

Radius Health, Inc.  
Form S-1/A  
April 21, 2014

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As filed with the Securities and Exchange Commission on April 21, 2014

Registration No. 333-194150

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

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AMENDMENT NO. 2  
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)  
**201 Broadway, 6th Floor**  
**Cambridge, Massachusetts 02139**  
**(617) 551-4700**

**80-0145732**  
(I.R.S. Employer  
Identification Number)

(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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**Copies To:**

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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)

**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, APRIL 21, 2014

**PRELIMINARY PROSPECTUS**

**Prospectus**

**Shares**

**Radius Health, Inc.**

**Common Stock**

We are offering \_\_\_\_\_ 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 between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ 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 12 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 \_\_\_\_\_ 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 \$ \_\_\_\_\_.

*Joint Book-Running Managers*

**Jefferies**

**Cowen and Company**

*Co-Lead Manager*

**Canaccord Genuity**

*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 or in any free writing prospectuses we have prepared. 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 December 31, 2013, which was €1.00 = \$1.3779. 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.

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 at lower doses as a selective estrogen-receptor modulator, or SERM, for the treatment of vasomotor symptoms such as hot flashes. In 2014, we expect to commence a Phase 1 clinical trial to evaluate RAD1901 for the treatment of BCBM, and we previously completed a successful Phase 2 clinical trial of RAD1901 for the treatment of vasomotor symptoms.

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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. 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.

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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.

***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 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 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



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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 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



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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, 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.

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In late 2014, we intend to advance the development of high-dose RAD1901 for the treatment of ER-positive BCBM with the initiation of a Phase 1b clinical trial.

***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  $\times$  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;

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

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



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**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.

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	shares
Common stock to be outstanding after the offering	shares
Option to purchase additional shares of common stock	We have granted the underwriters a 30-day option to purchase up to an additional            shares of our common stock.
Use of proceeds	We estimate that our net proceeds from this offering will be approximately \$            million at an assumed initial public offering price of \$            per share, which is the midpoint of the price range set forth on the cover page of this prospectus, 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 12 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
Directed share program	At our request, the underwriters have reserved up to            shares of our common stock offered by this prospectus for sale, at the initial public offering price, to our directors and officers and certain employees and other parties related to us. Shares purchased by our directors and officers will be subject to the 180-day lock-up restriction described in the "Underwriting" section of this prospectus. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.
The number of shares of our common stock outstanding after this offering is based on the 47,766,141 shares of our common stock outstanding as of March 31, 2014 and excludes the following potentially dilutive shares of common stock outstanding at March 31, 2014:	

6,143,839 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$3.19 per share;

3,547,280 shares of our common stock reserved for future issuance under our 2011 equity incentive plan; and

3,034,683 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$6.21 per share.





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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. Our historical results are not necessarily indicative of the results to be expected in the future.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS DATA:	YEARS ENDED DECEMBER 31,		
	2013	2012	2011
	(in thousands, except share and per share amounts)		
Operating expenses:			
Research and development	\$ 60,536	\$ 54,961	\$ 36,179
General and administrative	6,829	9,469	5,330
Loss from operations	(67,365)	(64,430)	(41,509)
Other income (expense), net	9,085	(2,095)	(236)
Interest (expense) income, net	(2,410)	(2,603)	(731)
Net loss	\$ (60,690)	\$ (69,128)	\$ (42,476)
Other comprehensive loss, net of tax:			
Unrealized (loss) gain from available-for-sale securities		(5)	8
Comprehensive loss	\$ (60,690)	\$ (69,133)	\$ (42,468)
(Loss) earnings attributable to common stockholders basic and diluted	\$ (78,161)	\$ (83,120)	\$ 253
(Loss) earnings per share basic	\$ (89.43)	\$ (98.99)	\$ 0.51
(Loss) earnings per share diluted	\$ (89.43)	\$ (98.99)	\$ 0.07
Weighted average shares basic	874,004	839,698	499,944
Weighted average shares diluted	874,004	839,698	3,454,276
Pro forma loss attributable to common stockholders basic and diluted <sup>(1)</sup> (unaudited)	\$ (60,690)		
Pro forma loss per share basic <sup>(1)</sup> (unaudited)	\$ (1.75)		
Pro forma loss per share diluted <sup>(1)</sup> (unaudited)	\$ (1.75)		
Weighted-average common shares used in computing pro forma earnings per share basic <sup>(1)</sup> (unaudited)	34,765,779		
Weighted-average common shares used in computing pro forma earnings per share diluted <sup>(1)</sup> (unaudited)	34,765,779		

(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 financial statements included elsewhere in this prospectus.

