

Radius Health, Inc.  
Form 10-K  
March 10, 2015

Use these links to rapidly review the document

[Table of Contents](#)

[ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.](#)

[PART IV](#)

[Table of Contents](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2014

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number: 001-35726

**Radius Health, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**950 Winter Street**

**Waltham, Massachusetts**

(Address of principal executive offices)

**80-0145732**

(I.R.S. Employer  
Identification No.)

**02451**

(Zip Code)

**617-551-4000**

(Registrant's telephone number, including area code)

Securities issued pursuant to Section 12(b) of the Act: **Common Stock**

Securities issued pursuant to Section 12(g) of the Act: **None**

**Title of each class**

**Name of each exchange on which registered**

Common Stock, par value \$0.0001 per share

The NASDAQ Global Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

## Edgar Filing: Radius Health, Inc. - Form 10-K

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated  
filer

Accelerated  
filer

Non-accelerated  
filer

Smaller reporting  
company

(Do not check if a  
smaller reporting  
company)

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

The aggregate market value of the registrant's common stock, \$0.0001 par value per share ("Common Stock"), held by non-affiliates of the registrant, based on the last sale price of the Common Stock at the close of business on June 30, 2014 was \$190.5 million. For the purpose of the foregoing calculation only, all directors and executive officers of the registrant are assumed to be affiliates of the registrant.

Number of shares outstanding of the registrant's common stock, par value \$0.0001 per share, as of March 5, 2015: 37,821,722

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2015 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K.

---

Table of Contents

**Radius Health, Inc.**

**Annual Report on Form 10-K**

**For the Fiscal Year Ended December 31, 2014**

**INDEX**

	<u>Special Note Regarding Forward-Looking Statements</u>	<u>1</u>
	<u>Currency and Conversions</u>	<u>2</u>
	<b><u>PART I</u></b>	
<u>ITEM 1:</u>	<u>Business</u>	<u>3</u>
<u>ITEM 1A:</u>	<u>Risk Factors</u>	<u>51</u>
<u>ITEM 1B:</u>	<u>Unresolved Staff Comments</u>	<u>77</u>
<u>ITEM 2:</u>	<u>Properties</u>	<u>77</u>
<u>ITEM 3:</u>	<u>Legal Proceedings</u>	<u>77</u>
<u>ITEM 4:</u>	<u>Mine Safety Disclosures</u>	<u>77</u>
	<b><u>PART II</u></b>	
<u>ITEM 5:</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>78</u>
<u>ITEM 6:</u>	<u>Selected Financial Data</u>	<u>79</u>
<u>ITEM 7:</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>80</u>
<u>ITEM 7A:</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>104</u>
<u>ITEM 8:</u>	<u>Financial Statements and Supplementary Data</u>	<u>105</u>
<u>ITEM 9:</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>142</u>
<u>ITEM 9A:</u>	<u>Controls and Procedures</u>	<u>142</u>
<u>ITEM 9B:</u>	<u>Other Information</u>	<u>144</u>
	<b><u>PART III</u></b>	
<u>ITEM 10:</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>145</u>
<u>ITEM 11:</u>	<u>Executive Compensation</u>	<u>148</u>
<u>ITEM 12:</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>148</u>
<u>ITEM 13:</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>149</u>
<u>ITEM 14:</u>	<u>Principal Accountant Fees and Services</u>	<u>149</u>
	<b><u>PART IV</u></b>	
<u>ITEM 15:</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>150</u>
	<u>Signatures</u>	<u>151</u>

---

Table of Contents

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*This report, including in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains, in addition to historical information, forward-looking statements. We may, in some cases, use words such as "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "continue," "should," "would," "could," "potentially," "will," "may" or similar words and expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K may include, among other things, statements about:*

*the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;*

*the success of our clinical studies for our investigational product candidates;*

*our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our investigational 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 investigational product candidates;*

*the safety profile and related adverse events of our investigational product candidates;*

*our ability to manufacture sufficient amounts of abaloparatide, RAD1901 and RAD140 for commercialization activities with target characteristics following regulatory approval;*

*our plans with respect to collaborations and licenses related to the development, manufacture or sale of our investigational 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 investigational 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 report.*

*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 Item 1A of this Annual Report on Form 10-K under the caption "Risk Factors." You should read these factors and the other cautionary statements made in this report as being applicable to all related forward-looking statements wherever they appear in this report. These risk factors are not exhaustive and other sections of this report may include additional factors which could adversely impact our business*

*and financial performance.*

Table of Contents

**CURRENCY AND CONVERSIONS**

In this report, references to "dollar" or "\$" are to the legal currency of the United States, and references to "euro" or "€" are to the single currency introduced on January 1, 1999 at the start of the third stage of European Economic and Monetary Union, pursuant to the Treaty establishing the European Communities, as amended by the Treaty on European Union and the Treaty of Amsterdam. Unless otherwise indicated, the financial information in this report has been expressed in U.S. dollars. Unless otherwise stated, the U.S. dollar equivalent information translating euros into U.S. dollars has been made, for convenience purposes, on the basis of the noon buying rate published by the Board of Governors of the Federal Reserve as of December 31, 2014, which was €1.00 = \$1.2101. Such translations should not be construed as a representation that the euro has been, could have been or could be converted into U.S. dollars at the rate indicated, any particular rate or at all.

Trademarks appearing in this report are the property of their respective holders.

Table of Contents

**PART I**

**ITEM 1. BUSINESS.**

*Unless otherwise provided in this report, all references in this report to "we," "us," "our company," "our," or the "Company" refer to Radius Health, Inc.*

**Overview**

We are a science-driven biopharmaceutical company focused on developing new therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases. Our lead development candidate is the investigational drug abaloparatide (BA058), a bone anabolic for potential use in the reduction of fractures in postmenopausal osteoporosis delivered via subcutaneous injection, which we refer to as abaloparatide-SC. We announced the 18-month top-line data from our Phase 3 clinical trial, or ACTIVE trial, evaluating abaloparatide-SC for potential use in the reduction of fractures in postmenopausal osteoporosis in December 2014. Patients from the abaloparatide-SC and placebo groups from our Phase 3 clinical trial are eligible to continue in an extension study, or ACTIVEExtend trial, in which they are receiving an approved alendronate therapy for osteoporosis management. We currently anticipate the first six months' results from the ACTIVEExtend trial to be available in the second quarter of 2015. We plan to submit a new drug application, or NDA, in the United States, and a marketing authorization application, or MAA, in Europe, during the second half of 2015 which will include results from the 18-month ACTIVE trial along with the first six months' results from the ACTIVEExtend trial. We hold worldwide commercialization rights to abaloparatide-SC, other than in Japan, and subject to a regulatory review and favorable regulatory outcome, we anticipate our first commercial sales of abaloparatide-SC will take place in 2016. We are leveraging our investment in abaloparatide-SC to develop a line extension that is designed to improve patient convenience by enabling administration of abaloparatide through an investigational short-wear-time transdermal patch, which we refer to as abaloparatide-TD. We hold worldwide commercialization rights for abaloparatide-TD.

Our current clinical product portfolio also includes the investigational drug RAD1901, a selective estrogen receptor down-regulator/degrader, or SERD, and RAD140, a nonsteroidal selective androgen receptor modulator, or SARM. We are developing RAD1901 at higher doses for the potential treatment of metastatic breast cancer or other estrogen receptor mediated oncology applications, and intend to advance its development with the initiation of Phase 1 clinical trials, including a maximum tolerated dose study that has commenced patient dosing and a Phase 1 clinical trial in metastatic breast cancer patients, which commenced in late 2014. At lower doses, RAD1901 acts as a selective estrogen receptor modulator, or SERM. Low-dose RAD1901 has shown potential to be effective for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study. We intend to commence a Phase 2b clinical trial in vasomotor symptoms in the second half of 2015. RAD140 resulted from an internal drug discovery program focused on the androgen receptor pathway, which is highly expressed in many breast cancers. Due to its receptor and tissue selectivity, potent oral activity and long duration half-life, RAD140 could have clinical potential in the treatment of breast cancer or possibly other conditions where androgen modulation may offer therapeutic benefit.

***Abaloparatide***

Abaloparatide is a novel synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a bone anabolic treatment for potential use in the reduction of fractures in postmenopausal osteoporosis. Osteoporosis is a disease that affects nearly 10 million people, with an additional approximately 43 million people at increased risk for the disease, in the United States. 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

Table of Contents

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, at more sites, at a faster rate, and in more patients than other drugs that are approved for the treatment of osteoporosis. We are developing two formulations of abaloparatide:

*Abaloparatide-SC* is an injectable subcutaneous formulation of abaloparatide. Our Phase 3 study of abaloparatide-SC is designed to evaluate whether abaloparatide-SC is superior to placebo for prevention of vertebral fracture. The study is also designed to evaluate whether abaloparatide-SC is superior to open-label teriparatide treatment 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. On December 21, 2014, we announced positive top-line data from the ACTIVE trial, evaluating the investigational drug abaloparatide-SC for potential use in the reduction of fractures in postmenopausal osteoporosis. In January 2015, based on comments on the draft Statistical Analysis Plan from the U.S. Food and Drug Administration, or FDA (or the Agency), we revised our statistical analysis of the Phase 3 top-line data. See "Abaloparatide Abaloparatide-SC."

Our Phase 3 study includes a 6-month extension period in order to obtain 24-months of fracture data, as requested by the FDA and the European Medicines Agency, or EMA. We currently anticipate the first six months' results from the ongoing ACTIVEExtend trial to be available in the second quarter of 2015. We believe that the abaloparatide-SC program is on-track for submission of an NDA for abaloparatide-SC to the FDA and submission of an MAA to EMA each of which incorporates the 24-month fracture data, in the second half of 2015. We will remain blinded at the patient and site level until such time as six months of the alendronate extension study is completed.

In July 2014, the FDA denied our request for breakthrough therapy designation for abaloparatide-SC, and indicated that, upon a new request, abaloparatide-SC would be considered for a breakthrough therapy designation if new clinical evidence demonstrates that patients dosed with abaloparatide-SC show substantial improvement in treatment of postmenopausal osteoporosis over existing therapies on one or more clinically significant endpoints. We believe that the recently completed analyses of the 18-month top-line results of our Phase 3 clinical trial and two abaloparatide Phase 2 clinical trials have shown potentially important clinical benefits relative to placebo and current anabolic therapies and that these data could support a breakthrough therapy designation. Once we have fully evaluated the 24-month results from the Phase 3 clinical trial, a decision will be made on whether to re-submit our request or to apply for one of the other FDA expedited review programs for new drugs that address unmet medical needs in the treatment of serious or life threatening conditions.

*Abaloparatide-TD* is a line extension of abaloparatide-SC in the form of a convenient, short-wear-time transdermal patch. In January 2014, we reported that in the Phase 2 clinical trial, abaloparatide-TD showed a statistically significant mean percent increase from baseline in BMD. We expect to initiate the clinical evaluation of the optimized abaloparatide-TD patch in the second half of 2015, with the goal of achieving comparability to abaloparatide-SC. We hold worldwide commercialization rights to abaloparatide-TD technology.

We also believe that, subject to further research and development, abaloparatide may have potential applications across a variety of skeletal or bone related diseases or medical conditions.

***RAD1901***

RAD1901 is a SERD that we believe crosses the blood-brain barrier and that we are evaluating for the potential treatment of metastatic breast cancer and other estrogen receptor mediated oncology applications. In studies completed to date, RAD1901 has been shown to bind with good selectivity to



Table of Contents

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. In 2014, the worldwide market for Faslodex was \$720.0 million. For ER-positive metastatic breast cancer patients with brain metastases, there are no approved targeted therapies that cross the blood-brain barrier with the potential to more effectively treat and potentially reduce both intracranial and extracranial metastatic breast cancer tumors.

In December 2014, we commenced a Phase 1 clinical trial of RAD1901 in the United States for the treatment of metastatic breast cancer. The Phase 1 study is a multicenter, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced estrogen receptor positive and HER2-negative breast cancer that is designed to determine the recommended dose for a Phase 2 study and includes a preliminary evaluation of the potential anti-tumor effect of RAD1901. We expect to report progress on this study in the first half of 2015 and to initiate additional Phase 1 clinical trials in the European Union in 2015. In June 2014, we initiated a Phase 1 maximum tolerated dose, or MTD, study of RAD1901 in healthy volunteers. The study is designed to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also to use 18F-estradiol positron emission tomography, or FES-PET, imaging to provide a pharmacodynamic assessment of estrogen receptor turnover following administration of RAD1901. Levels of RAD1901 in cerebrospinal fluid samples taken from study subjects will be measured to confirm that RAD1901 has crossed the blood-brain barrier. Based upon initial study results, FES-PET imaging of RAD1901 has demonstrated potent SERD activity. As of December 31, 2014, 40 subjects had completed dose escalation in the ongoing MTD study, and FES-PET imaging had been completed in a total of five subjects across two different doses. Each of these five subjects demonstrated, based on FES-PET imaging, suppression of the FES-PET signal to background levels after six days of dosing. In addition, RAD1901, at the doses that showed suppression of the FES-PET signal, was well tolerated in these patients.

In March 2014, we submitted to the FDA an application for orphan drug designation of RAD1901 for the treatment of breast cancer brain metastases. In June 2014, we received a response to our application from the FDA, requesting additional data with respect to our orphan drug designation application. We plan to meet with the FDA and are working to provide the Agency with the data requested to support orphan drug designation of RAD1901.

We are also developing RAD1901 at lower doses as a SERM, for the potential treatment of vasomotor symptoms. Historically, hormone replacement therapy, or HRT, with estrogen or progesterone has been 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 showed a reduction in the frequency and severity of moderate and severe hot flashes. We intend to commence a Phase 2b trial in vasomotor symptoms in the second half of 2015.

Additional information regarding our clinical trials, their designs and the results of previously completed clinical trials is described in the section entitled " Our Investigational Product Candidates." The U.S. National Institutes of Health also provides a database of human 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 annual report.

Table of Contents

**Our Opportunity**

*Osteoporosis*

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. All bones become more fragile and susceptible to fracture as the disease progresses. People tend to be unaware that their bones are getting weaker, and a person with osteoporosis can fracture a bone from even a minor fall. The debilitating effects of osteoporosis have substantial costs. Loss of mobility, admission to nursing homes and dependence on caregivers are all common consequences of osteoporosis. The prevalence of osteoporosis is growing and, according to the National Osteoporosis Foundation, or NOF, is significantly under-recognized and under-treated in the population. While the aging of the population is a primary driver of an increase in cases, osteoporosis is also increasing from the use of drugs that induce bone loss, such as chronic use of glucocorticoids and aromatase inhibitors that are increasingly used for breast cancer and the hormone therapies used for prostate cancer.

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

There are two main types of osteoporosis drugs currently available in the United States, anti-resorptive agents and anabolic agents. Anti-resorptive agents act to prevent further bone loss by inhibiting the breakdown of bone, whereas anabolic agents stimulate bone formation to build new, high-quality bone. According to industry sources, sales of these drugs in the United States, Japan and the five major markets in Europe exceeded \$6 billion in 2011. We believe there is a large unmet need in the market for osteoporosis treatment because existing therapies have been reported to have shortcomings in efficacy, tolerability and convenience. For example, one current standard of care, bisphosphonates, which are anti-resorptive agents, 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, reportedly 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 \$1.3 billion and \$1.0 billion, respectively, in 2014. 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 has the potential to increase BMD to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis with potential added advantages in convenience and safety.

*Our Investigational Drug Abaloparatide*

Abaloparatide is a novel synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a bone anabolic treatment for potential use in the reduction of fractures in postmenopausal osteoporosis. PTHrP, unlike parathyroid hormone, or PTH, is critical in

Table of Contents

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, subject to regulatory review and approval, it could have the potential to 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; and

less hypercalcemia.

*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 believe that by offering an alternative to daily injections, abaloparatide-TD, if successfully developed and approved, could have the potential to further improve patient outcomes by increasing patient acceptance.

During 2014, we made progress towards the development of an optimized, short-wear-time transdermal patch that may be capable of demonstrating comparability to abaloparatide-SC injection. We expect to initiate the clinical evaluation of the optimized abaloparatide-TD patch in the second half of 2015, with the goal of achieving comparability to 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.

***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 five-year survival rate of only 25%, compared with a greater than 99% 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 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 have the potential to be able to treat ER-dependent tumors without allowing ligand-independent resistance to develop, and to act on AI- and SERM-resistant ER-positive tumors.

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 breast cancer brain metastases. We believe a significant opportunity exists for a SERD that can more effectively treat ER-positive metastatic breast cancer, as well as cross the blood-brain barrier, and potentially reduce both intracranial and extracranial metastatic breast cancer tumors.

Table of Contents

*Our Investigational Drug RAD1901*

We are developing RAD1901 as a high-dose SERD in an oral formulation in Phase 1 clinical development for the potential treatment of metastatic breast cancer. 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 inhibits the proliferation of breast cancer cells, and antagonizes the stimulating effects of estrogen on cell proliferation. Furthermore, in breast cancer cell lines a dose dependent degradation of ER, has been observed. In a preclinical 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 marked regression of estrogen stimulated tumor growth. In healthy volunteers, FES-PET imaging of RAD1901 has shown suppression of the FES-PET signal to background levels after six days of dosing.

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. We believe that, subject to successful development, regulatory review and approval, RAD1901 could have the potential to offer the following advantages over other current standard of care treatments for ER-positive metastatic breast cancer:

ability to suppress estrogen receptor turnover;

favorable tolerability profile;

ability to penetrate the blood-brain barrier;

oral administration; and

treatment of hormone-resistant breast cancers.

In December 2014, we commenced a Phase 1 clinical trial of RAD1901 in the United States for the treatment of metastatic breast cancer. We expect to report progress on this study in the first half of 2015 and to initiate additional Phase 1 clinical trials in the European Union in 2015. In June 2014, we received a request from the FDA for additional data with respect to our March 2014 orphan drug designation application for RAD1901. We plan to meet with the FDA and are working to provide the Agency with the data requested to support designation of RAD1901 as an orphan drug.

*Our Investigational Drug RAD140*

RAD140 is a nonsteroidal selective androgen receptor modulator, or SARM, that resulted from an internal drug discovery program focused on the androgen receptor pathway which is highly expressed in many breast cancers. Due to its receptor and tissue selectivity, potent oral activity and long duration half-life, RAD140 could have clinical potential in the treatment of breast cancer.

***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 HRT with estrogen and/or progesterone has been considered the most efficacious approach to relieving menopausal symptoms such as hot flashes. However, data from the Women's

Table of Contents

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 Investigational Drug RAD1901*

We are developing RAD1901 as a low-dose SERM in an oral formulation for the treatment of vasomotor symptoms. The results of our Phase 2 proof of concept study in healthy perimenopausal women showed that RAD1901 at low doses 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.

We intend to commence a Phase 2b study during the second half of 2015 in perimenopausal women experiencing a high frequency of hot flashes at baseline.

**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 have completed a Phase 3 clinical trial of abaloparatide-SC and are preparing for the completion of the first six months of an extension trial for its potential use in the reduction of fractures in postmenopausal osteoporosis. We plan to submit an NDA for abaloparatide-SC in the United States, and an MAA in the European Union, during the second half of 2015.

