Durand pursuant to which Mr. Durand serves as our Chief Commercial Officer for an unspecified term. The agreement entitles Mr. Durand to receive an initial annual base salary of \$325,000, a one-time signing bonus of \$50,000 and the opportunity to earn an annual cash incentive award targeted at 30% of his base salary.

Our board of directors has approved the grant to Mr. Durand of an option to purchase 175,438 shares of our common stock for an exercise price per share equal to the offering price of our common stock in the offering to which this prospectus relates, such grant to be effective upon the effectiveness of the registration statement covering the offering. The option will vest as to 25% of the underlying shares on the first anniversary of the date Mr. Durand commenced employment with us and in 36 substantially equal monthly installments thereafter, subject to Mr. Durand's continued employment with us through the applicable vesting date. Fifty percent of the unvested shares subject to the option will vest immediately prior to a change of control of our company.

In the event we terminate Mr. Durand's employment without cause or he resigns for good reason, both as defined in his employment letter agreement, subject to his executing a release of claims, Mr. Durand will be entitled to receive (i) a prorated annual bonus for the year in which his termination occurs if our board of directors determines to award him a bonus, (ii) nine months of base salary continuation payments and (iii) payment of medical care premiums necessary for him to continue participating in our group medical plan for the six months following his termination. If Mr. Durand's termination without cause or resignation for good reason occurs within the 12 months following a change of control, in addition to the amounts set forth in clauses (ii) and (iii) of the preceding sentence, he will be entitled to receive accelerated vesting of all his equity awards and a prorated portion of his target annual bonus for the year of termination.

*Alan G. Harris, M.D., Ph.D.*

On February 21, 2014, we entered into an employment letter agreement with Dr. Harris pursuant to which he serves as our Executive Medical Officer for an unspecified term. The agreement entitles Dr. Harris to receive an initial annual base salary of \$325,000 and the opportunity to earn an annual cash incentive award targeted at 30% of his base salary. Our board of directors has approved the grant to Dr. Harris of an option to purchase 131,578 shares of our common stock for an exercise price per share equal to the offering price of our common stock in this offering, such grant to be effective upon the effectiveness of the registration statement covering this offering. The option will vest as to 25% of the underlying shares on February 21, 2015 and in 36 substantially equal monthly installments thereafter, subject to Dr. Harris's continued employment with us through the applicable vesting date.

In the event we terminate Dr. Harris's employment without cause or he resigns for good reason, both as defined in his employment letter agreement, subject to his executing a release of claims, Dr. Harris will be entitled to receive (i) a prorated annual bonus for the year in which his termination occurs if our board of directors determines to award him a bonus, (ii) nine months of base salary continuation payments and (iii) payment of medical care premiums necessary for him to continue participating in our group medical plan for the six months following his termination. If Dr. Harris's termination without cause or resignation for good reason occurs within the 12 months following a change of control, in addition to the amounts set forth in clauses (ii) and (ii) of the preceding sentence, he will be entitled to receive accelerated vesting of all his equity awards and a prorated portion of his target annual bonus for the year of termination.

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*John Yates, M.D.*

On December 22, 2013, we entered into an employment letter agreement with Dr. Yates pursuant to which he serves as our part-time Chief Medical Officer for an unspecified term. The agreement requires Dr. Yates to devote at least 50% of his business time to performing services for the Company and entitles Dr. Yates to receive an initial annual base salary of \$200,000. Dr. Yates is also eligible to earn an annual cash incentive award targeted at 30% of his base salary. The agreement does not entitle Dr. Yates to any severance payments upon a termination of employment.

In connection with his commencing employment with us, on February 16, 2014, we granted Dr. Yates an option to purchase 131,578 shares of our common stock for an exercise price per share equal to the fair market value of our stock, as determined by our board of directors, on that date. The option vests as to 25% of the underlying shares on December 23, 2014 and in twelve substantially equal quarterly installments thereafter, subject to Dr. Yates's continued employment with us through the applicable vesting date.

*B. Nicholas Harvey*

Our board of directors has approved a one-time, special bonus in an amount to be determined by our Chief Executive Officer, but not to exceed \$50,000, for Mr. Harvey.