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BALANCE SHEET DATA:	AS OF DECEMBER 31, 2013		
	ACTUAL	PRO	PRO FORMA
		FORMA(1)	AS ADJUSTED(1)(2)
	(unaudited, in thousands)		
Cash, cash equivalents and marketable securities	\$ 12,303	\$ 39,671	\$
Working capital	(22,675)	13,419	
Total assets	12,758	43,524	
Convertible preferred stock <sup>(3)</sup>	252,802		
Total stockholders' (deficit) equity	(277,301)	10,379	

(1)

Gives effect to:

the issuance and sale of 448,060 shares of our series B-2 convertible preferred stock for net proceeds of \$27.4 million, which occurred during the first quarter of 2014;

the declaration of a stock dividend of 29 shares of series A-6 convertible preferred stock, for each outstanding share of series A-5 convertible preferred stock, for a total of 186,847 shares of series A-6 convertible preferred stock. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Research and Development Agreements" for additional information;

the automatic conversion of all outstanding shares of our convertible preferred stock as of December 31, 2013, giving effect to the shares of series B-2 and A-6 convertible preferred stock described in the previous bullets, into 41,016,469 shares of our common stock in connection with this offering; and

the issuance of 5,171,472 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 December 31, 2013, all of which is described in more detail in the section of this prospectus entitled "Capitalization – Preferred Stock Dividends."

The third bullet above assumes that the series B-2 convertible preferred stock will convert into shares of common stock on a ten-for-one basis, which is dependent upon the the initial public offering price in this offering being equal to or exceeding \$6.142 per share. If the initial public offering price per share in this offering is less than \$6.142, then the number of shares issuable upon conversion will increase. See "Capitalization – Series B-2 Convertible Preferred Stock."

(2)

Gives further effect to: the issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range 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 \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, 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 \$ 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 \$ million, assuming that the public offering price is \$ 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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**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 quarter of . 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 \$60.7 million, \$69.1 million and \$42.5 million during the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of \$277.3 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 2011, we entered into our \$25.0 million credit facility with General Electric Capital Corporation, or GECC, as agent and lender, and Oxford Finance LLC, as lender. We drew \$12.5 million under our credit facility during 2011 and we drew the remaining \$12.5 million on May 29, 2012. Our credit facility contains a number of covenants that impose significant operating and financial restrictions on us. These covenants limit our ability to:

dispose of our business or certain assets;

change our business, management, ownership or business locations;

incur additional debt or liens;

make certain investments or declare dividends;

acquire or merge with another entity for consideration in excess of an allowable amount;

engage in transactions with affiliates; or

encumber our intellectual property.

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

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

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

voluntary or mandatory recall of products and related publicity requirements;

finest, 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 64,430 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 \$8.142. 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 6,829,580 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.

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

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with 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.

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**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 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

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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.

**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, 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



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requirements of patentability in view of claimed inventions are not always predictable. Additional intellectual property covering Abaloparatide-TD technology exists in the form of proprietary information protected as trade secrets. These can be accidentally disclosed to, independently derived by or misappropriated by competitors, possibly reducing or eliminating the exclusivity advantages of this form of intellectual property, thereby allowing those competitors more rapid entry into the marketplace with a competitive product thus reducing our 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.

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**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.

**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

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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.

**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.

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**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 \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$ per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the assumed public offering price. In addition, purchasers of common stock in this offering will have contributed approximately % of the aggregate cash price paid by all purchasers of our stock but will own only approximately % of our common stock outstanding after this offering.

**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 own, in the aggregate, approximately % 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 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;

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

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

**Future sales 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 \_\_\_\_\_ shares of our common stock outstanding. Of these shares, the shares sold in this offering will be freely tradable. The holders of 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 9,691,119 shares of our common stock reserved for issuance under our equity incentive plans, including 6,143,839 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 upon the listing of our common stock on the NASDAQ Global Market contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

a staggered board of directors;

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

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

prohibiting stockholder action by written consent;

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

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

requiring advance notification of stockholder nominations and proposals.

Section 203 of the Delaware General Corporation Law, or DGCL, prohibits, subject to some exceptions, "business combinations" between a Delaware corporation and an "interested stockholder," which is



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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 upon the listing of our common stock on the NASDAQ Global Market 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 \$ \_\_\_\_\_ million, assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, 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 \$ \_\_\_\_\_ million. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would result in an approximately \$ \_\_\_\_\_ 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 \$ \_\_\_\_\_ million, assuming that the public offering price is \$ \_\_\_\_\_ 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.