**Advance the development of RAD1901 for the treatment of metastatic breast cancer and vasomotor symptoms.** We have commenced a Phase 1 MTD study of RAD1901 in healthy volunteers and a Phase 1 study in patients with metastatic breast cancer. We expect to report progress on the study in patients with metastatic breast cancer in the first half of 2015 and to initiate additional Phase 1 clinical trials in the European Union in 2015. In addition, we plan to commence a Phase 2b study of RAD1901 for the treatment of vasomotor symptoms during the second half of 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 successful development and a favorable regulatory outcome, commercial launch two to three years after the approval and first commercial sale of abaloparatide-SC. We expect to initiate the clinical evaluation of the optimized abaloparatide-TD patch in the second half of 2015, with the goal of achieving pharmacokinetic equivalence to abaloparatide-SC. If abaloparatide-SC is approved by the FDA, we believe that we will only need to conduct either a pharmacokinetic equivalence or 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 product candidates that are approved by developing an internal sales force focused within the targeted indications on specialists in core strategic markets in the United States. We believe that we can effectively

Table of Contents

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 within the targeted indications 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 investigational product candidates focused on serious endocrine-related diseases and conditions. We may also consider opportunistically expanding our product portfolio through in-licensing, acquisitions or partnerships.

**Our Investigational Product Candidates**

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

**Abaloparatide**

*Overview*

Abaloparatide is a novel synthetic PTHrP that we are developing as a bone anabolic treatment for potential use in the reduction of fractures in postmenopausal 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 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



Table of Contents

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 PTH. 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 potential use in reduction of fractures in postmenopausal 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. We also believe that, subject to further research and development, abaloparatide may have potential applications across a variety of skeletal or bone related diseases or medical conditions.

***Abaloparatide-SC***

We are developing abaloparatide-SC as a once daily subcutaneous injection of abaloparatide for potential use in the reduction of fractures in postmenopausal osteoporosis. In April 2011, we commenced a 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 was designed to test our belief that abaloparatide is superior to placebo for prevention of vertebral fracture and to open-label Forteo for greater BMD improvement at major skeletal sites and for a lower occurrence of hypercalcemia. We also believed that the trial would show that BMD gains for abaloparatide patients occur earlier than for open-label Forteo patients. On December 21, 2014, we announced positive top-line data from the ACTIVE trial, evaluating the investigational drug abaloparatide-SC for potential use in the reduction of fractures in postmenopausal osteoporosis. On the primary endpoint, abaloparatide-SC (n=690, fracture rate 0.72%) achieved a statistically significant 83% reduction of incident vertebral fractures (defined as new and worsening vertebral fractures) as compared to the placebo-treated group (n=711, fracture rate 4.36%) (p<0.0001). The ACTIVE trial included an open-label teriparatide [rDNA origin] injection treatment group (n=717, fracture rate 0.98%) that showed a statistically significant 78% reduction of incident vertebral fractures as compared to the placebo-treated group (p<0.0001). On the secondary endpoints, as compared to placebo, abaloparatide-SC achieved: a statistically significant fracture-rate reduction of 43% in the adjudicated non-vertebral fracture subset of patients; a statistically significant reduction of 45% in the adjudicated clinical fracture group, which includes both vertebral and non-vertebral fractures; and a statistically significant difference in the time to first incident of nonvertebral fracture in both the adjudicated non-vertebral fracture (p=0.0489) and the clinical fracture subset of patients (p=0.0112). The open-label teriparatide injection treatment group, as compared to placebo, achieved a fracture-rate reduction of 28% in the adjudicated non-vertebral fracture subset of patients and a reduction of 29% in the adjudicated clinical fracture group; these differences were not statistically significantly different as compared to the placebo group. The fracture-rate reduction observed in the abaloparatide-SC treatment group, as compared to open-label teriparatide, was not statistically significant.



Table of Contents

In January 2015, the FDA provided us with comments on the draft SAP that was used for the analysis of the top-line data from the Phase 3 ACTIVE clinical trial. In its correspondence, the FDA recommended that the primary endpoint of incident vertebral fracture reduction be performed excluding worsening vertebral fractures and including only new vertebral fractures. Using the FDA-recommended analysis, on the primary endpoint of reduction of new vertebral fractures (excluding worsening), abaloparatide-SC (n=690, fracture rate 0.58%) achieved a statistically significant 86% reduction as compared to the placebo-treated group (n=711, fracture rate 4.22%) (p<0.0001). The open-label teriparatide injection treatment group (n=717, fracture rate 0.84%) showed a statistically significant 80% reduction of new vertebral fractures (excluding worsening) as compared to the placebo-treated group (p<0.0001). The FDA also recommended, for the secondary endpoint of non-vertebral fractures, that our definition was generally acceptable provided that sternal (breast bone) and patellar (knee cap) fractures were excluded. In the previously announced top-line data for the secondary endpoint of non-vertebral fracture reduction noted above, we had excluded sternum and patella fractures, and abaloparatide-SC (n=824, Kaplan-Meier estimated, or KM, fracture rate 2.7%) achieved a statistically significant reduction compared to the placebo-treated group (n=821, KM fracture rate 4.7%), and the hazard ratio for abaloparatide vs. placebo was 0.57 (p=0.0489); the open label teriparatide injection treatment group (n=818, KM fracture rate 3.3%) had a hazard ratio of 0.72 (p=NS) compared to the placebo-treated group. The FDA also recommended, for the secondary endpoint of BMD that we use an ANCOVA approach with the last observation carried forward for missing data. The MMRM method, which was used in the BMD secondary endpoint in the top-line data announced in December 2014, is to be applied for sensitivity analysis.

We have also 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. Specifically, our study showed that total hip BMD showed a more than five-fold benefit with abaloparatide-SC at a dose of 80 µg over Forteo after 24 weeks. Abaloparatide-SC at 80 µg 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 showed that patients who received an 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 showed that abaloparatide is generally safe and well tolerated.

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 data from the first six months of an extension study during which patients 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 reduction of fracture risk in postmenopausal women with severe 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. We plan to submit the NDA with the 24-month fracture data. We will remain

Table of Contents

blinded at the patient and site level until such time as the first six months of the extension study is completed.

On May 9, 2014, we submitted a request for breakthrough therapy designation request to the FDA for abaloparatide-SC for the treatment of postmenopausal osteoporosis. In July 2014, the FDA denied our request and indicated that, upon a new request, abaloparatide-SC would be considered for a breakthrough therapy designation if new clinical evidence demonstrates that patients dosed with abaloparatide-SC show substantial improvement in treatment of postmenopausal osteoporosis over existing therapies on one or more clinically significant endpoints. We believe that the recently completed analyses of the 18-month top-line results of our Phase 3 clinical trial and two abaloparatide Phase 2 clinical trials have shown potentially important clinical benefits relative to placebo and current anabolic therapies, including significant improvements in reducing the risk of osteoporotic fractures and in calcemic control. We believe these results could support a breakthrough therapy designation. Once we have evaluated the 24-month results from the Phase 3 clinical trial and the first six months of the extension study, we expect to make a decision as to whether to re-submit our request for breakthrough designation with a focus on the areas highlighted by the FDA or to apply for one of the other FDA expedited programs for new drugs that address unmet medical needs in the treatment of serious or life threatening conditions.

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

***Abaloparatide-TD***

We are developing abaloparatide-TD as a line extension of abaloparatide-SC in a short-wear-time transdermal patch formulation. In January 2014, we reported positive data from our Phase 2 clinical trial of abaloparatide-TD. The results showed 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. On December 21, 2014, we reported progress towards the development of an optimized, short-wear-time transdermal patch that may be capable of demonstrating comparability to abaloparatide-SC injection. In preliminary, nonhuman primate pharmacokinetic studies, prototype A7 achieved a desirable pharmacokinetic profile, with comparable AUC, C<sub>max</sub>, T<sub>max</sub> and T<sub>1/2</sub> relative to abaloparatide-SC. We believe that these results support continued clinical development toward future global regulatory submissions as a potential post-approval line extension of the investigational drug abaloparatide-SC. We expect to initiate the clinical evaluation of the optimized abaloparatide-TD patch in the second half of 2015, with the goal of achieving comparability to abaloparatide-SC. If abaloparatide-SC is already approved by the

Table of Contents

FDA, we believe that we will only need to conduct either a pharmacokinetic equivalence or 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's 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 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 were 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 trial 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 trial and discuss options for fulfilling the FDA's new request for 24-month fracture data in the context of the ongoing Phase 3 study. We subsequently met with the FDA on March 21, 2012 to discuss satisfying the 24-month data request while preserving the current 18-month primary endpoint. Based upon our discussion with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from a 6-month extension of the abaloparatide 80 µg and placebo groups in our Phase 3 study that will receive an approved alendronate (generic Fosamax) therapy for osteoporosis management. We intend to submit the NDA with the 24-month fracture data.

*Study population* The Phase 3 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 one-half standard deviations below the mean BMD of an ethnically matched 30-year-old man or woman, as applicable. The women enrolled in the study have a BMD t-score  $\leq -2.5$  and  $> -5.0$  at the lumbar spine or hip (femoral neck) as measured by dual energy x-ray absorptiometry, or DXA, and radiological evidence of two or more mild or one or more moderate lumbar or thoracic vertebral fractures, or history of low trauma forearm, humerus, sacral, pelvic, hip, femoral or tibial fracture within the past five years. Postmenopausal women older than 65 who met the above fracture criteria but had a t-score of  $\leq -2.0$  and  $> -5.0$  could also be enrolled. Women older than 65 who did not meet the fracture criteria could also be enrolled if their t-score was  $\leq -3.0$  and  $> -5.0$ . All patients were to be in good general health as determined by medical history, physical examination (including vital signs), and clinical laboratory testing. We believe this study population contains a patient population reflective of the type of severe osteoporosis patients that specialists will treat in their practices.

Table of Contents

*Study design*

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

abaloparatide at a dose of 80 µg;

a matching placebo; or

Forteo at a dose of 20 µg.

The study drug was blinded to patients and medical personnel until the randomization process was completed. Treatment with abaloparatide at a dose of 80 µg or placebo will remain blinded to all parties throughout the study. Forteo comes as a proprietary prefilled drug and device combination that cannot be repackaged. Therefore, its identity cannot be blinded to treating physicians and patients once use begins. Study medication is self-administered daily by subcutaneous injection for a maximum of 18 months. All enrolled patients also receive calcium and vitamin D supplementation from the time of enrollment until the end of the treatment period. It is recommended to patients that they also continue these supplements through the one month follow-up period.

*Primary efficacy endpoints* The primary efficacy endpoint is the number of patients treated with abaloparatide-SC that show new vertebral fractures at end-of-treatment when compared to placebo as evaluated by a blinded assessor according to a standardized graded scale of severity of the vertebral deformity. The sample size per treatment arm provides 90% power at a two-sided alpha to detect a superiority difference on vertebral fracture incidence between placebo patients and those who receive abaloparatide-SC at a dose of 80 µg.

*Secondary efficacy endpoints* Secondary efficacy parameters include reduction in the incidence of non-vertebral fractures to the wrist, hip and rib, for example, and reduction in moderate and severe vertebral fractures from baseline to end-of-treatment. Other secondary efficacy endpoints include changes in BMD of the spine, hip, femoral neck and wrist from baseline to end-of-treatment as assessed by DXA and as compared to Forteo, as well as the number of hypercalcemic events in abaloparatide-SC treated patients when compared to Forteo at end-of-treatment.

Additional secondary endpoints include change in standing height and changes in serum bone formation markers across treatment, such as P1NP, osteocalcin and bone-specific alkaline phosphatase.



Table of Contents

*Extension study design.*

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

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

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

Overall study safety is being monitored by an independent Data and Safety Monitoring Board.

On December 21, 2014, we announced positive top-line data from the ACTIVE trial, evaluating the investigational drug abaloparatide-SC for potential use in the reduction of fractures in postmenopausal osteoporosis. On the primary endpoint, abaloparatide-SC (n=690, fracture rate 0.72%) achieved a statistically significant 83% reduction of incident vertebral fractures (defined as new and worsening vertebral fractures) as compared to the placebo-treated group (n=711, fracture rate 4.36%) (p<0.0001). The ACTIVE trial included an open-label teriparatide [rDNA origin] injection treatment group (n=717, fracture rate 0.98%) that showed a statistically significant 78% reduction of incident vertebral fractures as compared to the placebo-treated group (p<0.0001). On the secondary endpoints, as compared to placebo, abaloparatide-SC achieved: a statistically significant fracture-rate reduction of 43% in the adjudicated non-vertebral fracture subset of patients; a statistically significant reduction of 45% in the adjudicated clinical fracture group, which includes both vertebral and non-vertebral fractures; and a statistically significant difference in the time to first incident of nonvertebral fracture in both the adjudicated non-vertebral fracture (p=0.0489) and the clinical fracture subset of patients (p=0.0112). The open-label teriparatide injection treatment group, as compared to placebo, achieved a fracture-rate reduction of 28% in the adjudicated non-vertebral fracture subset of patients and a reduction of 29% in the adjudicated clinical fracture group; these differences were not statistically significantly different as compared to the placebo group. The fracture-rate reduction observed in the

Table of Contents

abaloparatide-SC treatment group, as compared to open-label teriparatide, was not statistically significant.

In January 2015, the FDA provided us with comments on the draft SAP that was used for the analysis of the top-line data from the Phase 3 clinical trial. In its correspondence, the FDA recommended that the primary endpoint of incident vertebral fracture reduction be performed excluding worsening vertebral fractures and including only new vertebral fractures. Using the FDA-recommended analysis, on the primary endpoint of reduction of new vertebral fractures (excluding worsening), abaloparatide-SC (n=690, fracture rate 0.58%) achieved a statistically significant 86% reduction as compared to the placebo-treated group (n=711, fracture rate 4.22%) (p<0.0001). The open-label teriparatide injection treatment group (n=717, fracture rate 0.84%) showed a statistically significant 80% reduction of new vertebral fractures (excluding worsening) as compared to the placebo-treated group (p<0.0001). The FDA also recommended, for the secondary endpoint of non-vertebral fractures, that our definition was generally acceptable provided that sternal (breast bone) and patellar (knee cap) fractures were excluded. In the original top-line data announced for the secondary endpoint of non-vertebral fracture reduction noted above, we had excluded sternum and patella fractures, and abaloparatide-SC (n=824, Kaplan-Meier estimated, or KM, fracture rate 2.7%) achieved a statistically significant reduction compared to the placebo-treated group (n=821, KM fracture rate 4.7%), and the hazard ratio for abaloparatide vs. placebo was 0.57 (p=0.0489); the open label teriparatide injection treatment group (n=818, KM fracture rate 3.3%) had a hazard ratio of 0.72 (p=NS) compared to the placebo-treated group. The FDA also recommended, for the secondary endpoint of BMD that we use an ANCOVA approach with the last observation carried forward for missing data. The MMRM method, which was used in the BMD secondary endpoint in the top-line data announced in December 2014, is to be applied for sensitivity analysis.

The top-line results announced in December 2014 included the following results of comparative analyses of abaloparatide-SC versus teriparatide using the MMRM method on these BMD secondary endpoints:

Mean Percent Change In Bone Mineral Density (BMD) From Baseline (MMRM approach)

	Lumbar Spine			Total Hip			Femoral Neck		
	6 mo	12 mo	18 mo	6 mo	12 mo	18 mo	6 mo	12 mo	18 mo
Placebo	0.60%	0.45%	0.63%	0.31%	0.09%	0.10%	0.13%	0.41%	0.43%
abaloparatide-SC	6.58%**	9.77%**	11.20%*	2.32%**	3.41%**	4.18%**	1.72%**	2.65%**	3.60%**
teriparatide	5.25%*	8.28%*	10.49%*	1.44%*	2.29%*	3.26%*	0.87%*	1.54%*	2.66%*

\*\* p<0.0001 vs. placebo and teriparatide

\* p<0.0001 vs. placebo

Applying the ANCOVA approach with the last observation carried forward that the FDA recommended in its January 8, 2015 correspondence results in the following comparative analysis of the BMD secondary endpoints:

Mean Percent Change In Bone Mineral Density (BMD) From Baseline (ANCOVA approach)

	Lumbar Spine			Total Hip			Femoral Neck		
	6 mo	12 mo	18 mo	6 mo	12 mo	18 mo	6 mo	12 mo	18 mo
Placebo	0.55%	0.39%	0.48%	0.29%	0.10%	0.08%	0.12%	0.37%	0.44%
abaloparatide-SC	5.90%**	8.19%***	9.20%*	2.07%**	2.87%**	3.44%****	1.54%**	2.21%**	2.90%*****
Teriparatide	4.84%*	7.40%*	9.12%*	1.33%*	2.03%*	2.81%*	0.80%*	1.41%*	2.26%*

\* vs. placebo p<0.0001

\*\* vs. teriparatide p<0.0001

\*\*\* vs. placebo p< 0.0001 and vs. teriparatide p=0.0087

\*\*\*\* vs. placebo p< 0.0001 and vs. teriparatide p=0.0003

\*\*\*\*\* vs. placebo p< 0.0001 and vs. teriparatide p=0.0016





Table of Contents

The ACTIVE Trial also evaluated several potential safety measures, including blood calcium levels, orthostatic hypotension, nausea, dizziness and injection-site reactions. Among the most frequently reported adverse events, the following incidence rates were reported in the trial as part of the top-line 18-month results:

back pain: placebo (n=820) (10.0%), abaloparatide (n=822) (8.6%), teriparatide (n=818) (7.2%)

arthralgia: placebo (9.8%), abaloparatide (8.5%), teriparatide (8.6%)

upper respiratory tract infection: placebo (8.9%), abaloparatide (9.0%), teriparatide (9.8%)

hypercalciuria: placebo (8.9%), abaloparatide (10.9%), teriparatide (12.5%)

dizziness: placebo (6.1%), abaloparatide (10.0%), teriparatide (7.3%)

In December 2014, we reported hypercalcemia event rates using uncorrected serum calcium values of 1.2% for the placebo group (n=820), 6.0% for the abaloparatide-SC group (n=822) and 10.8% for the teriparatide group (n=818). The results for the primary analysis of the hypercalcemia event rate based on albumin corrected serum calcium are now available and are as follows: 0.37% for the placebo group (n=820), 3.41% for the abaloparatide-SC group (n=822) and 6.36% for the teriparatide group (n=818). Each of the abaloparatide group and teriparatide group had statistically significantly higher hypercalcemia event rates as compared to the placebo group, and the abaloparatide group had a statistically significant lower hypercalcemia event rate as compared to the teriparatide group (p=0.0055).

As part of the top-line 18-month results of the ACTIVE trial, we reported the results for several exploratory endpoints. For clinical fractures, abaloparatide-SC (n=824, KM fracture rate 3.9%) statistically significantly reduced clinical fractures compared to placebo (n=821, KM fracture rate 8.3%) with a hazard ratio=0.55 (p=0.0112); teriparatide (n=818, KM fracture rate 4.8%) had a hazard ratio = 0.71 (p=NS) compared to the placebo treated group.

For wrist fractures, abaloparatide-SC (n=824, KM fracture rate 0.5%) and teriparatide (n=818, KM fracture rate 2.0%) were not statistically significantly reduced compared to placebo (n=821, KM fracture rate 1.5%); wrist fractures were statistically significantly less for abaloparatide-SC than for the teriparatide treated group (p=0.0149).

Table of Contents

The following table sets forth the Kaplan-Meier curve of time to first incident non-vertebral fractures by treatment group in the intent-to-treat population:

**Kaplan Meier Curve of Time to First Incident Non-Vertebral Fractures (NVF) by Treatment Group  
(ITT Population)**

Table of Contents

The following table sets forth the Kaplan-Meier curve of time to first incident clinical fractures by treatment group in the intent-to-treat population:

**Kaplan Meier Curve of Time to First Incident Clinical Fracture by Treatment Group  
(ITT Population)**

We anticipate the first results from the ACTIVEExtend trial in the second quarter of 2015, and plan to submit a NDA to the FDA, and an MMA to the EMA, in the second half of 2015. The results from the ACTIVE trial and from the first six months of the ACTIVEExtend trial, together with the entire data set from the abaloparatide development program, are subject to regulatory review. We hold worldwide commercialization rights to abaloparatide-SC, other than in Japan, and with a favorable regulatory outcome, we anticipate the first commercial sales of abaloparatide-SC will take place in 2016.