**TRANSACTION BONUS PLAN**

We have adopted a 2013 Employee Bonus Plan, or the Bonus Plan, to encourage certain employees of the Company, including certain of the Company's executive officers, to focus their attention and efforts on the financial and operational goals of the Company, with the purpose of compensating the employees at the time of, and in connection with, the sale of the Company to a third party. The Bonus Plan provides that upon the consummation of an "event of sale," as defined in the Company's certificate of incorporation, each participating employee under the Bonus Plan who is then employed by the Company or was terminated without cause, died or was terminated due to disability within three months prior to the event of sale will receive a bonus payment from the Company equal to the employee's pro rata portion of a bonus pool amount equal to 6.5% of the total amount otherwise payable to all holders of shares of capital stock of the Company in connection with the event of sale. The pro rata portion of the Bonus Pool payable to each participating employee is generally based on the employee's percentage of all shares of the Company's common stock and securities convertible into shares of the Company's common stock (other than preferred stock) held by all participating employees. Payments made to any participating employee under the Bonus Plan are made after deducting the aggregate value of all proceeds otherwise legally available for distribution to the employee as a result of the event of sale in respect of any shares of the Company's common stock or securities convertible into shares of the Company's common stock held by the employee at the time of the event of sale.

The Bonus Plan will terminate upon the earliest to occur of (a) an underwritten public offering of our common stock, (b) the listing of our common stock for trading on a national securities exchange and (c) December 31, 2014, unless the termination date is extended with the unanimous approval of our Board of Directors. The terms and provisions of the Bonus Plan may be amended, and the Bonus Plan may be terminated, prior to an event of sale by our Board of Directors or a committee thereof, provided that the percentage used in calculating the aggregate bonus pool amount may only be increased with the unanimous approval of our Board of Directors.

Table of Contents**RETIREMENT PLANS**

We maintain a defined contribution retirement plan which is tax-qualified under Section 401(k) of the Internal Revenue Code. The plan allows participants to defer a portion of their annual compensation, subject to certain limitations imposed by the Internal Revenue Code. Our named executive officers are eligible to participate in our 401(k) plan on the same basis as all employees generally. During 2013, we did not provide matching or profit sharing contributions to the plan for any employees.

**OUTSTANDING EQUITY AWARDS AT 2013 FISCAL YEAR END**

The following table sets forth information regarding the outstanding equity awards held by our named executive officers as of December 31, 2013.

NAME	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#)		EQUITY INCENTIVE PLAN AWARDS: NUMBER OF SECURITIES UNDERLYING UNEXERCISED UNEARNED OPTIONS (#)		OPTION PRICE	OPTION EXPIRATION DATE
	EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISED		
Robert E. Ward						
C. Richard Lyttle	47,514				\$ 3.42	10/28/14
	40,283				\$ 2.05	7/12/17
	88,891				\$ 2.74	5/8/18
	37,884				\$ 2.74	12/3/18
	68,573		53,333 <sup>(1)</sup>		\$ 7.34	11/6/21
Andrew J. Fromkin						
Michael S. Wyzga	335,526		335,526 <sup>(2)</sup>		\$ 8.87	12/14/21
Louis Brenner	77,061		77,061 <sup>(3)</sup>		\$ 8.87	12/14/21
				27,500 <sup>(4)</sup>	\$ 8.87	12/14/21
B. Nicholas Harvey	23,417				\$ 2.05	7/12/17
	27,778				\$ 2.74	5/8/18
	11,838				\$ 2.74	12/3/18
	21,429		16,666 <sup>(5)</sup>		\$ 7.34	11/6/21

(1) This stock option vested as to 6.25% of the underlying shares on October 1, 2011 and as to 6.25% of such shares on the first day of each calendar quarter thereafter. The option will vest in full if we terminate Dr. Lyttle's service relationship with us.

(2) This stock option vests as to 25% of the underlying shares on December 5, 2012 and as to 6.25% of such shares on the first day of each calendar quarter thereafter. This option will continue to vest based upon their original vesting terms while Mr. Wyzga provides advisory services to us (or for six months following his resignation date if we earlier terminate Mr. Wyzga's services) during the Advisory Period (described above)

and will remain exercisable for three months following expiration of this period.

- (3) This stock option vested as to 25% of the underlying shares on November 9, 2012 and as to 6.25% of such shares on the first day of each calendar quarter thereafter.
- (4) This stock option vests, if at all, upon the date that the board of directors resolves that an NDA for our Abaloparatide-SC product has been submitted to the FDA on or prior to a specified date.
- (5) This stock option vests as to 6.25% of the underlying shares on October 1, 2011 and as to 6.25% of such shares on the first day of each calendar quarter thereafter.