We expect to use the net proceeds of this offering as follows:

approximately \$44.0 million to complete development, submit an NDA and MAA, and fund our efforts to obtain regulatory approval of Abaloparatide-SC;

approximately \$8.0 million to continue collaborative development work with 3M and to initiate the next phase of clinical studies for Abaloparatide-TD;

approximately \$5.0 million to pursue our application for orphan designation and initiate Phase 1 development of RAD1901 for the treatment of BCM; and

the remainder to begin establishing sales and marketing capabilities to commercialize our product candidates and for working capital and general corporate purposes, including for monthly principal and interest payments on our 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."

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 December 31, 2013, as follows:

on an actual basis;

on a pro forma basis to give effect to (1) the issuance and sale of 448,060 shares of series B-2 convertible preferred stock for net proceeds of \$27.4 million, which occurred during the first quarter of 2014 and which is described below under the caption " Series B-2 Convertible Preferred Stock"; (2) the declaration of a stock dividend of 29 shares of series A-6 convertible preferred stock, for each share of our outstanding shares of series A-5 convertible preferred stock for a total of 186,847 shares of series A-6 convertible preferred stock; (3) the automatic conversion of all outstanding shares of our convertible preferred stock into 41,016,469 shares of common stock in connection with this offering, (4) the issuance of 5,171,472 shares of common stock to the holders of our series B, A-1, A-2, and A-3 convertible preferred stock in connection with this offering in satisfaction of accumulated dividends as of December 31, 2013 and (5) 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 \_\_\_\_\_ shares of our common stock in this offering at an assumed public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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 DECEMBER 31, 2013</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	\$ 12,303	\$ 39,671	\$
Convertible preferred stock, par value \$.0001 per share: 3,916,443 shares authorized, 3,272,834 shares outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma, as adjusted.	252,802	\$	
<b>Stockholders' (deficit) equity:</b>			
Common stock, par value \$.0001 per share: 100,000,000 shares authorized, 879,370 shares issued and outstanding, actual; 200,000,000 shares authorized, 47,067,311 shares issued and outstanding, pro forma; 200,000,000 shares authorized, _____ shares issued and outstanding, pro forma as adjusted			5
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		287,675	
Accumulated other comprehensive loss			
Accumulated deficit	(277,301)	(277,301)	
<b>Total stockholders' (deficit) equity</b>	<b>(277,301)</b>	<b>10,379</b>	

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Total capitalization \$ (24,499) \$ 10,379 \$

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- (1) Each \$1.00 increase or decrease in the assumed public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of the pro forma as adjusted

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cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$ 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 \$ million, assuming that the public offering price is \$ 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.

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

3,800,942 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$3.09 per share as of December 31, 2013;

3,266,560 shares of our common stock reserved for future issuance under our 2011 equity incentive plan as of December 31, 2013; and

1,914,531 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$6.25 per share as of December 31, 2013; and

698,830 of our common stock issuable upon the listing of our common stock on the NASDAQ Global Market in satisfaction of accumulated dividends on our series B, B-2, A-1, A-2 and A-3 convertible preferred stock from January 1, 2014 through March 31, 2014.

***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 1,120,152 shares of our common stock with an exercise price of \$6.142 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) \$6.142 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 \$6.142 per share and that the series B-2 convertible preferred stock will convert into 4,480,600 shares of common stock upon the closing of this offering. If the initial public offering price in this offering is less than \$6.142 per share, you can calculate 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 \$5.142 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 871,373 shares.

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

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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 5,870,302. Each day after March 31, 2014, an additional \$9,440 accrues in respect of the series B convertible preferred

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stock, an additional \$6,032 accrues in respect of the series B-2 convertible preferred stock and \$42,984 accrues in respect of the series A-1, A-2 and A-3 convertible preferred stock. To calculate the number of additional shares of common stock that we will issue upon conversion of the series B, B-2, A-1, A-2 and A-3 convertible preferred stock in connection with this offering, you must add the products obtained by multiplying the daily accrual amount by the number of days beginning on April 1, 2014 and continuing through to the day that our shares are listed and dividing that amount by the applicable conversion price. As of March 31, 2014, the conversion price of the series A-1, A-2 and A-3 convertible preferred stock was \$7.443 per share, the conversion price of the series B convertible preferred stock was \$6.142 per share and conversion price of the series B-2 convertible preferred stock was \$6.142 per share.