Table of Contents*Abaloparatide-SC Phase 2 Clinical Trial*

We conducted a randomized, placebo-controlled, parallel group dose-finding Phase 2 study (Study BA058-05-002) in the United States, Argentina, India and the United Kingdom. A total of 270 patients (mean age: 65 years) entered the pretreatment period, 222 patients were randomized, and 221 patients received study treatment and were analyzed in the intent-to-treat, or ITT, population with 55 continuing into an additional 24 weeks of treatment. A total of 155 patients were included in the efficacy population (per protocol) in the initial 24 weeks of treatment. The purpose of the study was to evaluate the safety and efficacy of daily injections of abaloparatide-SC in women with osteoporosis. Postmenopausal women between the ages of 55 and 85 (inclusive) who had a BMD t-score  $\leq 2.5$  at the lumbar spine or hip (femoral neck) by DXA or a BMD t-score  $\leq 2$  and a prior low trauma fracture or an additional risk factor were candidates for this study. The study evaluated the effects of abaloparatide-SC at multiple doses (placebo, 20  $\mu\text{g}$ , 40  $\mu\text{g}$  and 80  $\mu\text{g}$ ) on recovery of BMD, a marker of fracture risk, and on biomarkers of anabolic and resorptive activity in bone. The study also included a Forteo treatment arm for reference. After the initial 24 weeks of treatment, eligible patients were offered a second 24 weeks of their assigned treatment. Safety was assessed throughout the study and reported on at both 24 weeks and 48 weeks. Abaloparatide-SC and placebo were self-administered using a prefilled cartridge in a pen-injector device. Forteo was self-administered as the marketed product at the approved dose of 20  $\mu\text{g}$  per day by subcutaneous injection. Four weeks prior to start of treatment, patients began taking calcium and vitamin D supplements that continued throughout the study.

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

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

Table of Contents

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

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

Table of Contents

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

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

Abaloparatide-SC was well tolerated at all doses and safety events were consistent with usual medical events in a study population of this age and gender. The safety profile was also similar to that of Forteo and there were no treatment-related serious adverse events, or SAE's. Adverse events were reported by 74% of patients in the first six months of treatment, with a similar incidence across all treatment groups. The majority of on-treatment events were mild-to-moderate in severity and there were no deaths reported. Treatment-related treatment-emergent adverse events were reported in approximately 30% of patients, with similar incidence across all treatment groups. Seven subjects discontinued due to adverse events: one in the abaloparatide 20 µg group, one in the abaloparatide 40 µg group, three in the abaloparatide 80 µg group and two in the Forteo group. Eight patients (four percent) experienced at least one SAE and the incidence of such events was similar across treatment groups. Five SAEs, unrelated to treatment, were reported in three patients. Local tolerance at the injection site was similar across treatment groups and fewer than 20% of subjects reported any symptoms, such as redness at the injection site across the many months of injections.

Table of Contents

The level of calcium in the blood, known as serum calcium levels, were monitored throughout the study and clinically significant elevated levels (greater than or equal to 10.5 milligrams per deciliter, or mg/dL) were observed in 40% of the Forteo group while also observed in four percent, 12%, 19% and 18% of the placebo, and abaloparatide-SC 20 µg, 40 µg and 80 µg groups, respectively. Most elevations were noted at the four-hour post- injection time point.

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

Sixteen patients had low titer antibodies against abaloparatide after 24 weeks of treatment. Of these, five were in the abaloparatide 20 µg group, six were in the abaloparatide 40 µg group and five were in the abaloparatide 80 µg group. There were no associated safety events or attenuation of treatment efficacy. One antibody-positive patient in the abaloparatide-SC 40 µg group was found to have possible evidence of neutralizing activity using an in vitro assay at 24 weeks without evidence of attenuation of drug efficacy; the patient achieved a 9.3% gain in total spine BMD at the week 24 assessment.

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

BMD continued to increase during the extended 24 weeks of treatment, with the largest percent increases in total spine BMD, femoral neck BMD and total hip BMD observed in the abaloparatide-SC 80 µg group, as shown in Figure C below. By week 48, mean percent changes in spine BMD were 0.7%, 5.1%, 9.8% and 12.9% for the placebo and, abaloparatide-SC 20 µg, 40 µg and 80 µg groups, respectively, while mean percent change from baseline in the Forteo group was 8.6%. At week 48, the mean femoral neck BMD in the abaloparatide-SC 80 µg group gained 4.1% compared to the mean of the Forteo group at 2.2%. The total gain in hip BMD was 0.7%, 2.0%, 2.1% and 2.7% for the placebo and abaloparatide-SC 20 µg, 40 µg and 80 µg groups, respectively, compared to 1.3% for the Forteo group.

Table of Contents

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

No treatment-related SAEs or deaths were reported during this time period. Two patients discontinued treatment, one for bilateral femoral hernias (abaloparatide-SC 80 µg) and one for moderate syncope (abaloparatide- SC 40 µg). Study-related adverse events occurred in a similar proportion of patients in each treatment group across the 52-week study period and the majority of events were mild or moderate in severity. The profile of events was not different during the second 24 weeks of study treatment.

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

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



Table of Contents

number of patients, differences between the results of the two studies may not be statistically or clinically meaningful.

Product	Abaloparatide-SC Phase 2(1)		AMG 785 Phase 2(2)	
	Abaloparatide	Forteo	AMG 785	Forteo
Dose	80 µg	20 µg	210 mg	20 µg
Dosing frequency	Daily	Daily	Monthly	Daily
No. of Injections per dose	1	1	3	1
Type of Injection	Self	Self	Physician	Self
Spine Mean Percent BMD Change from Baseline 24 weeks / 6 months	+6.7%	+5.5%	+8.2%	+4.8%
Spine Mean Percent BMD Change from Baseline 48 weeks / 12 months	+12.9%	+8.6%	+11.3%	+7.1%
Femoral Neck Mean Percent BMD Change from Baseline 48 weeks / 12 months	+4.1%	+2.2%	+3.7%	+1.1%

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

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

*Abaloparatide-SC Phase 1 Clinical Trials*

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

*Abaloparatide-TD Phase 2 Clinical Trials*

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

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

In the mITT population, the mean percent change from baseline in total spine BMD after six months of treatment increased with abaloparatide-TD dose (0.04%, 1.87%, 2.33% and 2.95% in the placebo, abaloparatide 50 µg, 100 µg and 150 µg groups, respectively). The test for a dose response

Table of Contents

was statistically significant ( $p < 0.0001$ ). The mean differences (active treatment - placebo) of the percent change from baseline in total spine BMD at six months were 1.83%, 2.29% and 2.91% in the abaloparatide-TD 50  $\mu\text{g}$ , 100  $\mu\text{g}$  and 150  $\mu\text{g}$  groups, respectively. The results for all abaloparatide-TD dose groups were statistically significantly better than placebo ( $p = 0.0066$ ,  $0.0005$ , and  $< 0.0001$ , respectively).

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

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

Table of Contents

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

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

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

*Abaloparatide-TD Phase 1 Clinical Trials*

We have completed three Phase 1 clinical trials that collectively evaluated the safety, pharmacokinetics, or PK, time course of delivery and dose ranging of abaloparatide-TD. Abaloparatide-TD was characterized by a rapid release of abaloparatide with a faster time to reach peak concentration as well as more rapid elimination in plasma compared to abaloparatide-SC. Peak transdermal drug levels were consistent with abaloparatide-SC. An optimal wear time of five minutes or less was identified as well as effective sites of application. Abaloparatide-TD showed an increase in the bone-formation marker P1NP in serum after seven days of exposure, consistent with bone-building activity, and was shown to be safe and well tolerated in all doses studied.

In order to further enhance BMD efficacy for abaloparatide-TD, we currently plan to modify the pharmacokinetic profile of abaloparatide-TD to more closely resemble that of abaloparatide-SC. On December 21, 2014, we reported progress towards the development of an optimized, short-wear-time

Table of Contents

transdermal patch that may be capable of demonstrating therapeutic comparability to abaloparatide-SC injection. In preliminary, nonhuman primate pharmacokinetic studies, prototype A7 achieved a desirable pharmacokinetic profile, with comparable AUC, C<sub>max</sub>, T<sub>max</sub> and T<sub>1/2</sub> relative to abaloparatide-SC. We believe that these results support continued clinical development toward future global regulatory submissions as a potential post-approval line extension of the investigational drug abaloparatide-SC. We expect to initiate the clinical evaluation of the optimized abaloparatide-TD patch in the second half of 2015, with the goal of achieving pharmacokinetic equivalence to abaloparatide-SC. If abaloparatide-SC is already approved by the FDA, we believe that we will only need to conduct either a pharmacokinetic equivalence or 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.

*Preclinical Pharmacology of Abaloparatide*

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

abaloparatide is a potent selective agonist of the human PTH type 1 receptor (PTH1R), with binding selectivity for the RG vs R0 receptor conformation compared to PTH(1-34) and greater selectivity than PTHrP(1-34);

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

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

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

safety pharmacology studies showed no respiratory, gastroenterologic, hematologic, renal or central nervous system effects.

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

Table of Contents

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

Results from the 16-month monkey OVX study have also shown significant BMD gains, together with increases in bone strength.

**RAD1901**

We exclusively licensed the worldwide rights to RAD1901 from Eisai Co. Ltd., or Eisai. We are developing RAD1901 as a SERD in Phase 1 clinical development for the potential treatment of metastatic breast cancer. We are also developing RAD1901, which at lower doses acts as a SERM, in an oral formulation as a potential treatment for vasomotor symptoms, commonly known as hot flashes or hot flushes.

*Pharmacologic Characteristics*

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

We are currently advancing the development of RAD1901 for potential use in the treatment of metastatic breast cancer in two Phase 1 studies. In June 2014, we initiated a Phase 1 MTD, study of RAD1901 in healthy volunteers. The study is designed to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also to use FES-PET imaging to provide a pharmacodynamic assessment of estrogen receptor turnover following administration of RAD1901. Levels of RAD1901 in cerebrospinal fluid samples taken from study subjects will be measured to confirm that RAD1901 has crossed the blood-brain barrier. Based upon initial study results, FES-PET imaging of RAD1901 has showed potent SERD activity. As of December 31, 2014, 40 subjects had completed dose escalation in the ongoing MTD study, and FES-PET imaging had been completed in a total of five subjects across two different doses. Each of these five subjects showed, based on FES-PET imaging, suppression of the FES-PET signal to background levels after six days of dosing. In addition, RAD1901, at the doses that showed suppression of the FES-PET signal, was well tolerated in these patients.

In December 2014, we commenced a Phase 1 clinical trial of RAD1901 in the United States for the treatment of metastatic breast cancer. The Phase 1 study is a multicenter, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced estrogen receptor positive

Table of Contents

and HER2-negative breast cancer that is designed to determine the recommended dose for a Phase 2 clinical trial and includes a preliminary evaluation of the potential anti-tumor effect of RAD1901. We expect to report progress on this study in the first half of 2015 and to initiate additional Phase 1 clinical trials in the European Union in 2015.

***Clinical Development Program***

*Phase 2 Study Vasomotor Symptoms*

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

No SAEs were reported during the course of the study. Overall, 69% of patients had an adverse event, generally mild or moderate in severity, with some evidence of dose dependency, and events were most commonly gastrointestinal symptoms and headaches. Three severe adverse events occurred, one in a placebo patient, none of which were considered treatment related. Two patients discontinued treatment due to an adverse event, neither in relation to the 10 mg dose.

*Phase 1 Study Vasomotor Symptoms*

We have conducted Phase 1 safety, PK and bioavailability studies of RAD1901 in 80 healthy postmenopausal women over a range of doses. Bioavailability was determined to be approximately 10%. Food effect was also investigated and the presence of food was determined to increase absorption and delay clearance of RAD1901. RAD1901 was generally well tolerated at all dose levels tested. All study-related adverse events were of mild intensity, with some increase in frequency at the higher doses in the multiple dose group, most commonly gastrointestinal symptoms and headaches. There were no SAEs observed.

**RAD140**

RAD140 is a nonsteroidal selective androgen receptor modulator, or SARM, that resulted from an internal drug discovery program focused on the androgen receptor pathway which is highly expressed in many breast cancers. Due to its receptor and tissue selectivity, potent oral activity and long duration half-life, RAD140 could have clinical potential in the treatment of breast cancer or possibly other conditions where androgen modulation may offer therapeutic benefit. We may choose to advance the RAD140 program internally or to collaborate with third parties for its further development and commercialization. Therefore, the date of any FDA approval of RAD140, if ever, cannot be predicted at this time. As a result of the uncertainties around the development strategy for RAD140, we are unable to determine the duration and costs to complete current or future clinical stages of development, if any, for our RAD140 investigational product candidate.

**Manufacturing**

We do not own or operate manufacturing facilities for the production of any of our investigational product candidates, nor do we have plans to develop our own manufacturing operations in the

Table of Contents

foreseeable future. The active pharmaceutical ingredient, or API, of abaloparatide is manufactured on a contract basis by Lonza Group Ltd., or Lonza, using a solid phase peptide synthesis assembly process, and purification by high pressure liquid chromatography. Abaloparatide-SC is supplied as a liquid in a multi-dose cartridge for use in a pen delivery device. The multi-dose cartridges are manufactured by Vetter Pharma Fertigung GmbH & Co. Abaloparatide-TD is manufactured by 3M based on their patented microneedle technology to administer drugs through the skin, as an alternative to subcutaneous injection. The API of RAD1901 is manufactured for us on a contract basis by Irix Pharmaceuticals, Inc.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our contract manufacturing organizations are required to manufacture our investigational product candidates under current Good Manufacturing Practice, or cGMP, conditions. cGMP is a regulatory standard for the production of human pharmaceuticals that imposes extensive procedural, substantive and record keeping requirements on the manufacturing process and associated production and testing facilities.

**Intellectual Property**

As of December 31, 2014, we owned or co-owned eight issued United States patents, as well as twelve pending U.S. patent applications and about 42 pending foreign patent applications in Europe and 15 other jurisdictions, and about 17 granted foreign patents. As of December 31, 2014, we had licenses to eight U.S. patents related to compositions and related uses thereof as well as numerous foreign counterparts to many of these patents and patent applications.

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our investigational product candidates and compositions, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

***Abaloparatide***

We acquired and maintain exclusive worldwide rights, excluding Japan, to certain patents, data and technical information related to abaloparatide through a license agreement with an affiliate of Ipsen. Composition of matter of abaloparatide is claimed in the United States (U.S. Patent No. 5,969,095), Europe, Australia, Canada, China, Hong Kong, South Korea, New Zealand, Poland, Russia, Singapore, Mexico, Hungary, and Taiwan. These patents have an expiration date of 2016 absent any U.S. patent term extension under the Hatch-Waxman Act. European Patent No. 0847278, which was included in the license from Ipsen and claimed the composition of matter of abaloparatide, lapsed due to Ipsen's failure to pay annuities. We are pursuing restoration of those patent rights. To date, the patent rights in Finland, France, Germany, Portugal, Spain and United Kingdom have been restored. We believe that the data and market exclusivity provided in Europe for a new chemical entity, coupled with the need for a potential competitor to conduct clinical trials will likely provide a longer barrier to entry than the patent protection provided by the original European patent term, which would have expired in 2016, plus a five year maximum Supplemental Protection Certificate. The Phase 3 clinical dosage of

Table of Contents

abaloparatide by the subcutaneous route for potential use in treating osteoporosis is covered by Patent No. 7,803,770 until the statutory term expires October 3, 2027 which may be extended to March 26, 2028 (statutory term extended with 175 days of patent term adjustment due to delays in patent prosecution by the United States Patent and Trademark Office, or USPTO) in the United States (absent any patent term extension under the Hatch-Waxman Act). The intended therapeutic formulation for abaloparatide-SC is covered by Patent No. 8,148,333 until 2027 in the United States (absent any patent term extension under the Hatch-Waxman Act). Related patents granted in China, Australia, Singapore, Japan, Israel, Mexico, New Zealand, Russia, and Ukraine, and currently pending in Europe, Canada, Brazil, Singapore, South Korea, India, Norway, and Hong Kong will have a patent expiration date of 2027. Patent applications which cover various aspects of abaloparatide for microneedle application are pending in the United States, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, New Zealand, Russia, Singapore, and Ukraine. Any patents that might issue from these applications will have an expiration date in 2032.

***RAD1901***

We exclusively licensed the worldwide rights to RAD1901 from Eisai. US Patent No. 7,612,114 (statutory term expires December 25, 2023 and may be extended up to August 18, 2026 with 967 days of patent term adjustment absent any Hatch-Waxman patent term extensions) and US Patent No. 8,399,520 (statutory term expires 2023) cover RAD1901 as a composition of matter as well as the use of RAD1901 for treatment of estrogen-dependent osteoporosis or estrogen-dependent breast cancer. Corresponding patents issued in Australia, Canada and Europe and pending in India will have an expiration date in 2023. Patent applications covering methods of using RAD1901 for the treatment of vasomotor symptoms are pending in the United States (published as US 2010/0105733A1), and granted in Canada and Europe; any issued patents will have an expiration date in 2027. Patent applications covering a dosage form have been filed in the United States, Europe, Canada and Mexico, and any claims that might issue from these applications will have an expiration date in 2031.

***RAD140***

The composition of matter of, and methods of using, RAD140 are covered by US Patent No. 8,067,448 (statutory term expires February 19, 2029, and may be extended to September 25, 2029, with 218 days of patent term adjustment due to delays by the USPTO) and U.S. Patent No. 8,268,872 (statutory term expires February 19, 2029 and may be extended to September 25, 2029 with patent term adjustment, subject to a terminal disclaimer of Patent No. 8,067,448). Related patents have been granted in Australia, Europe, Japan and Mexico and additional patent applications are pending in Brazil, Canada and India. Any patents issued from these filings will have an expiration in 2029.

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



Table of Contents

result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from a third party. There can be no assurance that we can obtain a license on a reasonable basis should we deem it necessary to obtain rights to an alternative technology that meets our needs. The failure to obtain a license may have a material adverse effect on our business, results of operations and financial condition.

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

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

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

**Competition**

The development and commercialization of new products to treat the targeted indications of our investigational product candidates is highly competitive, and our products, if approved, will face considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies, including Amgen, UCB, Merck & Co, Novartis, Lilly, Pfizer, Roche, Asahi Kasei, Corium and Zosano, that currently market and/or are seeking to develop products for similar indications. Many of our competitors have substantially more resources than we do, including financial, manufacturing, marketing, research and drug development resources. In addition, many of these companies have longer operating histories and more experience than us in preclinical and clinical development, manufacturing, regulatory and global commercialization.

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

RAD1901 for the treatment of metastatic breast cancer will face competition from SERDs, CNS-penetrant anti-cancer agents and from chemotherapy derivatives. We are aware that Roche is developing an oral SERD that would compete with RAD1901. RAD1901 will also face competition from other therapeutics in development for the treatment of hot flashes. We cannot assure you that our current investigational product candidates, if successfully developed and approved, will be able to compete effectively against these, or any other competing therapeutics that may become available on the market.

Table of Contents

**Collaborations and License Agreements**

***Nordic Bioscience***

*Abaloparatide-SC Phase 3 Clinical Trial* We have entered into agreements with Nordic Bioscience Clinical Development VII A/S, or Nordic, to conduct our Phase 3 clinical trial of abaloparatide-SC, or the Phase 3 Clinical Trial. On March 29, 2011, we entered into a Clinical Trial Services Agreement, or the Clinical Trial Services Agreement, with Nordic.