Table of Contents**2013 DIRECTOR COMPENSATION**

The following table summarizes the compensation earned by our non-employee directors during 2013. No director who is also an employee receives additional compensation for providing director services. Historically, we have not had any formal policy governing the compensation of directors, instead negotiating compensation for individual directors at the time they commence providing services. Mr. Graves, Mr. Hughes and Mr. Auerbach each receive an annual cash retainer of \$7,500 and a meeting fee of \$1,500 per board or committee meeting attended. None of our other directors receive cash compensation for providing director services to us.

During 2013, we did not grant equity-based awards as compensation to any of our non-employee directors.

<b>DIRECTOR NAME</b>	<b>FEEES EARNED OR PAID IN CASH (\$)</b>	<b>ALL OTHER COMPENSATION (\$)</b>	<b>TOTAL (\$)</b>
Alan H. Auerbach <sup>(1)</sup>	7,500		7,500
Ansbert K. Gadick, M.D. <sup>(2)</sup>			
Kurt C. Graves <sup>(3)</sup>	15,000		15,000
Owen Hughes <sup>(4)</sup>	6,500		6,500
Morana Jovan-Embiricos Ph.D. <sup>(5)</sup>		160,000 <sup>(8)</sup>	160,000
Martin Münchbach, Ph.D. <sup>(6)</sup>			
Elizabeth Stoner, M.D. <sup>(7)</sup>			

- (1) As of December 31, 2013, Mr. Auerbach held no stock awards and options to purchase 112,572 shares of our common stock.
- (2) As of December 31, 2013, Dr. Gadick held no stock awards or option awards.
- (3) As of December 31, 2013, Mr. Graves held no stock awards and options to purchase 112,572 shares of our common stock.
- (4) As of December 31, 2013, Mr. Hughes held no stock awards or option awards.
- (5) As of December 31, 2013, Dr. Jovan-Embiricos held no stock awards or option awards.
- (6) As of December 31, 2013, Dr. Münchbach held no stock awards or option awards.
- (7) As of December 31, 2013, Dr. Stoner held no stock awards and options to purchase 26,315 shares of our common stock.
- (8)

Represents consulting fees paid to Dr. Jovan-Embiricos in 2013. For additional information, see "Certain Relationships and Related Transactions Transactions with Related Persons Transaction with director" below.

We have adopted a non-employee director compensation policy that will become effective upon the listing of our common stock on a national securities exchange such as the NASDAQ Global Market. The policy provides for non-employee directors to receive an annual cash retainer of \$25,000 plus one or more additional annual cash retainers ranging from \$5,000 to \$10,000 for service on a board committee, as well as grants of options to purchase 30,000 shares of our common stock upon commencing service with us (vesting over a four-year period) and 10,000 shares of our common stock annually thereafter (vesting within one year of grant). Our board of directors has also approved, effective upon the effectiveness of the registration statement of which the prospectus is a part, the grant of an option to purchase 65,789 shares of our common stock to Mr. Graves and an option to purchase 32,894 shares of our common stock to Mr. Hughes, for an exercise price per share equal to the offering price of our common stock in the offering to which this prospectus relates. These options will vest as to 25% of the underlying shares on the first anniversary of the effective grant date and in 36 substantially equal monthly installments thereafter, subject to the director's continued service with us through the applicable vesting date.

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**2003 LONG-TERM INCENTIVE PLAN**

In the Merger, we assumed the Former Operating Company's 2003 Long Term Incentive Plan, or the 2003 Plan, and all options to acquire common stock of the Former Operating Company issued thereunder. Certain material terms of the 2003 Plan are summarized below. This summary is qualified by reference to the full text of the 2003 Plan, which has been filed as an exhibit to the registration statement of which this prospectus is a part.

The 2003 Plan is intended to assist us and our affiliates in attracting and retaining employees and consultants of outstanding ability and to promote the identification of their interests with those of our stockholders and our affiliates. Only incentive stock options, or ISOs, and non-statutory stock options have been granted under the 2003 Plan. As of March 31, 2014, we had 426,668 options issued and unexercised under the 2003 Plan, all of which were vested. In connection with the adoption and approval of the 2011 Equity Incentive Plan, we determined not to make any further awards under the 2003 Plan after November 7, 2011, which we refer to as the "suspension" of the 2003 Plan. No new awards may be granted under the 2003 Plan, but awards outstanding at the time of suspension remain outstanding in accordance with their terms. If an option or right expires or terminates for any reason (other than termination by virtue of the exercise of a related option or related right, as the case may be) without having been fully exercised, if shares of restricted stock are forfeited, or if shares covered by an incentive share award or performance award are not issued or are forfeited, the unissued or forfeited shares that had been subject to the award become available for the grant of additional awards under the 2011 Equity Incentive Plan.