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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 December 31, 2013 was \$(277.3) million or \$(315.34) per share of common stock, based on 879,370 shares of common stock outstanding as of December 31, 2013. 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 December 31, 2013 was \$10.4 million, or \$0.22 per share of common stock, based on 47,067,311 shares of common stock outstanding after giving effect to (1) the issuance and sale of 448,060 shares of series B-2 convertible preferred stock for net proceeds of \$27.4 million, which occurred during the first quarter of 2014 and which is described in the section of this prospectus entitled "Capitalization - Series B-2 Convertible Preferred Stock, (2) the declaration of a stock dividend of 29 shares of series A-6 convertible preferred stock, for each share of our outstanding shares of series A-5 convertible preferred stock for a total of 186,847 shares of series A-6 convertible preferred stock; (3) the automatic conversion of all of our outstanding convertible preferred stock into 41,016,469 shares of common stock in connection with this offering and (4) the assumed issuance of 5,171,472 shares of common stock in connection with this offering in satisfaction of accumulated dividends on our series B, A-1, A-2 and A-3 convertible preferred stock through December 31, 2013. 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 December 31, 2013 before giving effect to our sale of shares of common stock in this offering.

After giving further effect to our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma net tangible book value as of December 31, 2013 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in pro forma net tangible book value per share of \$ \_\_\_\_\_ to existing stockholders and immediate dilution of \$ \_\_\_\_\_ in pro forma net tangible book value per share to new investors purchasing common stock in this offering.

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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	\$
Historical net tangible book value (deficit) per share as of December 31, 2013	\$(315.34)
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	315.56
Pro forma net tangible book value per share as of December 31, 2013, before this offering	0.22
Increase in pro forma net tangible book value per share attributable to investors in this offering	
Pro forma as adjusted net tangible book value per share as of December 31, 2013, after this offering	
Dilution per share to new investors in this offering	\$

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase or decrease our pro forma net tangible book value by approximately \$ \_\_\_\_\_ million, our pro forma net tangible book value per share by approximately \$ \_\_\_\_\_ and dilution per share to new investors by approximately \$ \_\_\_\_\_, 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 \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share, and would decrease the dilution per share to new investors in this offering by \$ \_\_\_\_\_ per share, assuming that the assumed initial public offerin 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 \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share, and would increase the dilution per share to new investors in this offering by \$ \_\_\_\_\_ per share, assuming that the assumed initial public offerin 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, 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 offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering

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expenses payable by us. As the table shows, new investors purchasing shares in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	SHARES PURCHASED		TOTAL CONSIDERATION		AVERAGE PRICE PER SHARE
	NUMBER	PERCENT	AMOUNT	PERCENT	
Existing stockholders		%			%
New investors		%			%
<b>Total</b>		%	\$		100%

Each \$1.00 increase or decrease in the assumed public offering price of \$ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$ million and increase or decrease the percentage of total consideration paid by new investors by approximately %, 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 % 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 , or approximately % 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:

3,800,942 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$3.09 per share as of December 31, 2013;

3,266,560 shares of our common stock reserved for future issuance under our 2011 equity incentive plan as of December 31, 2013;

1,914,531 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$6.25 per share; and

698,830 shares of our common stock issuable 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 from January 1, 2014 through March 31, 2014.



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. Our historical results are not necessarily indicative of the results to be expected in the future.

STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS DATA	YEAR ENDED DECEMBER 31,		
	2013	2012	2011
	(in thousands, except share and per share amounts)		
Operating expenses:			
Research and development	\$ 60,536	\$ 54,961	\$ 36,179
General and administrative	6,829	9,469	5,330
Loss from operations	(67,365)	(64,430)	(41,509)
Other income (expense):			
Other income (expense), net	9,085	(2,095)	(236)
Interest (expense) income, net	(2,410)	(2,603)	(731)
Net loss	(60,690)	(69,128)	(42,476)
Other comprehensive loss, net of tax:			
Unrealized (loss) gain from available-for-sale securities		(5)	8
Comprehensive loss	\$ (60,690)	\$ (69,133)	\$ (42,468)
(Loss) earnings attributable to common stockholders	\$ (78,161)	\$ (83,120)	\$ 253
(Loss) earnings per share basic	\$ (89.43)	\$ (98.99)	\$ 0.51
(Loss) earnings per share diluted	\$ (89.43)	\$ (98.99)	\$ 0.07
Weighted average shares basic	874,004	839,698	499,944
Weighted average shares diluted	874,004	839,698	3,454,276
Pro forma loss attributable to common stockholders basic and diluted <sup>(1)(2)</sup> (unaudited)	\$ (60,690)		
Pro forma loss per share basic <sup>(1)</sup> (unaudited)	\$ (1.75)		
Pro forma loss per share diluted <sup>(1)</sup> (unaudited)	\$ (1.75)		
Weighted-average common shares used in computing pro forma earnings per share basic <sup>(1)</sup> (unaudited)	34,765,779		
Weighted-average common shares used in computing pro forma earnings per share diluted <sup>(1)</sup> (unaudited)	34,765,779		