The Clinical Trial Services Agreement has a five-year term unless it is sooner terminated. The Clinical Trial Services Agreement or any work statement under the agreement, or Work Statement, may be terminated by mutual agreement of the parties at any time. Either party may also terminate any Work Statement upon a material breach by the other party with respect to such Work Statement unless such other party cures the breach within the notice period specified in the Clinical Trial Services Agreement or, if the breach cannot be cured within such period, the party in breach commences efforts to cure the breach and diligently proceeds to cure the breach. Termination of any Work Statement does not result in termination of the Clinical Trial Services Agreement or any other Work Statements, which remain in force until terminated. Either party may also terminate a Work Statement if force majeure conditions have prevented performance by the other party for more than a specified period of time. We may also terminate a Work Statement with notice to Nordic if authorization and approval to perform any clinical study that is the subject of such Work Statement is withdrawn by the FDA; other toxicological test results support termination of the clinical study relating to such Work Statement for reasons of safety; or if the emergence of any adverse event or side effect in the clinical study relating to a Work Statement is of such magnitude or incidence in our opinion as to support termination.

The Clinical Trial Services Agreement contains customary risk allocation clauses with each party indemnifying the other in respect of third-party claims arising out of or resulting from: (1) the negligence or intentional misconduct of such party, its employees, agents or representatives in performing its obligations under the Clinical Trial Services Agreement or any Work Statement; and (2) any breach by such party of its representations and warranties under the Clinical Trial Services Agreement. We have agreed to indemnify Nordic in respect of third-party claims for product liability or personal injury arising from or relating to our products or our use of any deliverables. The Clinical Trial Services Agreement contains other customary clauses and terms as are common in similar agreements in the industry.

On March 29, 2011, we also entered into Work Statement NB-1 under the Clinical Trial Services Agreement, as amended on December 9, 2011, June 18, 2012, March 28, 2014 May 19, 2014 and July 22, 2014, or the Work Statement NB-1. 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. In addition, Nordic is entitled to a performance incentive payment, or Performance Incentive Payment, of \$500,000 for every 50 patients that, subsequent to March 28, 2014, complete all end-of-study procedures, up to a maximum aggregate amount of \$5.0 million. The Work Statement NB-1 provides for a total of up to approximately €41.2 million (\$49.8 million) of euro-denominated payments and a total of up to approximately \$3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus Performance Incentive Payments of up to \$5.0 million. These payments may be adjusted based upon actual sites opened, work performed or number of patients enrolled. In addition, pursuant to indemnification letters with each investigative site, we have agreed to indemnify the investigative sites performing services pursuant to the Work Statement NB-1 in respect of third-party claims of injury, illness or adverse side effects to a patient in the study that is the subject of the Work Statement NB-1 that are attributable to the Radius study drug.

Table of Contents

In connection with the Clinical Trial Services Agreement, we entered into a Stock Issuance Agreement on March 29, 2011, as amended and restated on May 16, 2011, and as further amended on February 21, 2013, March 28, 2014, and May 19, 2014, or the Stock Issuance Agreement. Pursuant to the Stock Issuance Agreement, Nordic purchased 6,443 shares of our Series A-5 preferred stock. In connection with the Work Statement NB-1, the shares of Series A-5 preferred stock held by Nordic were entitled to receive quarterly stock dividends payable in shares of our Series A-6 preferred stock, having an aggregate value of up to €36.8 million (\$44.5 million). The Stock Issuance Agreement further provided that in the event an initial public offering of our common stock occurred prior to June 30, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, discussed below, excluding Performance Incentive Payments, for all periods of time after 2014, would be changed from the right to receive stock to the right to receive a total cash payment from us of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. As we completed our initial public offering on June 11, 2014, payments owed to Nordic under the Stock Issuance Agreement have been paid in cash for periods after June 11, 2014.

*Abaloparatide-SC Phase 3 Clinical Extension Study* On February 21, 2013, we entered into a Work Statement NB-3, as amended on March 4, 2014, or the Work Statement NB-3, with Nordic. Pursuant to the Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial, and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management ("the Extension Study"). Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to €7.5 million (\$9.1 million) and \$1.1 million, respectively.

In addition, in connection with the Work Statement NB-3, the Stock Issuance Agreement provided that, beginning with the quarter ended March 31, 2013, Nordic was entitled to receive quarterly stock dividends on its shares of Series A-5 preferred stock, payable in shares of our Series A-6 preferred stock, in connection with services performed under the Work Statement NB-3, having an aggregate value of up to €7.5 million (\$9.1 million) and \$0.8 million. The Stock Issuance Agreement further provided that in the event an initial public offering of our common stock occurred prior to June 30, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, excluding Performance Incentive Payments, for all periods of time after 2014, would be changed from the right to receive stock to the right to receive a total cash payment from us of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. As we completed our initial public offering on June 11, 2014, payments owed to Nordic under the Stock Issuance Agreement have been paid in cash for periods after June 11, 2014.

*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 provided that we and Nordic would, subject to our compliance with certain requirements of our certificate of incorporation and applicable securities law, negotiate in good faith to enter into a Work Statement NB-2, or the Work Statement NB-2, and an amendment to the Amended and Restated Stock Issuance Agreement.

On February 21, 2013, we entered into the Work Statement NB-2. Pursuant to the Work Statement NB-2, Nordic provided clinical trial services relating to the Phase 2 clinical trial for abaloparatide-TD. Payments in cash under the Work Statement NB-2 are denominated in both euros and U.S. dollars and total up to €3.6 million (\$4.4 million) and \$0.3 million, respectively. In addition, pursuant to the Stock Issuance Agreement, Nordic was entitled to shares of our Series A-6 preferred stock payable as dividends upon shares of Series A-5 preferred stock held by Nordic, having an aggregate value of up to \$2.9 million. In December 2013, we issued Nordic 32,215 shares of our Series A-6 preferred stock, which constituted all shares of Series A-6 preferred stock due in connection with Work Statement NB-2.

Table of Contents

**3M**

In December 2008, we entered into a Feasibility Agreement with 3M whereby 3M assessed the feasibility of developing an abaloparatide-TD product and supplying the product for preclinical studies in an animal model. Upon successful completion of the feasibility study, during June 2009, we entered into a Development and Clinical Supplies Agreement with 3M under which 3M is responsible for the development of an abaloparatide-TD product and the manufacture of clinical and toxicology supplies of the abaloparatide-TD product for preclinical, Phase 1 and Phase 2 studies on an exclusive basis during the term of the agreement. In December 2012, we entered into an amendment to the Development and Clinical Supplies Agreement in which 3M agreed to develop and manufacture clinical and toxicology supplies for the Phase 3 abaloparatide-TD clinical study. In addition, 3M agreed that it will not use jointly owned intellectual property developed during and resulting from its work with us on abaloparatide-TD in relation to any other PTH or PTHrP analogue or derivative. We hold exclusive worldwide rights to this use of the 3M transdermal technology.

We pay 3M for services delivered pursuant to the Development and Clinical Supplies Agreement on a fee-for-service or a fee-for-deliverable basis as specified in the Development and Clinical Supplies Agreement. The Feasibility Agreement expired on or around September 2009. We have paid 3M approximately \$15.3 million, in the aggregate, through December 31, 2014 in respect to services and deliverables delivered pursuant to the Feasibility Agreement and the Development and Clinical Supplies Agreement.

The Development and Clinical Supplies Agreement, as amended, provides for services through December 31, 2017, unless it is sooner terminated. Either party may terminate the Development and Clinical Supplies Agreement upon a material breach by the other party unless such other party cures the alleged breach within the notice period specified in the Development and Clinical Supplies Agreement. The Development and Clinical Supplies Agreement contains customary risk allocation clauses with 3M indemnifying us in respect of third-party claims arising from any personal injury to the extent that such claim results from 3M's breach of warranty with respect to abaloparatide-TD meeting applicable specifications; and us indemnifying 3M in respect of third-party claims arising from our or our agent's use, testing or clinical studies of abaloparatide-TD. The Development and Clinical Supplies Agreement contains other customary clauses and terms as are common in similar agreements in the industry.

***Ipsen Pharma***

In September 2005, we entered into a License Agreement with Ipsen, as amended in September 2007 and May 2011, under which we exclusively licensed certain Ipsen compound technology and related patents covering abaloparatide to research, develop, manufacture and commercialize certain compounds and related products in all countries, except Japan (where we do not hold commercialization rights) and France (where our commercialization rights are subject to certain co-marketing and co-promotion rights retained by Ipsen). Ipsen also granted us an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen also granted us an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling us to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan (where we do not hold commercialization rights) and France (where our commercialization rights are subject to certain co-marketing and co-promotion rights retained by Ipsen). With respect to France, if Ipsen exercises its co-marketing and co-promotion rights, then Ipsen may elect to receive a percentage of the aggregate revenue from the sale of products by both parties in France (subject to a mid-double digit percentage cap), and Ipsen shall bear a corresponding percentage of the costs and expenses incurred by both parties with respect to such marketing and promotion efforts in France; Ipsen shall also pay us a mid-single digit royalty on Ipsen's allocable portion of aggregate revenue from the sale of products by both parties in France. Specifically, we licensed US

Table of Contents

Patent No. 5,969,095 (statutory term expires March 29, 2016), entitled "Analogues of Parathyroid Hormone," US Patent No. 6,544,949 (statutory term ends March 29, 2016), entitled "Analogues of Parathyroid Hormone," US Patent No. 6,544,949, (effective filing date March 29, 1996, statutory term ends March 29, 2016) entitled "Analogues of Parathyroid Hormone" and the corresponding foreign patents and continuing patent applications. European Patent No. 0847278, which was included in the license from Ipsen and claimed the composition of matter of abaloparatide, lapsed due to Ipsen's failure to pay annuities. We are pursuing restoration of those rights. To date, the patent rights in Finland, France, Germany, Portugal, Spain and United Kingdom have been restored. We believe that the data and market exclusivity provided in Europe for a new chemical entity, coupled with the need for a potential competitor to conduct clinical trials, will likely provide a longer barrier to entry than the patent protection provided by the original European patent term, which would have expired in 2016, plus a five year maximum Supplemental Protection Certificate.

We also 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 (statutory term expires October 3, 2027 and may be extended to March 26, 2028 with 175 days of patent term adjustment due to delays in patent prosecution by the United States Patent and Trademark Office, or USPTO), US Patent No. 8,148,333 (statutory term expires October 3, 2027 and may be extended to November 8, 2027 with 36 days of patent term adjustment due to delays in patent prosecution by the USPTO) and related patents and patent applications both in the United States and worldwide that cover the method of treating osteoporosis using the Phase 3 Clinical Trial dosage strength and form. A corresponding European application is pending with claims to the intended therapeutic formulation for abaloparatide-SC. Examination has been requested, but substantive examination has not yet commenced. Upon grant, this patent could be validated in any designated contracting or extension states and potentially could be considered for a Supplemental Protection Certificate depending upon the timing of its grant. Related cases granted in China, Australia, Singapore, Japan, Israel, Mexico, New Zealand, Russia and Ukraine, and currently pending in Europe, Canada, Brazil, Singapore, South Korea, India, Norway, and Hong Kong will have a patent expiration date of 2027. Patent applications which cover various aspects of abaloparatide for microneedle application are pending in the United States, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, New Zealand, Russia, Singapore, and Ukraine. Any patents that might issue from these applications will have an expiration date in 2032.

In consideration for the rights to abaloparatide and in recognition of certain milestones having been met to date, we have paid to Ipsen an aggregate amount of \$1.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. The range of milestone payments that could be paid under the agreement is €10.0 million to €36.0 million (\$12.1 million to \$43.6 million). Should abaloparatide be approved and subsequently become commercialized, we or our sublicensees will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product on a country by country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense abaloparatide to a third party, we are obligated to pay a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, we will be obligated to pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of our patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

Table of Contents

The License Agreement expires on a country by country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires, in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated.

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

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

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

*Eisai*

In June 2006, we exclusively licensed the worldwide (except Japan) rights to research, develop, manufacture and commercialize RAD1901 and related products from Eisai, or the Eisai Agreement. Specifically, we licensed the patent application that subsequently issued as US Patent No. 7,612,114 (statutory term expires December 25, 2023 and may be extended to August 18, 2026 with 967 days of patent term adjustment due to delays by the USPTO), entitled "Selective Estrogen Receptor Modulator," the corresponding foreign patent applications and continuing patent applications. As consideration for the rights to RAD1901, we paid Eisai an initial license fee of \$0.5 million. In connection with the License Agreement, we have agreed to pay Eisai certain fees in the range of \$1.0 million to \$20.0 million (inclusive of the \$0.5 million initial license fee), payable upon the achievement of certain clinical and regulatory milestones. In March 2015, we entered into an

Table of Contents

amendment to the Eisai Agreement, or the Eisai Amendment, to include Japan within the territory covered by the Eisai Agreement. In consideration for the rights to RAD1901 in Japan, we paid Eisai an initial license fee of \$0.4 million upon execution of the Eisai Amendment. The Eisai Amendment also provides for additional payments, payable upon the achievement of certain clinical and regulatory milestones in Japan.

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

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

The license agreement may be terminated by us with respect to the entire territory with prior notice to Eisai if we reasonably determine that the medical/scientific, technical, regulatory or commercial profile of the licensed product does not justify continued development or marketing. The license agreement can also be terminated by Eisai on a country-by-country basis at any time prior to the date on which we have submitted for either an FDA NDA approval or an EMA marketing approval with respect to a licensed product, upon prior written notice to us if Eisai makes a good faith determination that we have not used commercially reasonable efforts to develop the licensed product in the territory having reference to prevailing principles and time scales associated with the development, clinical testing and government approval of products of a like nature to such licensed product, unless such default is cured within the period specified in the license agreement or if not capable of being cured within such period we commence efforts to cure and make diligent efforts to do so. Either party may also terminate the license agreement upon a material breach by the other party unless such other party cures the alleged breach within the notice period specified in the license agreement. Either party may also terminate the license agreement upon the bankruptcy or insolvency of the other party. Eisai may also terminate the license agreement with prior notice if we are acquired by, or if we transfer all of our pharmaceutical business assets (or an essential part of such assets) or more than 50% of our voting stock to, any third party person or organization, or otherwise come under the control of, such a person or organization, whether resulting from merger, acquisition, consolidation or otherwise in the event that Eisai reasonably determines that the person or organization assuming control of us is not able to perform the license agreement with the same degree of skill and diligence that we would use, such determination being made with reference to the following criteria with respect to the person or organization assuming control of us: (1) whether such person or organization has the financial resources to assume our obligations with respect to development and commercialization of products; (2) whether such person or organization has personnel with skill and experience adequate to assume our obligations with respect to development and commercialization of products at the stage of development and commercialization as of the date of such change; and (3) whether such person or organization expressly assumes all obligations imposed on us by the license agreement and agrees to

Table of Contents

dedicate personnel and financial resources to the development and commercialization of the licensed product that are at least as great as those provided by us. Eisai shall further have the right to terminate if the acquiring person or organization: (a) has any material and active litigations with Eisai; or (b) is a hostile takeover bidder against us which has not been approved by our board of directors as constituted immediately prior to such change of control.

The license agreement contains customary risk allocation. We agreed to indemnify Eisai in respect of third-party claims arising out of or resulting from: (1) negligence, recklessness or intentional acts or omissions by us, our affiliates and licensees; (2) any breach by us of a representation, warranty or covenant; and (3) any personal injury arising out of the labeling, packaging, package insert, other materials or promotional claims with respect to any licensed product by us, our affiliates, licensees or distributors in the territory. Eisai agreed to indemnify us for (1) negligence, recklessness or intentional acts or omissions by Eisai or its affiliates and licensees and (2) any breach by Eisai of a representation, warranty or covenant. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

***Lonza***

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

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

The Development and Manufacturing Services Agreement contains customary risk allocation clauses with each party indemnifying the other in respect of third-party claims arising out of or resulting from: (i) the negligence or willful misconduct of such party, its affiliates and their respective officers, directors, employees and agents in performing its obligations under the Developing and Manufacturing Services Agreement; and (ii) any breach by such party of its representations and warranties under the Development and Manufacturing Services Agreement. We have agreed to indemnify Lonza in respect of third-party claims arising from or relating to the use of our product.

On December 23, 2011, we entered into Work Order No. 4, or Work Order No. 4, under that certain Development and Manufacturing Services Agreement with Lonza. Pursuant to Work Order No. 4, Lonza agreed to perform activities required for our submission of an NDA in the United States



## Edgar Filing: Radius Health, Inc. - Form 10-K

### Table of Contents

with the FDA and similar applications required by the EMA and other authorities, excluding authorities in Japan, for abaloparatide, including production of three validation batches. These activities will provide for full process qualification and all required documentation necessary for regulatory submissions of the NDA to the FDA and the NDA equivalents to such other authorities. The total compensation payable to Lonza from us for services performed under Work Order No. 4 is up to €363,500 plus up to €1.1 million (\$440,000, plus up to \$1.3 million), for the regulatory qualification and validation campaigns.

On December 10, 2014, we entered into Work Order No. 5, or Work Order No. 5, under that certain Development and Manufacturing Services Agreement with Lonza. Pursuant to Work Order No. 5, Lonza agreed to manufacture a batch of active pharmaceutical ingredient. The total compensation payable to Lonza from us for services performed under Work Order No. 5 is up to €400,000 (\$484,000).

On December 22, 2014, we entered into Work Order No. 6, or Work Order No. 6, under that certain Development and Manufacturing Services Agreement with Lonza. Pursuant to Work Order No. 6, Lonza agreed to perform activities required for our submission of an NDA in the United States with the FDA and similar applications required by the EMA and other authorities, excluding authorities in Japan, for abaloparatide, including stability testing. The total compensation payable to Lonza from us for services performed under Work Order No. 6 is up to €60,400 (\$73,100).

### **Government Regulation**

#### *United States FDA Process*

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution. We expect abaloparatide, RAD1901 and RAD140 will each be subject to review by the FDA as a drug pursuant to the NDA process, and we currently only have active IND applications in relation to abaloparatide and RAD1901 in the United States.

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

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

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

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

submission to the FDA of an NDA;

satisfactory completion of an FDA pre-approval inspection of one or more clinical trial site(s) at which the drug was studied in a clinical trial(s) to assess compliance with Good Clinical Practices, or GCP, regulations;

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

FDA review and approval of the NDA.



Table of Contents

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

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

Clinical trials necessary for product approval are typically conducted in three sequential phases, but the Phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board, or IRB, for each institution where the trials will be conducted, and each IRB must monitor the study until completion. Study subjects must provide informed consent and sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy the extensive GCP regulations and regulations for informed consent and privacy of individually identifiable information.

Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 1 studies are usually conducted in healthy individuals and are not intended to treat disease or illness. However, Phase 1b studies are conducted in healthy volunteers or in patients diagnosed with the disease or condition for which the study drug is intended, who present some biomarker, surrogate, or possibly clinical outcome that could be considered for "proof of concept." Proof of concept in a Phase 1b study typically confirms the hypothesis that the current prediction of biomarker, or outcome benefit is compatible with the mechanism of action.

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

Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its planned commercial form in an expanded patient population. A Phase 3 trial usually compares how well the study drug works compared with an inactive placebo and/or another approved medication. One group of patients may receive the investigational new drug being tested, while another group of patients may receive the comparator drug (already approved drug for the disease being studied), or placebo.