*Administration.* The compensation committee of the board of directors administers the 2003 Plan. In the event that there is no compensation committee, the board of directors administers the plan. The committee or the board may delegate authority to administer the 2003 Plan to any other committee.

*Incentive Stock Options.* ISOs are intended to qualify as "incentive stock options", as the term is defined in Section 422 of the Internal Revenue Code and are granted pursuant to incentive stock option agreements. The plan administrator determines the exercise price for an ISO, which may not be less than 100% of the fair market value of the stock underlying the option determined on the date of grant. Notwithstanding the foregoing, incentive options granted to employees who own, or are deemed to own, more than 10% of our voting stock, must have an exercise price not less than 110% of the fair market value of the stock underlying the option determined on the date of grant.

*Nonstatutory Stock Options.* Nonstatutory stock options are granted pursuant to nonstatutory stock option agreements. The plan administrator determines the exercise price for a nonstatutory stock option.

*Vesting.* Options granted under the plan generally vest in 16 quarterly installments, each quarterly installment being equal in number of shares as possible (as determined by us in our reasonable discretion), with the first quarterly installment vesting one quarter after the date of the grant, and an additional quarterly installment vesting on the first day of each calendar quarter thereafter, until all of the shares subject to the option are fully vested and the option may be exercised as to 100% of the shares issuable upon exercise thereof.

*Changes to Capital Structure.* In the event of certain types of changes in our capital structure, such as a share split, the number of shares and exercise price or strike price, if applicable, of all outstanding awards will be appropriately adjusted.

*Dividends.* Any award under the 2003 Plan may confer upon the recipient the right to receive dividend payments or dividend equivalent payments with respect to the shares subject to the award. Such dividend payments may be paid currently or credited to an account in favor of the recipient. Such dividends may be settled in cash or shares, as determined by the plan administrator.



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*Termination and Amendment.* Our board of directors may terminate, amend or modify the 2003 Plan and the compensation committee may amend the terms of outstanding awards at any time. However, stockholder approval of any amendment is required to the extent necessary to comply with applicable laws or the rules of any relevant stock exchange. No amendment may adversely affect the rights under an outstanding award without the holder's consent.

*Tax Withholding.* Participants must satisfy applicable tax withholding requirements with respect to any award granted under the 2003 Plan, and to the extent provided in the applicable award agreement and in accordance with rules prescribed by the compensation committee, may do so by: (a) cash, (b) authorizing us to withhold shares otherwise issuable under the award, or (c) delivery of previously owned shares.

**2011 EQUITY INCENTIVE PLAN**

We adopted the 2011 Equity Incentive Plan, or the 2011 Plan, on November 7, 2011, which our board of directors voted to amend on December 15, 2011, January 31, 2012, June 3, 2013, November 14, 2013, February 16, 2014 and April 15, 2014, and which 2011 Plan and amendments have been approved by our stockholders. Certain material terms of the 2011 Plan are summarized below. This summary is qualified by reference to the full text of the 2011 Plan, which has been filed as an exhibit to the registration statement of which this prospectus is a part.

The 2011 Plan provides for the grant of incentive stock options, or ISOs, to employees, and for the grant of nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, stock grants, performance units and performance awards to employees, consultants and non-employee directors, for the purposes of encouraging their ownership of common stock and providing additional incentives to promote the success of our business through the grant of awards of or pertaining to the common stock. ISOs are intended to be "incentive stock options," as that term is defined in Section 422 of the Code.

**Securities subject to the 2011 Plan**

Under the terms of the 2011 Plan, the aggregate number of shares of our common stock that may be subject to options and other awards is equal to the sum of (i) 3,675,446 shares and (ii) any shares of our common stock which as of the November 7, 2011 were available for issuance under the 2003 Plan or subject to awards under the 2003 Plan which are forfeited or lapse unexercised and which are not issued under the 2003 Plan, subject to a maximum aggregate number of shares issuable under the 2011 Plan of 4,254,385. The maximum number of shares that may be issued pursuant to ISOs is 4,254,385. The shares of common stock covered by the 2011 Plan are authorized but unissued shares, treasury shares or common stock purchased on the open market.