(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 financial statements included elsewhere in this prospectus.

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

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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.

Our current clinical product portfolio also includes a novel oral agent, RAD1901 at higher doses, a selective estrogen receptor down-regulator/degrader, or SERD. We are developing RAD1901 for the treatment of breast cancer brain metastases, or BCBM, and at lower doses as a selective estrogen-receptor modulator, or SERM, for the treatment of vasomotor symptoms such as hot flashes. In 2014, we expect to commence a Phase 1 clinical trial to evaluate RAD1901 for the treatment of BCBM, and we previously completed a successful Phase 2 clinical trial of RAD1901 for the treatment of vasomotor symptoms.

***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. 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.

***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 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.

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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 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;

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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 contracted research organizations, or CROs, salaries and related personnel costs, fees paid to consultants and outside service providers for regulatory and quality assurance support, licensing of drug compounds and other expenses relating to the manufacture, development, testing and enhancement of our product candidates. We expense our research and development costs as they are incurred.

None of the research and development expenses in relation to our product candidates are currently borne by third parties. Our lead product candidate is 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 December 31, 2013 were approximately \$144.0 million. We began tracking program expenses for Abaloparatide-TD in 2007, and program expenses from inception to December 31, 2013 were approximately \$29.6 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to December 31, 2013 were approximately \$15.5 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to December 31, 2013 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.





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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 \$71.0 million, including \$35.0 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 financial statements included elsewhere in this report).

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 (in thousands):

	<b>YEAR ENDED DECEMBER 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Abaloparatide-SC	\$ 45,977	\$ 44,692	\$ 27,046
Abaloparatide-TD	11,459	6,040	6,369
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 and 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 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 reduced to \$76.27 as of December 31, 2013.

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**Other income (expense)**

For the years ended December 31, 2013 and 2012, other income (expense) primarily reflects changes in the fair value of the series A-6 convertible preferred stock liability from the date of the initial accrual to the reporting date as discussed in note 11 to our financial statements 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.

**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

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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 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).

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**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, 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 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. The other liability 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

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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.

**Years Ended December 31, 2013 and December 31, 2012**

	YEARS ENDED		CHANGE	
	DECEMBER 31, 2013	2012	\$	%
	(in thousands)			
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**

	YEARS ENDED		CHANGE	
	DECEMBER 31, 2012	2011	\$	%
	(in thousands)			
<b>Operating expenses:</b>				
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%
<b>Other (expense) income:</b>				
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.

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*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.

**LIQUIDITY AND CAPITAL RESOURCES**

From inception to December 31, 2013, we have incurred an accumulated deficit of \$277.3 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and expenses supporting those activities. 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 December 31, 2013 is \$12.3 million. 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, pursuant to which we may raise up to approximately \$40.2 million through the issuance of (1) up to 655,000 shares of our Series B-2 preferred stock, or the Series B-2 Shares, and (2) warrants to acquire up to 1,637,500 shares of our common stock, with an exercise price of \$6.142 per share. During February and March 2014, we consummated several 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, or Series B-2, and warrants to purchase up to a total of 1,120,152 shares of our common stock.

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 . 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):

	<b>YEARS ENDED DECEMBER 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Net cash (used in) provided by:			
Operating activities	\$ (45,017)	\$ (43,158)	\$ (35,896)
Investing activities	3,971	27,435	(23,800)
Financing activities	34,696	9,248	74,242
Net (decrease) increase in cash and cash equivalents	\$ (6,350)	\$ (6,475)	\$ 14,546

**Cash Flows from Operating Activities**

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,

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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**

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 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.