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

Table of Contents

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

The FDA has various programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those intended to treat serious or life-threatening diseases or conditions, those with the potential to address unmet medical needs for those disease or conditions, and those that provide meaningful benefit over existing treatments. For example, a sponsor may be granted FDA designation of a drug candidate as a "breakthrough therapy" if the drug candidate is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is designated as breakthrough therapy, FDA will expedite the development and review of such drug. From time to time, we anticipate applying for such programs where we believe we meet the applicable FDA criteria. A company cannot be sure that any of its drugs will qualify for any of these programs, or even if a drug does qualify, that the review time will be reduced. On May 9, 2014, we submitted a request for breakthrough therapy designation to the FDA for abaloparatide-SC for the treatment of postmenopausal osteoporosis. In July 2014, the FDA denied our request and indicated that, upon a new request, abaloparatide-SC would be considered for a breakthrough therapy designation if new clinical evidence demonstrates that patients dosed with abaloparatide-SC show substantial improvement in treatment of postmenopausal osteoporosis over existing therapies on one or more clinically significant endpoints. We believe that the recently completed analyses of the 18-month top-line results of our Phase 3 clinical trial and two abaloparatide Phase 2 clinical trials have shown potentially important clinical benefits relative to placebo and current anabolic therapies, including significant improvements in reducing the risk of osteoporotic fractures and in calcemic control. We believe these results could support a breakthrough therapy designation. Once we have evaluated the 24-month results from the Phase 3 clinical trial, we expect to make a decision as to whether or not to re-submit our request for breakthrough designation with a focus on the areas highlighted by the FDA or to apply for one of the other FDA expedited programs for new drugs that address unmet medical needs in the treatment of serious or life threatening conditions.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and will not approve the product unless the manufacturing and production and testing facilities are in compliance with cGMP regulations. If the NDA and the manufacturing facilities are deemed acceptable by the FDA, it may issue an approval letter, or in some cases, a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication(s). A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also require,

Table of Contents

as a condition of NDA approval, post-marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions. Approval may also be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution or promotion of a drug product. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-marketing studies or clinical trials. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market.

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

*Post-Approval Requirements* Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to: (1) report certain adverse reactions to the FDA, (2) comply with certain requirements concerning advertising and promotional labeling for their products, and (3) continue to have quality control and manufacturing procedures conform to cGMP regulations after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of ongoing compliance with cGMP regulations. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. We have used and intend to continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, including recall or withdrawal of the product from the market.

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

The Hatch-Waxman Act provides five years of data exclusivity for new chemical entities, which generally (except as discussed below) prevents the FDA from accepting ANDAs and 505(b)(2) applications containing the protected active ingredient during the five-year period. We expect to be eligible for five years of data exclusivity following any FDA approval of abaloparatide-SC.

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

Table of Contents

505(b)(2) applications for the protected use but will not prohibit the FDA from accepting or approving ANDAs or 505(b)(2) applications for other products containing the same active ingredient.

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

***European Union EMA Process***

In the EU, medicinal products are authorized following a similar demanding process as that required in the United States and applications are based on the ICH Common Technical Document. In the European Union, medicines can be authorized by using either the centralized authorization procedure or national authorization procedures.

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

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

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

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

Table of Contents

procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In light of the fact that there is no policy at the EU level governing pricing and reimbursement, the 28 EU Member States each have developed their own, often varying, approaches. In many EU Member States, pricing negotiations must take place between the holder of the marketing authorization and the competent national authorities before the product is sold in their market with the holder of the marketing authorization required to provide evidence demonstrating the pharmaco-economic superiority of its product in comparison with directly and indirectly competing products. We have reviewed our development program, proposed Phase 3 study design, and overall non-clinical and clinical data package and believe they support future regulatory approval of abaloparatide-SC in the EU. In December 2012 and November 2014, we met with the Swedish Medical Products Agency, or MPA, to review the design and the overall progress of the Phase 3 study. The MPA confirmed that the program, based on the current single pivotal trial design, could support the submission and potential approval of an MAA in the EU, depending on the results of the Phase 3 study.

*Good manufacturing practices* Like the FDA, the EMA, the competent authorities of the EU Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing of pharmaceutical and biologic products prior to approving a product. If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Once we or our partners commercialize products, we will be required to comply with cGMP, and product-specific regulations enforced by, the European Commission, the EMA and the competent authorities of EU Member States following product approval. Also like the FDA, the EMA, the competent authorities of the EU Member States and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our or our partners' equipment, facilities, or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations or the withdrawal of our product from the market.

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

New medicinal products in the EU can receive eight years of data exclusivity coupled with two years of market exclusivity, and a potential one year extension, if the marketing authorizations holder obtains an authorization for one or more new therapeutic indications that demonstrates "significant clinical benefit" in comparison with existing therapies; this system is usually referred to as "8+2+1". We expect to be eligible for at least ten years of exclusivity (8 years of data exclusivity + 2 years of market exclusivity) following any approval of abaloparatide-SC. At this time we do not believe that there are orphan or pediatric applications for abaloparatide that would be likely to result in a grant of exclusivity or supplemental protection certificate in the EU.

Abridged applications cannot rely on an innovator's data until after expiry of the 8-year data exclusivity term; applications for a generic product can be submitted after that 8<sup>th</sup> year, but the product cannot be marketed until the end of the market exclusivity term.

Table of Contents

***Other International Markets Drug approval process***

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

***Pricing and Reimbursement***

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

There is no legislation at the EU level governing the pricing and reimbursement of medicinal products in the EU. As a result, the competent authorities of each of the 28 EU Member States have adopted individual strategies regulating the pricing and reimbursement of medicinal products in their territory. These strategies often vary widely in nature, scope and application. However, a major element that they have in common is an increased move towards reduction in the reimbursement price of medicinal products, a reduction in the number and type of products selected for reimbursement, and an increased preference for generic products over innovative products. These efforts have mostly been executed through these countries' existing price-control methodologies. The government of the UK announced the phase-out of its established Pharmaceutical Pricing Reimbursement Scheme approach in January 2014 and the adoption of a new value-based pricing approach, at least for new product introductions. Under this approach, in a complete departure from established methodologies, reimbursement levels of each drug will be explicitly based on an assessment of value, looking at the benefits for the patient, unmet need, therapeutic innovation, and benefit to society as a whole. It is increasingly common in many EU Member States for Marketing Authorization Holders to be required to demonstrate the pharmaco-economic superiority of their products as compared to products already subject to pricing and reimbursement in specific countries. In order for drugs to be evaluated positively under such criteria, pharmaceutical companies may need to re-examine, and consider altering, a number of traditional functions relating to the selection, study, and management of drugs, whether currently marketed, under development, or being evaluated as candidates for research and/or development.

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



Table of Contents

uncertainty exists as to the reimbursement status of newly approved healthcare products by third-party payers.

***Sales and Marketing***

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

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

Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. The majority of states also have anti-kickback and false claims laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers. Our activities

Table of Contents

could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The PPACA, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our actions could be subject to the penalty provisions of the pertinent state authorities.

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

***Other Laws and Regulatory Processes***

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

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

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

Table of Contents

**Employees**

As of December 31, 2014, we employed 25 full-time employees and 1 part-time employee, 8 of whom held Ph.D. or M.D. degrees. Sixteen of our employees were engaged in research and development activities and 10 were engaged in support administration, including business development and finance. We intend to use CROs and other third parties to perform our clinical studies and manufacturing.

**Corporate Information**

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

**Legal Proceedings**

We are not currently involved in any material legal proceedings.

**Investor Information**

Financial and other information about us is available on our website at [www.radiuspharm.com](http://www.radiuspharm.com). We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission, or the SEC. In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected, without charge, at the SEC's public reference room at 100 F Street NE, Washington, DC 20549, or at the SEC's internet address at [www.sec.gov](http://www.sec.gov). These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing. Information related to the operation of the SEC's public reference room may be obtained by calling the SEC at 800-SEC-0330.

**ITEM 1A. RISK FACTORS.**

*Our business faces significant risks and uncertainties. Certain important factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC.*

**Risks Related to Our Business**

**Risks Related to Our Financial Position and Need for Capital**

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

To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or FDA, and other foreign regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Currently,

Table of Contents

our only product candidates are abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140, and none of these product candidates is approved by the FDA or other foreign regulatory authorities for sale. Therefore, for the foreseeable future, we will have to fund our operations and capital expenditures with our existing cash and cash equivalents and marketable securities, or through strategic financing opportunities, future offerings of our equity, and/or the incurrence of debt. We believe that our existing resources will be sufficient to fund our planned operations into the fourth quarter of 2016. We have based this estimate on assumptions that may prove to be wrong, and we could use up our available capital resources sooner than we currently expect. If we fail to obtain additional capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any product candidates from the FDA and other foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts for any product candidate that is approved, forego attractive business opportunities or discontinue our operations entirely. Any additional sources of financing may not be available or may not be available on favorable terms and will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies.

***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 \$62.5 million, \$60.7 million, and \$69.1 million for the years ended December 31, 2014, 2013, and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of \$344.2 million. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

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

seek regulatory approvals for product candidates;

implement additional internal systems and infrastructure; and

hire additional personnel.

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. Our failure to achieve or maintain profitability or to raise additional capital could negatively impact the value of our securities.

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

In May 2014, we entered into our new \$30.0 million credit facility with Solar Capital Ltd., as collateral agent and lender, and Oxford Finance LLC, as lender. We drew \$21.0 million under our new credit facility on May 30, 2014, and used approximately \$9.3 million to repay our existing credit facility. Pursuant to an amendment to the credit facility, we drew an additional \$4.0 million on July 10, 2014. Our new credit facility contains a number of covenants that impose significant operating and financial restrictions on us, including covenants that limit our ability to:

dispose of our business or certain assets;

Table of Contents

change our business, management, ownership or business locations;

incur additional debt or liens;

make certain investments or declare dividends;

acquire or merge with another entity;

enter into licensing agreements;

engage in transactions with affiliates; or

encumber our intellectual property.

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

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

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

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

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

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

continuing to undertake preclinical development and clinical trials;

participating in regulatory approval processes;



Table of Contents

formulating and manufacturing products; and

conducting sales and marketing activities for products if approved.

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140, or any product candidate we may acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its indicated use. This



Table of Contents

demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for proposed uses. The FDA has substantial discretion in the drug approval process and may require us to 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 or other foreign regulatory authority policy with respect to clinical trials that change the requirements for approval;

unforeseen safety issues;

determination of dosing issues;

lack of effectiveness during clinical trials;

slower than expected rates of patient recruitment and enrollment;

failure of sites to comply with requirements for conducting clinical trials;

inability to monitor patients adequately during or after treatment; and



Table of Contents

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

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

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

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

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

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

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

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

All of our product candidates are still in preclinical or clinical development. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval, if ever. If our product candidates result in undesirable side effects or have characteristics that are unexpected, we may need to abandon their development. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Table of Contents

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

regulatory authorities may withdraw approvals of such product;

regulatory authorities may require additional warnings on the label;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

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

our reputation may suffer.

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

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

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

Edgar Filing: Radius Health, Inc. - Form 10-K

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;

Table of Contents

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

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

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

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

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

cost-effectiveness of our product relative to competing products;

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

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

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

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

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

Table of Contents

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 foreign regulatory authorities. In addition, many of our competitors have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

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

**Risks Related to Our Dependence on Third Parties**

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

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

Table of Contents

***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 (\$58.8 million) and a total of up to approximately \$4.4 million plus up to an additional \$5.0 million in aggregate performance incentive payments, payable in cash or stock depending on the timing of the closing of an underwritten offering of shares of our common stock. We also agreed to sell shares of capital stock to Nordic that were exchanged in 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 automatically converted into 28,258 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market. Pursuant to the terms of our agreements with Nordic, we were required to issue to Nordic shares of stock with an aggregate value of up to approximately €44.3 million (\$53.6 million) and \$0.8 million in consideration of Nordic's management of the Phase 3 clinical trial. These shares of stock accrued at a quarterly rate based on the progress of the Phase 3 clinical trial and were issuable at a price per share equal to the greater of (1) the fair market value of our common stock as of the applicable accrual date or (2) \$81.42 and rounding down the resulting quotient to the nearest whole number. On each of December 31, 2013 and March 31, 2014, our Board of Directors declared a stock dividend to pay all shares of stock that had accrued as of such dates and that were anticipated to accrue through December 31, 2014, representing an aggregate of 682,958 shares of our Series A-6 convertible preferred stock that automatically converted into 2,995,453 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market. Following the completion of our initial public offering of shares of our common stock on June 11, 2014, or our initial public offering, all compensation remaining payable to Nordic in consideration of their management of our Phase 3 clinical trial became payable in cash.

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

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



Table of Contents

submissions could be compromised, which could have a material adverse effect on our business and the value of our common stock.

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

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

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

While we are currently in discussions, to date, we have not entered into a long-term agreement with any of Lonza, Vetter or Ypsomed, each of whom currently produces abaloparatide or related components on a purchase order basis for us. Accordingly, Lonza, Vetter and Ypsomed could terminate

Table of Contents

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

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

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

Our 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, for any controlled substances, and corresponding state agencies to ensure strict compliance with cGMP, and other government regulations and corresponding foreign standards and failure to comply with cGMP or corresponding foreign standards can result in compliance actions that may limit a manufacturer's production or prohibit a manufacturer from producing some or all products at a facility. 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 other foreign regulatory authority or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues

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

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

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

Table of Contents

additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

**Risks Related to Marketing and Sale of Our Products**

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

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

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

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

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 against existing therapies if they are approved. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In

Table of Contents

addition, companies doing business in different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business. These risks could render our products or technologies obsolete or non-competitive.

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

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

government and health administration authorities;

private health maintenance organizations and health insurers; and

other healthcare payers.

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

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

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

### **Risks Related to Our Intellectual Property**

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

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

Table of Contents

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

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

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

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

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

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

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

Table of Contents

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.

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

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

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

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

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and

Table of Contents

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.

***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

Table of Contents

patent applications and issued patents. In order to help ensure that we comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents for which we are an assignee or co-assignee, we employ competent legal help and related professionals as needed to comply with those requirements. Our outside patent counsel uses Computer Packages, Inc. for patent annuity payments. We depend on Eisai and/or Ipsen to comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents we have licensed. 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.



Table of Contents

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

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

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

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

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

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

**Risks Related to Legislation and Administrative Actions**

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

From time to time, legislation is implemented to reign in rising healthcare expenditures. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA. PPACA includes a number of provisions affecting the pharmaceutical industry, including annual, non-deductible fees on any entity that manufactures or imports some types of branded prescription drugs and biologics and increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program. In addition,

Table of Contents

among other things, PPACA also establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research. In addition, other legislative changes have been proposed and adopted since PPACA was enacted. 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 two percent per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. The full impact on our business of these new laws is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the pharmaceutical industry generally or our business in particular.

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

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

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

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

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

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

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

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare

Table of Contents

providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

**Risks Related to Employee Matters and Managing Growth**

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

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

Table of Contents

important new innovations, but the new laws may have an effect on these activities. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability.

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

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

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

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

the potential for unknown liabilities and expenses;

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

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

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

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

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

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

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

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

#### **Risks Relating to Our Securities**

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

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

Edgar Filing: Radius Health, Inc. - Form 10-K

results of clinical trials of our product candidates or those of our competitors;

our operating performance and the operating performance of similar companies;

Table of Contents

the success of competitive products;

the overall performance of the equity markets;

the number of shares of our common stock publicly owned and available for trading;

threatened or actual litigation;

changes in laws or regulations relating to our products, including changes in the structure of healthcare payment systems;

any major change in our board of directors or management;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

large volumes of sales of our shares of common stock by existing stockholders;

general political, economic and market conditions; and

the other factors described in this "Risk factors" section.

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

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

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

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

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

## Edgar Filing: Radius Health, Inc. - Form 10-K

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting

Table of Contents

obligations as a publicly traded company or comply with the requirements of the SEC or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common shares, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain.

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

Our directors and executive officers, together with their affiliates, beneficially own a significant portion of our outstanding common stock. As a result, these stockholders, acting together, would have the ability to significantly influence the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

delaying, deferring or preventing a change in corporate control;

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

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

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

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

Pursuant to our equity incentive plans, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. We have reserved 4,559,510 shares of our common stock for issuance under our equity incentive plans as of December 31, 2014, which includes 3,220,380 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2014, and will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, as of December 31, 2014, warrants to purchase 1,379,671 shares of our common stock were outstanding. Shares of our common stock issued upon exercise of these warrants may be sold in the public market, subject to prior registration, or under an exemption from registration. Furthermore, in connection with the public offering of our common stock in January 2015, our directors, officers and their affiliated entities entered into 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 exercisable or exchangeable for shares of our common stock for a period of 90 days, subject to a possible extension under certain circumstances. After the expiration of the lock-up period, these shares may be sold in the public market, subject to prior registration or under an exemption from registration, including compliance with Rule 144. If any of these additional shares



Table of Contents

are sold, or if it is perceived that they will be sold, the price of our common stock could decline substantially.

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

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

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

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

a staggered board of directors;

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

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

prohibiting stockholder action by written consent;

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

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

requiring advance notification of stockholder nominations and proposals.

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

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

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

As of December 31, 2014, we had \$319.7 million of federal and \$246.5 million of state net operating loss carryforwards available to offset future taxable income. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation 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



Table of Contents

previously occurred. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

Our corporate headquarters are located in Waltham, Massachusetts. On May 14, 2014, we entered into a lease for our corporate offices with BP Bay Colony LLC for approximately 8,490 rentable square feet of space in the building located at 950 Winter Street, Waltham, Massachusetts 02451. We also lease an office suite in the building located at 55 Madison Avenue, Morristown, New Jersey 07960. The lease for the Morristown facility commenced in August 2014 and terminates in July 2015. We believe that our existing office space is adequate to meet current requirements but anticipate the need to lease additional or substitute space to accommodate our expansion plans which we anticipate will be available as needed.

**ITEM 3. LEGAL PROCEEDINGS.**

We are not currently involved in any material legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

Table of Contents**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock has been traded on the NASDAQ Global Market under the symbol "RDUS" since the initial public offering of our common stock on June 6, 2014. Prior to that time there was no public market for our common stock. The following table presents reported quarterly high and low per share sale prices of our common stock on The NASDAQ Global Market for the periods presented.

<b>2014</b>	<b>High</b>	<b>Low</b>
Quarter ended June 30, 2014 (beginning June 6, 2014)	\$ 14.60	\$ 7.46
Quarter ended September 30, 2014	24.28	8.09
Quarter ended December 31, 2014	42.57	16.55

On March 5, 2015, the closing price of our common stock was \$46.18 per share as reported on the NASDAQ Global Market.

**Stock Performance Graph**

The graph set forth below compares the cumulative total stockholder return on our common stock between June 6, 2014 (the date of the initial public offering of our common stock) and December 31, 2014, with the cumulative total return of (a) the Nasdaq Biotechnology Index and (b) the Nasdaq Composite Index, over the same period. This graph assumes the investment of \$100 on June 6, 2014 in our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index and assumes the reinvestment of dividends, if any. The graph assumes our closing sales price on June 6, 2014 of \$8.01 per share as the initial value of our common stock and not the initial offering price to the public of \$8.00 per share.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from the Nasdaq Stock Market LLC, a financial data provider and a source believed to be reliable. The Nasdaq Stock Market LLC is not responsible for any errors or omissions in such information.

**Comparison of Total Return\***  
**Among Radius Health Inc., the NASDAQ Composite Index, and the**  
**NASDAQ Biotechnology Index**

---

\*

**\$100 invested on June 6, 2014 in stock or index**



Table of Contents

**Holders**

As of March 5, 2015, there were 73 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Dividends**

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

**Recent Sales of Unregistered Securities**

We did not make any sales of unregistered securities during the fourth quarter of the fiscal year ended December 31, 2014.