To the extent that an option or stock-settled stock appreciation right terminates, expires or lapses for any reason or is cancelled without having been exercised in full or to the extent any other award is forfeited, any shares subject to the award (to the extent of such termination, expiration, lapse, cancellation or forfeiture) may be used again for new grants under the 2011 Plan. Shares tendered or withheld to satisfy the grant or exercise price or tax withholding obligation pursuant to any award or the exercise price of an option may be used again for new grants under the 2011 Plan.

The maximum number of shares of our common stock that may be subject to one or more awards to a participant pursuant to the 2011 Plan during any calendar year is 548,245 and the maximum amount that may be paid to a participant in cash during any calendar year with respect to cash-based awards is \$2,000,000. However, these limits will not apply to certain awards granted under the 2011 Plan until the earliest to occur of the first material modification of the 2011 Plan following the date on which our common stock is listed on any securities exchange or designated on an interdealer quotation system, which we refer to as the Public Trading Date, the issuance of all of the shares reserved for issuance under the 2011 Plan, the expiration of the 2011 Plan or the first meeting of our stockholders at which directors are

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to be elected that occurs after the close of the third calendar year following the calendar year in which the Public Trading Date occurs.

**Administration**

The 2011 Plan provides that the compensation committee of our board of directors administers the 2011 Plan, although our board of directors may exercise any powers and responsibilities assigned to the compensation committee at any time.

The compensation committee has the authority to administer and interpret the 2011 Plan, including the power to determine eligibility, the types and sizes of awards, the price, timing and other terms and conditions of awards and the acceleration or waiver of any vesting or forfeiture restriction. The compensation committee may delegate to one or more directors or officers the authority to grant or amend awards subject to certain limitations set forth in the 2011 plan.

**Eligibility**

Persons eligible to participate in the 2011 Plan include employees, consultants and non-employee directors of the Company and our affiliates, as determined by the compensation committee. Only our employees and certain of our parent and subsidiary corporations, should we have any in the future, are eligible to receive grants of options intended to qualify as ISOs.

**Stock options**

The 2011 Plan authorizes the grant of stock options, including ISOs and nonqualified stock options. Under the 2011 Plan, the exercise price of ISOs granted pursuant to the 2011 Plan will not be less than the fair market value of the common stock on the date of grant, and the exercise price of nonqualified stock options granted pursuant to the 2011 Plan will be determined by the compensation committee. Stock options are subject to such vesting and exercisability conditions as are determined by the compensation committee and set forth in a written stock option agreement. In no event may an ISO have a term of more than 10 years. ISOs granted to any person who owns, as of the date of grant, stock possessing more than 10% of the total combined voting power of all classes of our stock are required to have an exercise price that is not less than 110% of the fair market value of the common stock on the date of grant and may not have a term of more than five years.

**Stock appreciation rights**

A stock appreciation right, or SAR, is the right to receive payment of an amount equal to the excess of the fair market value of a share of common stock on the date of exercise of the SAR over the grant price of the SAR. The grant price of each SAR granted under the 2011 Plan will be no less than the fair market value of a share of common stock on the date of grant of the SAR. The compensation committee is authorized to issue SARs in such amounts and on such terms and conditions as it may determine, consistent with the terms of the 2011 Plan.

**Restricted stock**

Restricted stock is the grant of shares of common stock at a price, if any, determined by the compensation committee, which shares are nontransferable and may be subject to forfeiture until specified vesting conditions are met. Restricted stock will be evidenced by a written agreement. During the period of restriction, restricted stock is subject to restrictions and vesting requirements, as provided by the compensation committee. The restrictions may lapse in accordance with a schedule or other conditions determined by the compensation committee.

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**Restricted stock units**

A restricted stock unit provides for the issuance of a share of common stock at a future date upon the satisfaction of specific conditions set forth in the applicable award agreement. The compensation committee will specify, or permit the restricted stock unit holder to elect, the conditions and dates upon which payments under the restricted stock units will be made, which dates may not be earlier than the date as of which the restricted stock units vest and which conditions and dates will be subject to compliance with Section 409A of the Code. On the distribution dates, we will transfer to the participant one unrestricted, fully transferable share of the common stock (or the fair market value of one such share of common stock in cash) for each restricted stock unit scheduled to be paid out on such date and not previously forfeited.