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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 December 31, 2013, 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 December 31, 2013, we have received aggregate net cash proceeds of \$210.9 million from the sale of shares of our preferred stock as follows:

<b>ISSUE</b>	<b>YEAR</b>	<b>NO. SHARES</b>	<b>NET PROCEEDS (IN THOUSANDS)</b>
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
Total		21,735,332	\$ 210,857

(1)

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

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 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 reduced to \$76.27 as of December 31, 2013.

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

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our series B convertible preferred stock or Series B, which are convertible into an aggregate of 7,000,980 shares of our common stock and warrants to purchase up to a total of 1,750,248 shares of our common stock at an exercise price of \$6.142 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 2,843 shares of our common stock.

The shares of our Series B convertible preferred stock, or the Series B, are convertible, in whole or in part, at the option of the holder at any time into shares of common stock, on a ten-for-one basis at an initial effective conversion price of \$6.142 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 Series A-3 convertible preferred stock was reduced from \$8.142 to \$7.627 as of December 31, 2013. Accordingly, each share of Series A-1, Series A-2 and Series A-3 is convertible into 10.675 shares of our common stock as of December 31, 2013.

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, par value \$.0001 per share, and (2) warrants to acquire up to 1,637,500 shares of its common stock, at an exercise price of \$6.142 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 a ten-for-one basis at an initial effective conversion price of \$6.142 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

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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 times (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 1,120,152 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 \$7.627 to \$7.443. Accordingly, each share of Series A-1, Series A-2 and Series A-3 is currently convertible into 10.939 shares of common 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 (\$988,919) 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

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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 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 (\$16,454) 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. Any Performance Incentive Payment will 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. Should an IPO not be consummated by us prior to May 31, 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 the 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

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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, 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) \$8.142 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, or, after the automatic conversion into common stock of our preferred stock, 4,381,240 shares of our common stock. 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 provides 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. The Second Stock Issuance Agreement Amendment 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 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, 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 December 31, 2013, we had (1) a liability of \$4.8 million reflected in accrued expenses and other current liabilities 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 \$11.6 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, 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, 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

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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) \$8.142 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, or, after the automatic conversion into common stock of our preferred stock, 257,720 shares of our common stock. 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 provides 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. The Second Stock Issuance Agreement Amendment 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, for per patient costs incurred for patients that had enrolled in the Extension Study and Second Extension.

As of December 31, 2013, we had (1) a liability of \$0.6 million reflected in accrued expenses and other current liabilities 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 \$0.5 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.

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*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 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) \$8.142 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, or, after the automatic conversion into common stock of our preferred stock, 322,150 shares of common stock. 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.

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, 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



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preparatory and other start-up costs to initiate the Phase 2 Clinical Trial during the year ended December 31, 2012.

As of December 31, 2013, we had a liability of \$0.5 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.

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.

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 (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				
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. 2 to the Stock Issuance Agreement, if an initial public offering occurs prior to May 31, 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

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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 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

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(\$13.8 million to \$49.6 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 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 189,529 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,

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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 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 February 2013, FASB issued Accounting Standards Update No. 2013-02, *Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income* ("ASU 2013-02"). Under ASU 2013-02, an entity is required to provide information about amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. ASU 2013-02 does not change the current requirements for reporting net income or other comprehensive income in the financial statements. We adopted ASU 2013-02 on January 1, 2013. Its adoption did not have a material impact on our results of operations, financial position or cash flows.

**NEW 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 do not expect adoption of ASU 2013-11 will 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. There is no actual effective date for the amendment in ASU 2013-12 and we do not expect ASU 2013-12 will have a material impact on our results of operations, financial position or cash flows.

Table of Contents**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.

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 at lower doses as a selective estrogen-receptor modulator, or SERM, for the treatment of vasomotor symptoms such as hot flashes. In 2014, we expect to commence a Phase 1 clinical trial to evaluate RAD1901 for the treatment of BCBM, and we previously completed a successful Phase 2 clinical trial of RAD1901 for the treatment of vasomotor symptoms.

***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. 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.

*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

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Phase 3 bridging study and to subsequently submit for approval. We hold worldwide commercialization rights to Abaloparatide-TD technology.

***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 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.

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.

**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

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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 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

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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.

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.



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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.

In late 2014, we intend to advance the development of high-dose RAD1901 for the treatment of ER-positive BCBM with the initiation of a Phase 1b clinical trial.

***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 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

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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.

**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.

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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**

*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.

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.

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*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. 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) and total hip (2.7% increase from baseline). 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.

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

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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.

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.

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*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