**Use of Proceeds from Public Offering of Common Stock**

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

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

**Purchases of Equity Securities by the Issuer or Affiliated Purchasers**

There were no repurchases of shares of common stock made during the fourth quarter of the fiscal year ended December 31, 2014.

**ITEM 6. SELECTED FINANCIAL DATA.**

You should read the following selected financial data together with our financial statements and the related notes contained in Item 8 of Part II of this Annual Report on Form 10-K. We have derived the statements of operations data for each of the three years ended December 31, 2012, 2013 and 2014 and the balance sheets data as of December 31, 2013 and 2014 from the audited financial statements contained in Item 8 of Part II of this Form 10-K. The selected balance sheet data as of December 31, 2010, 2011 and 2012 and the statement of operations data for the years ended December 31, 2010 and 2011 has been derived from the audited financial statements for such years not included in this Form 10-K.

The financial information set forth below for the years ended December 31, 2010 and 2011 have been recast to reflect the adoption of Accounting Standards Update No. 2011-05, *Presentation of Comprehensive Income*.

The historical financial information set forth below may not be indicative of our future performance and should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our historical financial statements and notes to those

## Edgar Filing: Radius Health, Inc. - Form 10-K

### Table of Contents

statements included in Item 7 of Part II and Item 8 of Part II, respectively, of this Annual Report on Form 10-K.

Statement of Operations and Comprehensive Loss Data	Year Ended December 31,				
	2014	2013	2012	2011	2010
(in thousands)					
Operating expenses:					
Research and development	\$ 45,719	\$ 60,536	\$ 54,961	\$ 36,179	\$ 11,692
General and administrative	13,674	6,829	9,469	5,330	3,630
Restructuring					217
Loss from operations	(59,393)	(67,365)	(64,430)	(41,509)	(15,539)
Other (expense) income:					
Other (expense) income, net	(713)	9,085	(2,095)	(236)	824
Interest (expense) income, net	(2,373)	(2,410)	(2,603)	(731)	85
Net loss	(62,479)	(60,690)	(69,128)	(42,476)	(14,630)
Other comprehensive loss, net of tax:					
Unrealized (loss) gain from available-for-sale securities	(21)		(5)	8	(18)
Comprehensive loss	\$ (62,500)	\$ (60,690)	\$ (69,133)	\$ (42,468)	\$ (14,648)
Net (loss) earnings attributable to common stockholders	\$ (71,479)	\$ (78,161)	\$ (83,120)	\$ 113	\$ (26,773)

Balance Sheet Data	As of December 31,				
	2014	2013	2012	2011	2010
(in thousands)					
Cash and cash equivalents	\$ 28,518	\$ 12,303	\$ 18,653	\$ 25,128	\$ 10,582
Marketable securities	76,758		4,000	31,580	7,969
Working capital	86,774	(22,675)	8,026	56,607	15,448
Total assets	108,417	12,758	25,300	63,637	18,969
Long-term liabilities	24,394	1,945	38,222	19,806	
Total liabilities	44,953	37,257	55,312	26,589	3,385
Total convertible preferred stock and redeemable convertible preferred stock		252,802	170,649	156,658	143,836
Total liabilities, convertible preferred stock, redeemable convertible preferred stock and stockholders' equity (deficit)	108,417	12,758	25,300	63,637	18,969

### **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

*You should read the following discussions in conjunction with our consolidated financial statements and related notes included in this report. This discussion includes forward-looking statements that involve risk and uncertainties. As a result of many factors, such as those set forth under "Risk Factors," actual results may differ materially from those anticipated in these forward-looking statements.*

#### **Executive Overview**

We are a science-driven biopharmaceutical company focused on developing new therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases. Our lead development candidate is the investigational drug abaloparatide (BA058), a bone anabolic for potential use in the





Table of Contents

reduction of fracture risk in postmenopausal women with severe osteoporosis delivered via subcutaneous injection, which we refer to as abaloparatide-SC. We announced the 18-month top-line data from our Phase 3 clinical trial evaluating abaloparatide-SC for potential use in the reduction of fracture risk in postmenopausal women with severe osteoporosis in December 2014. Patients from the abaloparatide and placebo groups from our Phase 3 clinical trial are eligible to continue in the ACTIVEExtend trial, in which they are receiving an approved alendronate therapy for osteoporosis management. We currently anticipate the first results from the first six months of the ACTIVEExtend trial to be available in the second quarter of 2015. Following completion of the first six months of the extension study, we plan to submit a new drug application, or NDA, in the United States, and a marketing authorization application, or MAA, in Europe, during the second half of 2015. We hold worldwide commercialization rights to abaloparatide-SC, other than in Japan, and subject to a regulatory review and favorable regulatory outcome, we anticipate our first commercial sales of abaloparatide-SC will take place in 2016. We are leveraging our investment in abaloparatide-SC to develop a line extension that is designed to improve patient convenience by enabling administration of abaloparatide through an investigational short-wear-time transdermal patch, which we refer to as abaloparatide-TD. We hold worldwide commercialization rights for abaloparatide-TD.

Our current clinical product portfolio also includes the investigational drug RAD1901, a selective estrogen receptor down regulator/degrader, or SERD, and the investigational drug RAD140, a nonsteroidal selective androgen receptor modulator, or SARM. We are developing RAD1901 at higher doses for potential use in the treatment of metastatic breast cancer, and intend to advance its development with the initiation of Phase 1 clinical trials, including a maximum tolerated dose study that has commenced patient dosing and a Phase 1 clinical trial in metastatic breast cancer patients which commenced in late 2014. At lower doses, RAD1901 acts as a selective estrogen-receptor modulator, or SERM. Low-dose RAD1901 has shown potential to be effective for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study. We intend to commence a Phase 2b clinical trial in vasomotor symptoms in the second half of 2015.

***Abaloparatide***

Abaloparatide is a novel synthetic peptide analog of parathyroid hormone-related protein, or PTHrP, that we are developing as a bone anabolic treatment for potential use in the reduction of fracture risk in postmenopausal women with severe osteoporosis. Osteoporosis is a disease that affects nearly 10 million people, with an additional approximately 43 million people at increased risk for the disease, in the United States. 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, at more sites, at a faster rate, and in more patients, 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. Our Phase 3 study of abaloparatide-SC is designed to evaluate whether abaloparatide-SC is superior to placebo for prevention of vertebral fracture. The study is also designed to evaluate whether abaloparatide-SC is superior to open-label teriparatide 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. On December 21, 2014, we announced positive top-line data from the Phase 3 clinical trial (ACTIVE) of the investigational drug abaloparatide-SC, or the ACTIVE Trial, evaluating the investigational drug abaloparatide-SC for potential use in the reduction of fractures in postmenopausal osteoporosis. On the primary endpoint, abaloparatide-SC (n=690, fracture rate 0.72%) achieved a statistically significant 83% reduction of incident vertebral fractures (defined as new and worsening vertebral fractures) as compared

Table of Contents

to the placebo-treated group (n=711, fracture rate 4.36%) (p<0.0001). The ACTIVE trial included an open-label teriparatide [rDNA origin] injection treatment group (n=717, fracture rate 0.98%) that showed a statistically significant 78% reduction of incident vertebral fractures as compared to the placebo-treated group (p<0.0001). On the secondary endpoints, as compared to placebo, abaloparatide-SC achieved: a statistically significant fracture-rate reduction of 43% in the adjudicated non-vertebral fracture subset of patients; a statistically significant reduction of 45% in the adjudicated clinical fracture group, which includes both vertebral and non-vertebral fractures; and a statistically significant difference in the time to first incident of nonvertebral fracture in both the adjudicated non-vertebral fracture (p=0.0489) and the clinical fracture subset of patients (p=0.0112). The open-label teriparatide injection treatment group, as compared to placebo, achieved a fracture-rate reduction of 28% in the adjudicated non-vertebral fracture subset of patients and a reduction of 29% in the adjudicated clinical fracture group; these differences were not statistically significantly different as compared to the placebo group. The fracture-rate reduction observed in the abaloparatide-SC treatment group, as compared to open-label teriparatide, was not statistically significant.

In January 2015, the U.S. Food and Drug Administration, or FDA, provided us with comments on the draft Statistical Analysis Plan, or SAP, that was used for the analysis of the top-line data from the Phase 3 clinical trial. In its correspondence, the FDA recommended that the primary endpoint of incident vertebral fracture reduction be performed excluding worsening vertebral fractures and including only new vertebral fractures. Using the FDA-recommended analysis, on the primary endpoint of reduction of new vertebral fractures (excluding worsening), abaloparatide-SC (n=690, fracture rate 0.58%) achieved a statistically significant 86% reduction as compared to the placebo-treated group (n=711, fracture rate 4.22%) (p<0.0001). The open-label teriparatide injection treatment group (n=717, fracture rate 0.84%) showed a statistically significant 80% reduction of new vertebral fractures (excluding worsening) as compared to the placebo-treated group (p<0.0001). The FDA also recommended, for the secondary endpoint of non-vertebral fractures, that our definition was generally acceptable provided that sternal (breast bone) and patellar (knee cap) fractures were excluded. In the original top-line data announced for the secondary endpoint of non-vertebral fracture reduction noted above, we had excluded sternum and patella fractures, and abaloparatide-SC (n=824, Kaplan-Meier estimated, or KM, fracture rate 2.7%) achieved a statistically significant reduction compared to the placebo-treated group (n=821, KM fracture rate 4.7%), and the hazard ratio for abaloparatide vs. placebo was 0.57 (p=0.0489); the open label teriparatide injection treatment group (n=818, KM fracture rate 3.3%) had a hazard ratio of 0.72 (p=NS) compared to the placebo-treated group. The FDA also recommended, for the secondary endpoint of bone mineral density, or BMD, that we use an Analysis of Covariance, or ANCOVA, approach with the last observation carried forward for missing data. The Mixed-Effect Model For Repeated Measures, or MMRM, method, which was used in the BMD secondary endpoint in the top-line data announced in December 2014, is to be applied for sensitivity analysis.

Our Phase 3 study includes a 6-month extension period in order to obtain 24-months of fracture data, as requested by the FDA. Patients from the abaloparatide and placebo groups from our Phase 3 clinical trial are eligible to continue in an extension study, in which they are receiving an approved alendronate therapy for osteoporosis management. We currently anticipate the first results from the first six months of the ACTIVEExtend trial to be available in the second quarter of 2015. We believe that the abaloparatide-SC program is on-track for submission of an NDA for abaloparatide-SC to the FDA, and submission of an MAA to the European Medicines Agency, or EMA, each of which incorporates the 24-month fracture data, in the second half of 2015. We will remain blinded at the patient and site level until such time as the ACTIVEExtend trial is completed.

Table of Contents

On May 9, 2014, we submitted a request for a breakthrough therapy designation to the FDA for abaloparatide-SC for the treatment of postmenopausal osteoporosis. In July 2014, the FDA denied our request and indicated that, upon a new request, abaloparatide-SC would be considered for a breakthrough therapy designation if new clinical evidence demonstrates that patients dosed with abaloparatide-SC show substantial improvement in treatment of postmenopausal osteoporosis over existing therapies on one or more clinically significant endpoints. We believe that the recently completed analyses of the 18-month top-line results of our Phase 3 clinical trial and two abaloparatide Phase 2 clinical trials have shown potentially important clinical benefits relative to placebo and current anabolic therapies, including significant improvements in reducing the risk of osteoporotic fractures and in calcemic control. We believe these results could support a breakthrough therapy designation. Once we have evaluated the 24-month results from the Phase 3 clinical trial, we expect to make a decision as to whether to re-submit our request for breakthrough therapy designation with a focus on the areas highlighted by the FDA or to apply for one of the other FDA expedited programs for new drugs that address unmet medical needs in the treatment of serious or life threatening conditions.

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

We also believe that, subject to further research and development, abaloparatide may have potential applications across a variety of skeletal or bone related diseases or medical conditions.

***RAD1901***

RAD1901 is a SERD that we believe crosses the blood-brain barrier and that we are evaluating for potential use in the treatment of metastatic breast cancer and other estrogen receptor mediated oncology applications. RAD1901 has been shown to bind with good selectivity to the estrogen receptor and to have both estrogen-like and estrogen-antagonistic effects in different tissues. 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. In 2014, the worldwide market for Faslodex was \$720.0 million. For patients with brain metastases, there are no approved targeted therapies that cross the blood-brain barrier.

In December 2014, we commenced a Phase 1 clinical trial of RAD1901 in the United States for the treatment of metastatic breast cancer. The Phase 1 study is a multicenter, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced estrogen receptor positive

Table of Contents

and HER2-negative breast cancer that is designed to determine the recommended dose for a Phase 2 clinical trial and includes a preliminary evaluation of the potential anti-tumor effect of RAD1901. We expect to report progress on this study in the first half of 2015 and to initiate additional Phase 1 clinical trials in the European Union in 2015. In June 2014, we initiated a Phase 1 maximum tolerated dose, or MTD, study of RAD1901 in healthy volunteers. The study is designed to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also to use 18F-estradiol positron emission tomography, or FES-PET, imaging to provide a pharmacodynamic assessment of estrogen receptor turnover following administration of RAD1901. Levels of RAD1901 in cerebrospinal fluid samples taken from study subjects will be measured to confirm that RAD1901 has crossed the blood-brain barrier. Based upon initial study results, FES-PET imaging of RAD1901 has shown potent SERD activity. As of December 31, 2014, 40 subjects had completed dose escalation in the ongoing MTD study, and FES-PET imaging had been completed in a total of five subjects across two different doses. Each of these five subjects showed, based on FES-PET imaging, suppression of the FES-PET signal to background levels after six days of dosing. In addition, RAD1901, at the doses that showed suppression of the FES-PET signal, was well tolerated in these patients.

In March 2014, we submitted to the FDA an application for orphan drug designation of RAD1901 for the treatment of breast cancer brain metastases. In June 2014, we received a response to our application from the FDA requesting additional data with respect to our orphan drug designation application. We plan to meet with the FDA and are working to provide them with the data requested to support orphan drug designation of RAD1901.

We are also developing RAD1901 at lower doses as a SERM, for the potential treatment of vasomotor symptoms. Historically, hormone replacement therapy, or HRT, with estrogen or progesterone has been 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 showed a reduction in the frequency and severity of moderate and severe hot flashes. We intend to commence a Phase 2b clinical trial in vasomotor symptoms in the second half of 2015.

Our efforts and resources are focused primarily on developing abaloparatide-SC, abaloparatide-TD, RAD1901 and our other pharmaceutical investigational 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 regulatory approval for abaloparatide-SC from the FDA, or equivalent foreign regulatory authorities. However, developing pharmaceutical products is a lengthy and very expensive process. Accordingly, our success depends not only on demonstrating the safety and efficacy of abaloparatide, but also on our ability to finance the development of these product candidates, which will require substantial additional funding to complete development and submit applications seeking 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, 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 or distribution capabilities and thus our ability to market abaloparatide once approved 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.

Table of Contents**Financial Overview*****Research and Development Expenses***

Research and development expenses consist primarily of clinical testing costs, including payments in cash and stock made to contract 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 investigational product candidates. We expense our research and development costs as they are incurred.

None of the research and development expenses in relation to our investigational product candidates are currently borne by third parties. Our lead investigational product candidate is abaloparatide and it currently represents the largest portion of our research and development expenses for our investigational product candidates. We began tracking program expenses for abaloparatide-SC in 2005, and program expenses from inception to December 31, 2014 were approximately \$176.0 million. We began tracking program expenses for abaloparatide-TD in 2007, and program expenses from inception to December 31, 2014 were approximately \$31.1 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to December 31, 2014 were approximately \$17.8 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to December 31, 2014 were approximately \$5.2 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs.

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

We estimate that future development costs for abaloparatide-SC may exceed \$52.0 million, including \$18.0 million for clinical costs, \$21.0 million for license and milestone payments and NDA submission fees, \$10.0 million for manufacturing costs and \$3.0 million for preclinical costs. For abaloparatide-TD, we estimate that future development costs may exceed \$29.0 million, including \$18.0 million for clinical costs, \$7.0 million for manufacturing costs, and \$4.0 million for preclinical costs and NDA submission fees.

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

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

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Abaloparatide-SC	\$ 32,044	\$ 45,977	\$ 44,692
Abaloparatide-TD	1,493	11,459	6,040
RAD1901	2,250		59
RAD140			18

85

Table of Contents

***General and Administrative Expenses***

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

Our results also include stock-based compensation expense as a result of the issuance of stock 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, entered into on May 23, 2011 with General Electric Capital Corporation, or GECC, as agent and lender, and Oxford Finance, as a lender, or the Original Credit Facility, and our loan and security agreement entered into on May 30, 2014 with Solar Capital Ltd., or Solar, as agent and lender, and Oxford Finance, as lender, or the New Credit Facility. Under the Original Credit Facility, we drew \$12.5 million under an initial and second term loan during the year ended December 31, 2011 and an additional \$12.5 million under a third term loan during the year ended December 31, 2012. Under the New Credit Facility, we drew \$21.0 million under an initial term loan on May 30, 2014 and \$4.0 million under a second term loan on July 10, 2014.

On May 30, 2014, we used approximately \$9.3 million of the New Credit Facility to repay all the amounts owed under the Original Credit Facility.

***Other Income (Expense)***

For the years ended December 31, 2014 and 2013, other income (expense) primarily reflects changes in the fair value of our warrant liability and the series A-6 convertible preferred stock liability and stock asset from the date of the initial accrual to the reporting date as discussed in note 8 to our financial statements included in this Annual Report.

**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

Table of Contents

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 consulting 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 stock, and the risk-free interest rate over the expected life of the option. Due to the limited trading history of our common stock since our June 2014 initial public offering, 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.

Table of Contents

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.

***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, 2014, we held financial assets that were measured using Level 1 and Level 2 inputs. As of December 31, 2013, we held financial assets and liabilities that were 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 domestic corporate debt 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. Prior to our initial public offering, assets and liabilities measured using Level 3 inputs included our stock asset, stock liability, other liability and warrant liability. The stock asset represented the prepaid balance and the stock liability represented 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 upon listing 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 represented 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 was 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 were based upon the fair value of our series A-6 convertible preferred stock as determined using the probability-weighted expected return method, or PWERM. Upon completion of our initial public offering, any payments owed by us to Nordic in relation to the Nordic Work Statements were changed from the right to receive shares of Series A-6 to the right to receive a total cash payment of \$4.3 million.



Table of Contents

As of December 31, 2013, the warrant liability represented 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 was calculated using the Black-Scholes option pricing method. Upon completion of our initial public offering, the outstanding warrants to purchase shares of A-1 convertible preferred stock were converted into the right to purchase shares of common stock and the Company's warrant liability was reclassified to equity.

As of December 31, 2014, we held no Level 3 assets or liabilities.