**Performance units**

Performance units represent the participant's right to receive an amount, based on the value of the common stock, if performance goals established by the compensation committee are achieved. The compensation committee will determine the applicable performance period, the performance goals and such other conditions that apply to the performance unit. The performance criteria upon which performance goals are established may include: (i) cash flow (before or after dividends), (ii) earnings per share (including, without limitation, earnings before interest, taxes, depreciation and amortization), (iii) stock price, (iv) return on equity, (v) stockholder return or total stockholder return, (vi) return on capital (including, without limitation, return on total capital or return on invested capital), (vii) return on investment, (viii) return on assets or net assets, (ix) market capitalization, (x) economic value added, (xi) debt leverage (debt to capital), (xii) revenue, (xiii) sales or net sales, (xiv) backlog, (xv) income, pre-tax income or net income, (xvi) operating income or pre-tax profit, (xvii) operating profit, net operating profit or economic profit, (xviii) gross margin, operating margin or profit margin, (xix) return on operating revenue or return on operating assets, (xx) cash from operations, (xxi) operating ratio, (xxii) operating revenue, (xxiii) market share improvement, (xxiv) general and administrative expenses and (xxv) customer service. Performance goals may be expressed in terms of overall Company performance or the performance of a division, business unit, subsidiary or an individual and measured on an absolute or relative basis or to a designated comparison group, in each case as specified by the compensation committee.

**Performance awards**

A performance award is cash bonus award, stock bonus award, performance award or incentive award that is paid in cash, shares of common stock or a combination of both, as determined by the compensation committee. The compensation committee will determine the applicable performance period, the performance goals and such other conditions that apply to the performance award.

**Stock grants**

A stock grant is a grant in the form of shares of common stock. The number or value of shares of any stock grant will be determined by the compensation committee.

**Dividends, dividend equivalents**

The 2011 Plan authorizes the compensation committee to provide a participant with the right to receive dividends or dividend equivalents with respect to shares of common stock covered by an award granted under the 2011 Plan. Dividends and dividend equivalents may be settled in cash or shares of common stock, as determined by the compensation committee.

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**Payment methods**

Under the 2011 Plan, payments made upon exercise of an option may be made by cash or check or, subject to the approval of the compensation committee, by:

if our common stock is traded on an established market, through a formal cashless exercise program in which a market sell order is placed with a broker with respect to shares of common stock then-issuable upon exercise or vesting of an award, and the broker is directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate payments required (provided that payment of such proceeds is then made to the Company upon settlement of such sale);

shares of common stock issuable pursuant to the award or previously held; or

such other legal consideration deemed acceptable by the compensation committee.

**Forfeiture of unvested awards; leave of absence**

Upon the termination of service of the holder of an option or stock appreciation right, unless otherwise provided by the compensation committee, the award generally will expire on a date not later than three months after the termination of service. Except as otherwise determined by the compensation committee, in the event that the employment or services of the holder of an award is terminated, the unvested portion of the award will generally be forfeited or may be subject to repurchase by us, and will cease to vest or become exercisable after the termination.

The compensation committee may provide that an award will continue to vest for some or all of the period of a leave of absence, or that vesting of an award will be tolled during a leave of absence, consistent with applicable law.

**Transferability**

Generally, awards under the 2011 Plan may only be transferred by will or the laws of descent and distribution, unless and until such award has been exercised or the shares underlying such award have been issued and all restrictions applicable to such shares have lapsed. However, subject to certain terms and conditions, the compensation committee may permit a holder to transfer a nonqualified stock option or shares of restricted stock to any "family member" under applicable securities laws.

**Adjustments**

In the event of a declaration of a stock dividend, stock split, reverse stock split, recapitalization, reclassification, reorganization or similar occurrence, the compensation committee will make appropriate adjustments to:

the number and kind of shares available for future grants;

the number and kind of shares covered by each outstanding award;

the grant or exercise price under each outstanding award; and

the repurchase right of each share of restricted stock.

**Corporate transactions**

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In the event of a "change of control" (as defined in the 2011 Plan), our compensation committee may take any action it deems necessary or appropriate, including to accelerate an award in whole or in part. A SAR granted in tandem with a stock option that can only be exercised during limited periods following a change of control of us may entitle the holder to receive an amount based on the highest price paid or offered for the common stock in a transaction relating to the change of control or paid during the 30-day period immediately preceding the change of control.

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The compensation committee also has the authority under the 2011 Plan to take certain other actions with respect to outstanding awards in the event of a corporate transaction, including provision for the cash-out, termination, assumption or substitution of such awards.

Upon a liquidation or dissolution of the Company, except as otherwise provided in an applicable award agreement or another agreement between the award holder and the Company, all forfeiture restrictions and/or performance goals with respect to an award will automatically be deemed terminated or satisfied, as applicable.

**Expiration, Termination and Amendment**

Our board of directors may terminate, amend or modify the 2011 Plan and the compensation committee may amend the terms of outstanding awards at any time. However, stockholder approval of any amendment is required to the extent necessary to comply with applicable laws or the rules of any relevant stock exchange. No amendment may impair the rights under an outstanding award without the holder's consent unless, prior to a change of control, the compensation committee determines the amendment is required or advisable to satisfy any law or regulation or avoid adverse financial accounting consequences or that the amendment is not reasonably likely to significantly diminish the benefits provided under the award or that any such diminution has been adequately compensated.

The term of the 2011 Plan will expire on the tenth anniversary of the date on which it was originally approved by the Board, unless earlier terminated by the Board.

**Tax withholding**

We may require participants to discharge applicable withholding tax obligations with respect to any award granted to the participant. The plan administrator may in its discretion allow a holder to meet any withholding tax obligations by electing to have us withhold shares of common stock otherwise issuable under any award (or allow the return of shares of common stock) having a fair market value equal to the sums required to be withheld.

**RISK ASSESSMENT IN COMPENSATION PROGRAMS**

We have assessed our compensation programs and concluded that our compensation practices do not create risks that are reasonably likely to have a material adverse effect on us.

**DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Our amended and restated bylaws provide for the indemnification of officers, directors and third parties acting on our behalf if such persons act in good faith and in a manner reasonably believed to be in and not opposed to our best interest, and, with respect to any criminal action or proceeding, such indemnified party had no reason to believe his or her conduct was unlawful.

To the extent that indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. If a claim for indemnification against these liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of our company in the successful defense of any action, suit or proceeding) is asserted by any of our directors, officers or controlling persons in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether this indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

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**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

**TRANSACTIONS WITH RELATED PERSONS**

Since January 1, 2011, we have engaged in the following transactions with our directors, executive officers and holders of more than five percent of our voting securities, and affiliates or immediate family members of our directors, executive officers and holders of more than five percent of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

**Reporting and overhead**

From October 2010 until the closing of the Merger, the Former Operating Company funded our ongoing Exchange Act filing requirements and other costs associated with investigating and analyzing an acquisition. Management estimates such amounts to be de minimis. We have used the office space and equipment of MPM Asset Management LLC, our sole stockholder prior to the redemption completed in connection with the Merger, and those of the Former Operating Company from time to time, in all cases, at no cost to us.

**Transactions with Former Operating Company related persons**

As described above, Dr. Lyttle, a former director and current Chairman of our Scientific Advisory Board, was the President and Chief Executive Officer of the Former Operating Company prior to the Merger, and each of Dr. Lyttle and Mr. Auerbach, Dr. Gadick and Mr. Fleming, each current directors, served as directors of the Former Operating Company prior to the Merger. In addition, certain investment funds affiliated with MPM Asset Management LLC (our sole stockholder prior to the Merger), including MPM BioVentures III Fund, were investors in the Former Operating Company prior to the Merger. Dr. Gadick, the Managing Director of MPM Capital was a control person of ours prior to the Merger and affiliated with major stockholders of the Former Operating Company prior to the Merger. The shares held by MPM Asset Management LLC were repurchased by us for an aggregate purchase price 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 \$110,725 contemporaneously with the closing of the Merger.

**Series A-1 preferred stock financing**

On May 11, 2011, certain accredited investors in a series A-1 convertible preferred stock financing entered into an irrevocable legally binding commitment to purchase \$64.3 million of series A-1 preferred stock in three closings. The first closing occurred on May 17, 2011 and resulted in gross proceeds of approximately \$21.4 million through the sale of 2,631,845 shares of the Former Operating Company's series A-1 preferred stock. Those shares were exchanged in the Merger for an aggregate of 263,177 shares of our series A-1 preferred stock. The second closing occurred on November 18, 2011 and we received gross proceeds of approximately \$21.4 million through the sale of 263,178 shares of our series A-1 preferred stock. The third closing occurred on December 14, 2011 and we received gross proceeds of approximately \$21.4 million through the sale of 263,180 shares of series A-1 preferred stock.