**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, 2014 and December 31, 2013**

	Years Ended December 31,		Change	
	2014	2013	\$	%
	(in thousands)			
Operating expenses:				
Research and development	\$ 45,719	\$ 60,536	\$ (14,817)	24%
General and administrative	13,674	6,829	6,845	100%
Loss from operations	(59,393)	(67,365)	(7,972)	12%
Other (expense) income:				
Other (expense) income, net	(510)	9,085	9,595	106%
Loss on retirement of note payable	(203)		203	100%
Interest (expense) income, net	(2,373)	(2,410)	(37)	2%
Net loss	\$ (62,479)	\$ (60,690)	\$ 1,789	3%

*Research and development expenses* For the year ended December 31, 2014, research and development expense was \$45.7 million compared to \$60.5 million for the year ended December 31, 2013, a decrease of \$14.8 million, or 24%. This decrease is primarily a result of a decrease in the total professional contract service costs associated with the development of abaloparatide-SC and abaloparatide-TD, partially offset by an increase in professional contract services costs associated with the development of RAD1901. During the year ended December 31, 2014, we incurred professional contract service costs associated with the development of abaloparatide-SC, abaloparatide-TD and RAD1901 of \$32.0 million, \$1.5 million and \$2.3 million, respectively, compared to \$46.0 million, \$11.5 million and zero, respectively, for the year ended December 31, 2013. The decrease in contract service costs associated with the development of abaloparatide-SC is primarily a result of the completion of the Phase 3 18-month fracture study in October 2014. Additionally, fewer patients were enrolled in the 6-month extension study as of December 31, 2014, as compared to the year ended December 31, 2013, as certain patients completed treatment. We expect that costs associated with the development of abaloparatide-SC will continue to decrease over the course of the clinical trial as patients complete treatment under the 18-month fracture study and first six months of the extension study. In addition, there will be variability from quarter to quarter in the costs for abaloparatide-SC, driven primarily by the euro/dollar exchange rate, which is more fully described below under "Research and Development Agreements." The decrease in contract service costs associated with the development of abaloparatide-TD is a result of the completion of the Phase 2 clinical trial (which began dosing patients in September 2012) in September 2013. The increase in contract service costs associated with

## Edgar Filing: Radius Health, Inc. - Form 10-K

### Table of Contents

the development of RAD1901 is a result of the initiation of various preclinical, clinical, and manufacturing activities in 2014.

*General and administrative expenses* For the year ended December 31, 2014, general and administrative expense was \$13.7 million compared to \$6.8 million for the year ended December 31, 2013, an increase of \$6.8 million, or 100%. This increase was primarily due to an increase in compensation costs of \$4.5 million, including an increase of \$3.9 million in non-cash stock-based compensation expense as a result of the issuance of new option awards during 2014, as well as the acceleration of vesting for a portion of our Chief Executive Officer's outstanding option awards, in accordance with his employment agreement, upon completion of our initial public offering. This increase can also be attributed to higher legal fees and consulting support costs of approximately \$1.7 million during the year ended December 31, 2014.

*Other (expense) income, net* For the year ended December 31, 2014, other expense, net of other income, was \$0.5 million, as compared to other income, net of expense during the year ended December 31, 2013 of \$9.1 million. Other expense, net of other income, primarily reflects changes in the fair value of the stock asset, stock liability, other liability and warrant liability as discussed in notes 8 and 10 to our financial statements included in this Annual Report on Form 10-K. The \$0.5 million of other expense, net of income, for the year ended December 31, 2014 was primarily due to an increase in the fair value of our warrant liability as a result of an overall increase in the fair value of the underlying common stock from December 31, 2013 to June 6, 2014. Following our initial public offering on June 6, 2014, our warrant liability was reclassified to equity. 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.

*Loss on retirement of note payable* For the year ended December 31, 2014, loss on retirement of note payable was \$0.2 million. This loss was a result of the prepayment of our Original Credit Facility on May 30, 2014.

*Interest (expense) income* For the year ended December 31, 2014, interest expense, net of interest income, was \$2.4 million, consistent with \$2.4 million for the year ended December 31, 2013.

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

	Years Ended December 31,		Change	
	2013	2012	\$	%
	(in thousands)			
<b>Operating expenses:</b>				
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%
<b>Other (expense) income:</b>				
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)	12%

*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

Table of Contents

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.

*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.

*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 8 and 10 to our financial statements included in this Annual Report. 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.

**Liquidity and Capital Resources**

From inception to December 31, 2014, we have incurred an accumulated deficit of \$344.2 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various investigational product candidates and expenses supporting those activities. Our total cash, cash equivalents and marketable securities balance as of December 31, 2014 was \$105.3 million. We have financed our operations since inception primarily through the public offerings of our common stock, private sale of preferred stock, borrowing under credit facilities and the receipt of \$5.0 million in fees associated with an option agreement.

We believe that the aggregate proceeds from the public offering of shares of our common stock that we completed in January 2015, together with our cash, cash equivalents and marketable securities as of December 31, 2014, will be sufficient to fund our operations into the fourth quarter of 2016. We expect to finance the future development costs of abaloparatide-SC, abaloparatide-TD and RAD1901 with our existing cash and cash equivalents and marketable securities, or through strategic financing opportunities that could include, but are not limited to, partnering or other collaboration agreements, or the completion of an additional public offering. However, there is no guarantee that any of these financing opportunities will be available to us on favorable terms, and some could be dilutive to existing stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development and commercialization activities, the results of our clinical trials, and the potential approval of our products by the FDA and EMA. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any investigational product candidates from the FDA and other foreign regulatory authorities.

Table of Contents

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

	Years ended December 31,		
	2014	2013	2012
Net cash (used in) provided by:			
Operating activities	\$ (48,345)	\$ (45,017)	\$ (43,158)
Investing activities	(78,065)	3,971	27,435
Financing activities	142,625	34,696	9,248
Net increase (decrease) in cash and cash equivalents	\$ 16,215	\$ (6,350)	\$ (6,475)

***Cash Flows from Operating Activities***

Net cash used in operating activities during the year ended December 31, 2014 was \$48.3 million, which was primarily the result of a net loss of \$62.5 million, partially offset by \$11.2 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of \$3.0 million. The \$62.5 million net loss was primarily due to expenses incurred in connection with our ongoing Phase 3 clinical trial of abaloparatide-SC. The \$11.2 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$7.1 million, \$2.7 million of research and development expenses settled in stock, and a \$0.5 million increase in the fair value of our warrant liability and stock liability as a result of an increase in the fair value of the underlying convertible preferred stock and common stock from December 31, 2013 to June 6, 2014.

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 trial of abaloparatide-SC and our Phase 2 clinical study of abaloparatide-TD, which finished dosing patients during the three months ended September 30, 2013. The \$6.0 million net non-cash adjustments to reconcile net loss to net cash used in operations included \$13.1 million of research and development expenses settled in stock and stock-based compensation expense of \$1.5 million, and was partially offset by a \$9.1 million reduction in the fair value of our warrant liability, stock liability and other liability as a result of a decline in the fair value of the underlying convertible preferred stock from December 31, 2012 to December 31, 2013.

Net cash used in operating activities for the year ended December 31, 2012 was \$43.2 million, which was primarily the result of a net loss of \$69.1 million, partially offset by changes in working capital of \$6.4 million and \$19.5 million of non-cash adjustments to reconcile net loss to net cash used in operations, including \$15.1 million of research and development expenses settled in stock. The \$69.1 million net loss and \$15.1 million of research and development expenses settled in stock are primarily due to expenses incurred in connection with our Phase 3 clinical trial 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 used in investing activities for the year ended December 31, 2014 was \$78.1 million, as compared to net cash provided by investing activities of \$4.0 million for the year ended December 31, 2013.

The net cash used in investing activities during the year ended December 31, 2014 was primarily a result of \$97.7 million in purchases of marketable securities and \$0.9 million of purchases of property

Table of Contents

and equipment, partially offset by \$20.5 million of net proceeds received from the sale or maturity of marketable securities. 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.

***Cash Flows from Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2014 was \$142.6 million, as compared to \$34.7 million of net cash provided by financing activities for the year ended December 31, 2013.

Net cash provided by financing activities during the year ended December 31, 2014 consisted of \$50.4 million of net proceeds from our initial public offering, \$53.4 million of net proceeds from our additional public offering that closed October 7, 2014, \$27.4 million of net proceeds from the issuance of our series B-2 convertible preferred stock in February and March of 2014, and \$24.6 million of net proceeds from our New Credit Facility, partially offset by payments under our Original Credit Facility of \$13.2 million.

Net cash provided by financing activities for the 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.

***Financings***

*Sales of Common Stock*

On June 11, 2014, we completed our initial public offering whereby we sold 6,500,000 shares of our common stock at a price of \$8.00 per share. The shares began trading on the NASDAQ Global Market on June 6, 2014. In connection with the completion of the offering, all outstanding shares of our convertible preferred stock converted into 19,465,132 shares of common stock, and 2,862,654 shares of common stock were issued in satisfaction of accumulated dividends accrued on the preferred stock. In addition, all outstanding warrants to purchase shares of A-1 convertible preferred stock and warrants to purchase shares of series B-2 convertible preferred stock were converted into the right to purchase 149,452 shares of common stock and our warrant liability was reclassified to equity. On June 18, 2014 and June 25, 2014, the underwriters purchased an additional 512,744 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the initial public offering. As a result of the closing of the initial public offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$50.4 million.

On October 7, 2014, we completed an additional public offering whereby we sold 2,750,000 shares of common stock at a price of \$18.25 per share, for aggregate proceeds, net of underwriting discounts,

Table of Contents

commissions and offering costs, of approximately \$46.9 million. On October 7, 2014, the underwriters purchased an additional 378,524 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately \$53.4 million.

On January 28, 2015, we completed a public offering of 4,000,000 shares of our common stock at a price of \$36.75 per share, for aggregate estimated proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$137.8 million. On January 28, 2015, the underwriters purchased an additional 600,000 shares in the aggregate by exercising an option to purchase additional shares that was granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the underwriters' option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately \$158.6 million.

*Sales of Preferred Stock*

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

Issue	Year	No. Shares	Net Proceeds (in thousands)
Series B redeemable convertible preferred stock(1)	2003, 2004, 2005	1,599,997	\$ 23,775
Series C redeemable convertible preferred stock(1)	2006, 2007, 2008	10,146,629	82,096
Series A-1 convertible preferred stock(1)	2011	9,223,041	61,591
Series A-5 convertible preferred stock(1)	2011	64,430	525
Series B convertible preferred stock	2013	701,235	42,870
Series B-2 convertible preferred stock	2014	448,060	27,368
<b>Total</b>		<b>22,183,392</b>	<b>\$ 238,225</b>

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

On February 14, 2014, we entered into a Series B-2 Convertible Preferred Stock and Warrant Purchase Agreement, or Purchase Agreement, pursuant to which we were able to raise up to approximately \$40.2 million through the issuance of (1) up to 655,000 series B-2 Shares convertible preferred stock, or Series B-2, par value \$.0001 per share, and (2) warrants to acquire up to 718,201 shares of our common stock, at an exercise price of \$14.004 per share.

Shares of our Series B-2 were convertible, in whole or in part, at the option of the holder at any time into shares of common stock, on an approximately 4.386-for-one basis at an initial effective conversion price of \$14.004 per share. Shares of our Series B-2 were automatically convertible into shares of our common stock upon the closing of an initial public offering on or prior to June 30, 2014 at a conversion rate determined by dividing the initial purchase price of \$61.42 per share by the lower of (1) \$14.004 per share and (2) the initial public offering price, or upon listing of the common stock on a national securities exchange after June 30, 2014 at the then applicable conversion rate. Holders of shares of Series B-2 were 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 were payable, as accrued, upon liquidation, event of sale, and conversion to common stock, including upon mandatory conversion of the Series B-2 upon the closing of our initial public offering on or prior to June 30, 2014 or upon listing of the common stock on a national securities exchange after June 30, 2014. The holders of shares of Series B-2 were also entitled to dividends declared or paid on any shares of common stock.

Table of Contents

Shares of Series B-2 ranked 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 ranked equally with each other share of Series B-2 and 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 were entitled to be paid first out of the assets available for distribution, before any payment was 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 was to consist of one and a half (1.5) times the original issuance price of \$61.42, plus all accrued but unpaid dividends.

On February 14, 2014, February 19, 2014, February 24, 2014, March 14, 2014 and March 28, 2014, we consummated closings under the Series B-2 Purchase Agreement, whereby, in exchange for aggregate proceeds to us of approximately \$27.5 million, we issued an aggregate of 448,060 Series B-2 Shares and warrants to purchase up to a total of 491,293 shares of our common stock.

Each share of Series B-2 had 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 was then convertible.

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

The issuances in February and March 2014 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 the Anti-Dilution Adjustment, the effective conversion price of each share of Series A-1, Series A-2 and Series A-3 was reduced to \$16.970. Accordingly, each share of Series A-1, Series A-2 and Series A-3 was convertible into approximately 4.798 shares of common stock.

Upon completion of our initial public offering, all shares of Series B-2 were converted into shares of our common stock at a conversion rate of 7.678, which is equal to the initial purchase price, divided by the initial public offering price of \$8.00 per share.

*Debt Borrowings*

On May 30, 2014, we entered into our New Credit Facility with Solar and Oxford Finance, pursuant to which Solar and Oxford agreed to make available to us \$30.0 million in the aggregate subject to certain conditions to funding. An initial term loan was made on May 30, 2014 in an aggregate principal amount equal to \$21.0 million, or the Initial Term Loan.

We were originally required to make interest-only payments through June 1, 2015, and beginning on July 1, 2015, we were required to make payments of principal and accrued interest in equal monthly installments over a term of 36 months. However, as we were able to consummate public offerings of our common stock which resulted in the receipt of at least \$65.0 million in aggregate net cash proceeds prior to May 31, 2015, as of December 31, 2014, we are permitted to make interest-only payments through December 1, 2015 rather than July 1, 2015, and beginning on January 1, 2016, we will be required to make principal and accrued interest payments in equal monthly installments over a term of 30 months.

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

Table of Contents

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

On July 10, 2014, we entered into a first amendment to the New Credit Facility, or the First Amendment. Pursuant to the terms of the First Amendment, a second term loan of \$4.0 million was drawn on July 10, 2014. The terms of the First Amendment, among other things,

provide us with, subject to certain customary funding conditions, additional term loans in an aggregate principal amount of \$4.0 million upon the closing of the First Amendment, or the Modified Term B Loan. All other terms applicable to the Original Term B Loan remain applicable to the Modified Term B Loan. The Original Term B Loan are replaced by the Modified Term B Loan. We borrowed the full amount of the Modified Term B Loan on July 10, 2014.

provide us the ability to borrow additional term loans in an aggregate amount of \$5.0 million, or the Term C Loan, at any time through December 31, 2014. In order to draw the Term C Loan, we had to, in addition to other customary conditions, either (a) close public or private stock offerings, equity raises or strategic partner arrangements resulting in \$13.0 million in aggregate net proceeds after the closing of the First Amendment, or (b) as it relates specifically to RAD1901, complete both the maximum tolerable dose trial and enroll the first patient in the breast cancer brain metastasis trial. Although we closed a public offering resulting in over \$13.0 million in aggregate net proceeds after the closing of the First Amendment, we did not exercise our right to draw the Term C Loan prior to December 31, 2014.

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

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

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

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

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



## Edgar Filing: Radius Health, Inc. - Form 10-K

### Table of Contents

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

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

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

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

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

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

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

### ***Contractual Obligations and Commitments***

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. We enter into contracts in the normal course of business with CROs for preclinical and clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments. In addition, we have certain obligations to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing



Table of Contents

of an NDA, approval by the FDA or product launch). The table below excludes these potential payments we may be required to make under our agreements because the timing of payments and actual amounts paid under those agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations, and those agreements are cancelable upon written notice by us and therefore, not long-term liabilities. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information.

Our contractual obligations result from property leases for office space and amounts due under our New Credit Facility. However, more information regarding significant contracts with CROs and our obligations to make future payments to third parties that become due and payable upon achievement of certain development, regulatory and commercial milestones can be found below under "Research and Development Agreements" and "License Agreement Obligations".

The following table summarizes our contractual obligations at December 31, 2014:

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations	\$ 1,428	\$ 328	\$ 601	\$ 499	\$
New Credit Facility	25,000		20,000	5,000	
<b>Total</b>	<b>\$ 26,428</b>	<b>\$ 328</b>	<b>\$ 20,601</b>	<b>\$ 5,499</b>	<b>\$</b>

**Research and Development Agreements**

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

Pursuant to the Work Statement NB-1, we 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 Phase 3 Clinical Trial schedule may alter the timing, but not the aggregate amounts of the payments. In addition, Nordic is entitled to a performance incentive payment, or Performance Incentive Payment, of \$500,000 for every 50 patients that, subsequent to March 28, 2014, complete all end-of-study procedures, up to a maximum aggregate amount of \$5.0 million. The Work Statement NB-1, provides for a total of up to approximately €41.2 million (\$49.8 million) of euro-denominated payments and a total of up to approximately \$3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus Performance Incentive Payments. These payments may be adjusted based upon actual sites opened, work performed or number of patients enrolled.

Pursuant to the Stock Issuance Agreement, Nordic purchased 6,443 shares of our Series A-5 convertible preferred stock. In connection with the Work Statement NB-1, the shares of Series A-5 convertible preferred stock held by Nordic were entitled to receive quarterly stock dividends payable in shares of our Series A-6 convertible preferred stock, having an aggregate value of up to €36.8 million (\$44.5 million), or the NB-1 Accruing Dividend. The Stock Issuance Agreement further provided that in the event an initial public offering of our common stock occurred prior to June 30, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, as discussed below, excluding Performance Incentive Payments, for all periods of time after 2014 would

Table of Contents

change 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. As we completed our initial public offering on June 11, 2014, payments owed to Nordic under the Stock Issuance Agreement have been paid in cash for all periods after June 11, 2014.

Prior to the issuance of shares of stock to Nordic in satisfaction of the NB-1 Accruing Dividend, the liability to issue shares of stock was accounted for as a liability on our balance sheet, based upon the fair value of the series A-6 convertible preferred stock as determined using PWERM. Changes in the fair value from the date of accrual to the date of issuance of shares of our series A-6 convertible preferred stock were recorded as a gain or loss in other (expense) income 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 20-month period, except for research and development expense for the amounts due under the fourth amendment to the Work Statement NB-1, which we recognize on a per patient basis when the end-of-study visit and all other required procedures are completed. We recorded \$8.2 million, \$31.6 million, and \$30.8 million of research and development expense during the years ended December 31, 2014, 2013, and 2012, respectively, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Trial.

As of December 31, 2014, we had a liability of \$5.6 million 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* On February 21, 2013, we entered into the Work Statement NB-3, as amended on March 4, 2014, or the Work Statement NB-3. Pursuant to the Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial, and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management ("the Extension Study").

Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to €7.5 million (\$9.1 million) and \$1.1 million, respectively. In addition, the Stock Issuance Agreement provided that, beginning with the quarter ended March 31, 2013, Nordic was entitled to receive quarterly stock dividends on its shares of Series A-5 convertible preferred stock, payable in shares of our Series A-6 convertible preferred stock, having an aggregate value of up to €7.5 million (\$9.1 million) and \$0.8 million, or the NB-3 Accruing Dividend. The Stock Issuance Agreement further provided that in the event an initial public offering of our common stock occurred prior to June 30, 2014, any payments owed by us to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, excluding Performance Incentive Payments, for all periods of time after 2014 would change 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. As we completed our initial public offering on June 11, 2014, payments owed to Nordic under the Stock Issuance Agreement have been paid in cash for all periods after June 11, 2014.

Prior to the issuance of shares of stock to Nordic in satisfaction of the NB-3 Accruing Dividend, the liability to issue shares of stock was accounted for as a liability on our balance sheet, based upon the fair value of our series A-6 convertible preferred stock as determined using PWERM. Changes in the fair value from the date of accrual to the date of issuance of shares of our series A-6 convertible preferred stock are recorded as a gain or loss in other (expense) income in the statement of operations.