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The following table sets forth the number of shares of our series A-1 preferred stock that we issued at the three closings:

NAME(1)	SHARES OF SERIES A-1 PREFERRED STOCK
Entities affiliated with MPM Capital <sup>(2)</sup>	384,261
The Wellcome Trust	76,566
HealthCare Ventures VII	58,953
Entities affiliated with Saints Capital <sup>(3)</sup>	49,127
BB Biotech Ventures II	84,536
Scottish Widows (Healthcare Private Equity)	20,416
Raymond F. Schinazi	1,487
David E. Thompson Revocable Trust	588
H. Watt Gregory, III	397
The Richman Trust	195
Breining Family Trust	120
Brookside Capital Partners Fund, L.P.	122,820
Biotech Growth N.V.	122,820
Ipsen	17,326
<b>Total</b>	<b>939,612</b>

- (1) See "Security Ownership of Certain Beneficial Owners and Management" for more information about shares held by these entities.
- (2) Consists of 15,096 shares issued to MPM BioVentures III, L.P., 224,528 shares issued to MPM BioVentures III-QP, L.P., 18,975 shares of our series A-1 preferred stock issued to MPM BioVentures III GmbH & Co. Beteiligungs K.G., 6,779 shares issued to MPM BioVentures III Parallel Fund, L.P., 4,346 shares issued to MPM Asset Management Investors 2003 BVIII LLC and 114,537 shares issued to MPM Bio IV NVS Strategic Fund, L.P.
- (3) Consists of 48,641 shares issued to OBP IV Holdings LLC and 486 mRNA II Holdings LLC.

**Series A-5 preferred stock issuance**

Concurrently with the first closing of the series A-1 preferred stock financing, the Former Operating Company issued 64,430 shares of series A-5 preferred stock to Nordic for gross proceeds of approximately \$0.5 million. These shares were exchanged in the Merger for 6,443 shares of our series A-5 convertible preferred stock.

**Our new stockholders' agreement**

We entered into a stockholders' agreement in May 2011, amended and restated this agreement in February 2014 and further amended and restated this agreement in April 2014, which agreement will become effective in connection with the offering. We refer to this agreement as our new stockholder's agreement.



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*Registration rights.* The new stockholders' agreement provides our stockholders with certain resale, demand and piggyback registration rights as described under "Description of Capital Stock - Registration Rights Pursuant to our New Stockholders' Agreement."

*Indemnification in connection with registration rights.* The new stockholders' agreement contains customary cross-indemnification provisions, pursuant to which we are obligated by the terms and conditions of the new stockholders' agreement to indemnify any selling stockholders in a public offering in the event of material misstatements or omissions in a registration statement attributable to us, and the selling stockholders are obligated to indemnify us for material misstatements or omissions attributable to them.

Table of Contents**Series B preferred stock financing**

On April 23, 2013, certain accredited investors entered into a Series B Convertible Preferred Stock and Warrant Purchase Agreement, pursuant to which we consummated a first closing whereby in exchange for aggregate proceeds of approximately \$43.0 million, we issued 700,098 shares of our series B convertible preferred stock and warrants to purchase up to a total of 767,651 shares of common stock. On May 10, 2013, we consummated a second closing whereby in exchange for aggregate proceeds of approximately \$0.1 million, we issued 1,137 shares of our series B convertible preferred stock and warrants to purchase up to a total of 1,246 shares of common stock.

The following table sets forth the number of shares of our series B convertible preferred stock and common stock warrants that were issued in the two closings:

NAME(1)	SHARES OF SERIES B CONVERTIBLE PREFERRED STOCK	COMMON STOCK WARRANTS
F2 Biosciences III, L.P.	325,627	357,047
Entities affiliated with MPM Capital <sup>(2)</sup>	162,813	178,523
Biotech Growth N.V.	97,688	107,114
Brookside Capital Partners Fund, L.P.	81,407	89,262
BB Biotech Ventures II, L.P.	32,563	35,705
Raymond F. Schinazi	1,067	1,170
The Richman Trust	70	76
<b>Total</b>	701,235	768,897

(1) See "Security ownership of certain beneficial owners and management" for more information about shares held by these entities.

(2) Consists of 5,103 shares issued to MPM BioVentures III, L.P, 75,899 shares issued to MPM BioVentures III-QP,L.P., 6,414 shares issued to MPM BioVentures III BmbH & Co. Beteiligungs KG, 2,291 shares issued to MPM BioVentures III Parallel Fund