We recognize research and development expense for the amounts due to Nordic under the Work Statement NB-3 ratably over the estimated per patient treatment periods beginning upon enrollment or over a nine-month and 19-month period, respectively. We recorded \$9.6 million and \$4.5 million of

## Edgar Filing: Radius Health, Inc. - Form 10-K

### Table of Contents

research and development expense during the year ended December 31, 2014 and 2013 for per patient costs incurred for patients that had enrolled in the Extension Study and Second Extension.

As of December 31, 2014, we had a liability of \$5.9 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

*Abaloparatide-TD Phase 2 Clinical Trial* On July 26, 2012, we entered into a Letter of Intent, or the Phase 2 Letter of Intent with Nordic, which provided that we and Nordic would, subject to our compliance with certain requirements of our certificate of incorporation and applicable securities law, negotiate in good faith to enter into a Work Statement NB-2, or the Work Statement NB-2, and an amendment to the Amended and Restated Stock Issuance Agreement.

On February 21, 2013, we entered into Work Statement NB-2. Pursuant to the Work Statement NB-2, Nordic provided clinical trial services relating to the Phase 2 clinical trial of abaloparatide-TD, or the Phase 2 Clinical Trial. Payments in cash under the Work Statement NB-2 are denominated in both euros and U.S. dollars and total up to €3.6 million (\$4.4 million) and \$0.3 million, respectively. In addition, pursuant to the Stock Issuance Agreement, Nordic was entitled to shares of our Series A-6 convertible preferred stock payable as dividends on the shares of Series A-5 convertible preferred stock held by Nordic, having an aggregate value of up to \$2.9 million. In December 2013, we issued Nordic 32,215 shares of our Series A-6 convertible preferred stock, which constituted all shares of Series A-6 convertible preferred stock due in connection with Work Statement NB-2.

We recognized 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 nil, \$4.1 million and \$1.4 million of research and development expense during the years ended December 31, 2014, 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 preparatory and other start-up costs to initiate the Phase 2 Clinical Trial during the year ended December 31, 2012. As of December 31, 2014, all obligations due to Nordic under Work Statement NB-2 had been paid.

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 \$1.3 million, \$3.9 million, and \$6.0 million for pass through costs during years ended December 31, 2014, 2013, and 2012, respectively.

We estimate that our future cash obligations to Nordic in relation to Work Statement NB-1 and Work Statement NB-3 will approximate the following as of December 31, 2014 (in thousands):

	TOTAL(1)		LESS THAN 1 YEAR(1)		1 - 3 YEARS(1)		MORE THAN 4 - 5 YEARS			
	EURO DENOMINATED PAYMENTS		EURO DENOMINATED PAYMENTS		EURO DENOMINATED PAYMENTS		EURO DENOMINATED PAYMENTS			
	USD	USD	USD	USD	USD	USD	USD	USD		
	EUR EQUIVALENT PAYMENTS	EUR EQUIVALENT PAYMENTS	EUR EQUIVALENT PAYMENTS	EUR EQUIVALENT PAYMENTS	EUR EQUIVALENT PAYMENTS	EUR EQUIVALENT PAYMENTS	EUR EQUIVALENT PAYMENTS	EUR EQUIVALENT PAYMENTS		
Work Statement NB-1	€4,351	\$ 5,265	248	€4,351	\$ 5,265	248	€	\$	\$	\$
Work Statement NB-3	4,440	5,373	4,300	3,165	3,830	4,300	1,275	1,543		
<b>Total Payments</b>	<b>€8,791</b>	<b>\$ 10,638</b>	<b>4,548</b>	<b>€7,516</b>	<b>\$ 9,095</b>	<b>4,548</b>	<b>€1,275</b>	<b>\$ 1,543</b>	<b>\$</b>	<b>\$</b>

(1)

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.

(2) USD equivalent is based upon the noon buying rate published by the Board of Governors of the Federal Reserve on December 31, 2014.

Table of Contents

***License Agreement Obligations***

*Abaloparatide*

In September 2005, we exclusively licensed the worldwide rights (except Japan) to abaloparatide and analogs from an affiliate of Ipsen Pharma SAS, or Ipsen, including US Patent No. 5,969,095 (statutory term expires March 29, 2016) entitled "Analogues of Parathyroid Hormone" that claims abaloparatide and US Patent No. 6,544,949, (statutory term expires March 29, 2016) entitled "Analogues of Parathyroid Hormone" that claims abaloparatide and US Patent No. 6,544,949, (effective filing date March 29, 1996, statutory term expires March 29, 2016), entitled "Analogues of Parathyroid Hormone" that claims methods of treating osteoporosis using abaloparatide and pharmaceutical compositions comprising abaloparatide, and the corresponding foreign patents and continuing patent applications. European Patent No. 0847278, which was included in the license from Ipsen and claimed the composition of matter of abaloparatide, lapsed due to Ipsen's failure to pay annuities. We are pursuing restoration of those rights. To date, the patent rights in Finland, France, Germany, Portugal, Spain and United Kingdom have been restored. We believe that the data and market exclusivity provided in Europe for a new chemical entity, coupled with the need for a potential competitor to conduct clinical trials will likely provide a longer barrier to entry than the patent protection provided by the original European patent term, which would have expired in 2016, plus a five year maximum Supplemental Protection Certificate.

We also 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 (statutory term expires October 3, 2027, and may be extended to March 26, 2028 with 175 days of patent term adjustment due to delays in patent prosecution by the United States Patent and Trademark Office, or USPTO), US Patent No. 8,148,333 (statutory term expires October 3, 2027 and may be extended to November 8, 2027 with 36 days of patent term adjustment due to delays in patent prosecution by the USPTO) and related patents and patent applications both in the United States and worldwide that cover the method of treating osteoporosis using the Phase 3 Clinical Trial dosage strength and form. A corresponding European application is pending with claims to the intended therapeutic formulation for abaloparatide-SC. Examination has been requested, but substantive examination has not yet commenced. Upon grant, this patent could be validated in any designated contracting or extension states and potentially could be considered for a Supplemental Protection Certificate depending upon the timing of its grant. Related cases granted in China, Australia, Singapore, Japan, Israel, Mexico, New Zealand, Russia and Ukraine, and currently pending in Europe, Canada, Brazil, Singapore, South Korea, India, Norway, and Hong Kong will have a patent expiration date of 2027. Patent applications which cover various aspects of abaloparatide for microneedle application are pending in the United States, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, New Zealand, Russia, Singapore, and Ukraine. Any patents that might issue from these applications will have an expiration date in 2032.

In consideration for the rights to abaloparatide and in recognition of certain milestones having been met to date, we have paid to Ipsen an aggregate amount of \$1.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. The range of milestone payments that could be paid under the agreement is €10.0 million to €36.0 million (\$12.1 million to \$43.6 million). Should abaloparatide be approved and subsequently become commercialized, we or our sublicensees will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense abaloparatide to a third party, we are obligated to pay a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The

Table of Contents

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. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

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

**RAD1901**

We exclusively licensed the worldwide rights to RAD1901 from Eisai Co. Ltd., or Eisai. In particular, we have licensed US Patent No. 7,612,114 (statutory term expires December 25, 2023 and may be 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 (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 be approved and subsequently become commercialized, we will be obligated to pay to Eisai a royalty in a variable mid-single digit range based on net sales of the product on a country-by-country basis for a period that expires on the later of (1) the date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the product is not covered by data protection clauses, and the sales of lawful generic version of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated. The latest valid claim is expected to expire, barring any extension thereof, on August 18, 2026. The royalty rate shall then be subject to reduction and the royalty obligation will expire at such time as sales of lawful generic version of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. We were also granted the right to sublicense with prior written approval from Eisai. If we sublicense RAD1901 to a third party, we will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees we receive from such sublicensee and royalties in a variable mid-single digit range based on net sales of the sublicensee. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

***Net Operating Loss Carryforwards***

As of December 31, 2014, we had federal and state net operating loss carryforwards of approximately \$319.7 million and \$246.5 million, respectively, the use of which may be limited, as described below. If not utilized, the net operating loss carryforwards will expire at various dates through 2034.

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



Table of Contents

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

***Off-Balance Sheet Arrangements***

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

**Recently Adopted Accounting Standards**

In July 2013, the Financial Accounting Standards Board ("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 under ASU 2013-11 were effective for interim and annual fiscal periods beginning after December 15, 2013, with early adoption permitted. We adopted ASU 2013-11 on January 1, 2014. Its adoption did not have a material impact on our results of operations, financial position, or cash flows.

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

**New Accounting Standards**

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). ASU 2014-15 provides guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The amendments under ASU 2014-15 are effective for interim and annual fiscal periods beginning after December 15, 2016, with early adoption permitted. We plan to adopt ASU 2013-12 on January 1, 2015. We do not expect the adoption to have a material impact on our results of operations, financial position or cash flows.

Table of Contents

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

We are exposed to market risk related to changes in interest rates. As of December 31, 2014 and 2013, we had cash, cash equivalents, and marketable securities of \$105.3 million and \$12.3 million, respectively, consisting of money market funds, domestic corporate debt securities, domestic corporate commercial paper, and cash equivalents. This exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10 percent change in interest rates would not have a material effect on the fair market value of our portfolio. We generally have the ability to hold our short-investments until maturity, and therefore we would not expect our operating results or cash flows to be affected by any significant degree by the effect of a change in market interest rates on our investments. We carry our investments based on publicly available information. As of December 31, 2014 and 2013, we do not have any hard to value investment securities or securities for which a market is not readily available or active.

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

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

Table of Contents

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

**FINANCIAL STATEMENTS**

**Radius Health, Inc.**

**Index to Financial Statements**

	<b>PAGE</b>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>106</u>
<u>Balance Sheets as of December 31, 2014 and 2013</u>	<u>107</u>
<u>Statements of Operations and Comprehensive Loss for the years ended December 31, 2014, 2013 and 2012</u>	<u>108</u>
<u>Statements of Convertible Preferred Stock, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2014, 2013 and 2012</u>	<u>109</u>
<u>Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012</u>	<u>111</u>
<u>Notes to Financial Statements</u>	<u>112</u>

Table of Contents

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of Radius Health, Inc.

We have audited the accompanying balance sheets of Radius Health, Inc. as of December 31, 2014 and 2013, and the related statements of operations and comprehensive loss, convertible preferred stock, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Radius Health, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Radius Health Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 10, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 10, 2015

Table of Contents**Radius Health, Inc.****Balance Sheets****(In thousands, except share and per share amounts)**

	<b>December 31, 2014</b>	<b>December 31, 2013</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 28,518	\$ 12,303
Marketable securities	76,758	
Prepaid expenses and other current assets	2,057	334
Total current assets	107,333	12,637
Property and equipment, net	842	76
Other assets	242	45
Total assets	\$ 108,417	\$ 12,758
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 2,292	\$ 300
Accrued expenses and other current liabilities	18,267	22,007
Current portion of note payable, net of discount		13,005
Total current liabilities	20,559	35,312
Note payable, net of current portion and discount	24,394	
Warrant liability		1,945
Commitments and contingencies		
Series B-2 Convertible Preferred Stock, \$.0001 par value; no shares and 655,000 shares authorized, no shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		
Series B Convertible Preferred Stock, \$.0001 par value; no shares and 980,000 shares authorized, no shares and 701,235 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		43,892
Series A-1 Convertible Preferred Stock, \$.0001 par value; no shares and 1,000,000 shares authorized, no shares and 939,612 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		78,737
Series A-2 Convertible Preferred Stock, \$.0001 par value; no shares and 983,213 shares authorized, no shares and 983,208 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		93,977
Series A-3 Convertible Preferred Stock, \$.0001 par value; no shares and 142,230 shares authorized, no shares and 142,227 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		12,232
Series A-4 Convertible Preferred Stock, \$.0001 par value; no shares and 4,000 shares authorized, no shares and 3,998 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		271
Series A-5 Convertible Preferred Stock, \$.0001 par value; no shares and 7,000 shares authorized, no shares and 6,443 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		525
Series A-6 Convertible Preferred Stock, \$.0001 par value; no shares and 800,000 shares authorized, no shares and 496,111 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		23,168
Stockholders' equity (deficit):		
Common stock, \$.0001 par value; 200,000,000 shares and 100,000,000 shares authorized, 32,924,535 shares and 385,664 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		3
Additional paid-in-capital	407,720	
Accumulated other comprehensive loss	(21)	
Accumulated deficit	(344,238)	(277,301)
Total stockholders' equity (deficit)	63,464	(277,301)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 108,417	\$ 12,758

See accompanying notes to financial statements.

Table of Contents**Radius Health, Inc.****Statements of Operations and Comprehensive Loss****(In thousands, except share and per share amounts)**

	<b>December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
<b>OPERATING EXPENSES:</b>			
Research and development	\$ 45,719	\$ 60,536	\$ 54,961
General and administrative	13,674	6,829	9,469
Loss from operations	(59,393)	(67,365)	(64,430)
<b>OTHER (EXPENSE) INCOME:</b>			
Other (expense) income, net	(510)	9,085	(2,095)
Loss on retirement of note payable	(203)		
Interest income	94	30	64
Interest expense	(2,467)	(2,440)	(2,667)
<b>NET LOSS</b>	<b>\$ (62,479)</b>	<b>\$ (60,690)</b>	<b>\$ (69,128)</b>
<b>OTHER COMPREHENSIVE LOSS, NET OF TAX:</b>			
Unrealized loss from available-for-sale securities	(21)		(5)
<b>COMPREHENSIVE LOSS</b>	<b>\$ (62,500)</b>	<b>\$ (60,690)</b>	<b>\$ (69,133)</b>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS BASIC AND DILUTED</b> (Note 12)	<b>\$ (71,479)</b>	<b>\$ (78,161)</b>	<b>\$ (83,120)</b>
<b>LOSS PER SHARE:</b>			
Basic and diluted	\$ (4.04)	\$ (203.91)	\$ (225.71)
<b>WEIGHTED AVERAGE SHARES:</b>			
Basic and diluted	17,699,487	383,310	368,261

See accompanying notes to financial statements.

Table of Contents

**Radius Health, Inc.**  
**Statements of Convertible Preferred Stock, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
(In thousands, except share and per share amounts)

	Series B-2		Series B		Series A-1		Series A-2		Series A-3		Series A-4		Series A-5		Series A-6	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance at December 31, 2011					939,612	\$ 65,675	983,208	\$ 79,979	142,227	\$ 10,208	3,998	\$ 271	6,443	\$ 525		\$
Net loss																
Unrealized loss on available-for-sale securities																
Stock options exercised																
Issuance of convertible preferred stock																
Retention of dividends on convertible preferred stock						6,282		6,735		974						
Stock-based compensation expense																
Balance at December 31, 2012					939,612	\$ 71,957	983,208	\$ 86,714	142,227	\$ 11,182	3,998	\$ 271	6,443	\$ 525		\$
Net loss																
Stock options exercised																
Issuance of convertible preferred stock			701,235	41,514											496,111	23,160
Retention of dividends on convertible preferred stock				2,378		6,780		7,263		1,050						
Stock-based compensation expense																
Balance at December 31, 2013		\$	701,235	\$ 43,892	939,612	\$ 78,737	983,208	\$ 93,977	142,227	\$ 12,232	3,998	\$ 271	6,443	\$ 525	496,111	\$ 23,160
Net loss																
Unrealized loss on available-for-sale securities																
Issuance of convertible preferred stock	448,060	26,152													186,847	10,100
Retention of dividends on convertible preferred stock		685		1,515		3,084		3,246		470						
Issuance of warrants																
Exercise of warrants																



Edgar Filing: Radius Health, Inc. - Form 10-K

Stock options exercised																	
Stock-based compensation expense																	
Balance of common stock, convertible preferred stock to common stock classification warrant liability to additional paid in capital	(448,060)	(26,837)	(701,235)	(45,407)	(939,612)	(81,821)	(983,208)	(97,223)	(142,227)	(12,702)	(3,998)	(271)	(6,443)	(525)	(682,958)	(33,271)	
Balance at December 31, 2014	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	

See accompanying notes to financial statements.

Table of Contents

**Radius Health, Inc.**  
**Statements of Convertible Preferred Stock, Redeemable Convertible**  
**Preferred Stock and Stockholders' Equity (Deficit) (Continued)**  
(In thousands, except share and per share amounts)

	Common Stock		Stockholders' Equity (Deficit)			Total Stockholders' (Deficit) Equity				
			Additional Paid-In- Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit					
	Shares	Amount				Amount	Amount	Amount	Amount	
Balance at December 31, 2011	283,047	\$	\$	2,744	\$	5	\$	(122,359)	\$	(119,610)
Net loss								(69,128)		(69,128)
Unrealized loss from available-for-sale securities								(5)		(5)
Stock options exercised	97,281			279						279
Issuance of preferred stock										
Accretion of dividends on preferred stock				(4,818)				(9,174)		(13,992)
Stock-based compensation expense				1,795						1,795
Balance at December 31, 2012	380,328	\$	\$		\$		\$	(200,661)	\$	(200,661)
Net loss								(60,690)		(60,690)
Stock options exercised	5,336			13						13
Issuance of preferred stock										
Accretion of dividends on preferred stock				(1,521)				(15,950)		(17,471)
Stock-based compensation expense				1,508						1,508
Balance at December 31, 2013	385,664	\$	\$		\$		\$	(277,301)	\$	(277,301)
Net loss								(62,479)		(62,479)
Unrealized loss from available-for-sale securities								(21)		(21)
Issuance of preferred stock										
Accretion of dividends on preferred stock				(4,542)				(4,458)		(9,000)
Issuance of warrants				41						41
Exercise of warrants	20,435									
Stock options exercised	49,382			170						170
Stock-based compensation expense				7,070						7,070
Issuance of common stock, net	10,141,268		1	103,803						103,804
Conversion of convertible preferred stock into common stock	22,327,786		2	298,061						298,063
Reclassification of warrant liability to additional paid in capital				3,117						3,117
Balance at December 31, 2014	32,924,535	\$	3	\$ 407,720	\$	(21)	\$	(344,238)	\$	63,464

See accompanying notes to financial statements.

Table of Contents**Radius Health, Inc.****Statements of Cash Flows****(In thousands)**

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
<b>CASH FLOWS USED IN OPERATING ACTIVITIES:</b>			
Net loss	\$ (62,479)	\$ (60,690)	\$ (69,128)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	77	27	44
Amortization of premium on short-term investments, net	429	27	101
Stock-based compensation expense	7,070	1,508	1,795
Research and development expense settled in stock	2,717	13,118	15,067
Change in fair value of other current assets, warrant liability and other liability	505	(9,087)	2,069
Non-cash interest	295	387	449
Loss on retirement of note payable	57		
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(1,639)	1,721	4,623
Other long-term assets	(105)		35
Accounts payable	1,991	(250)	237
Accrued expenses and other current liabilities	2,737	8,222	1,550
Net cash used in operating activities	(48,345)	(45,017)	(43,158)
<b>CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(857)	(2)	(40)
Purchases of marketable securities	(97,678)	(17,070)	(18,989)
Sales and maturities of marketable securities	20,470	21,043	46,464
Net cash (used in) provided by investing activities	(78,065)	3,971	27,435
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>			
Proceeds from exercise of stock options	170	13	279
Net proceeds from the issuance of preferred stock, net	27,368	42,870	
Proceeds from note payable, net	24,555		12,500
Proceeds from issuance of common stock, net	103,804		
Deferred financing costs	(116)		(31)
Payments on note payable	(13,156)	(8,187)	(3,500)
Net cash provided by financing activities	142,625	34,696	9,248
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	16,215	(6,350)	(6,475)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	12,303	18,653	25,128
CASH AND CASH EQUIVALENTS AT END OF YEAR	\$ 28,518	\$ 12,303	\$ 18,653
<b>SUPPLEMENTAL DISCLOSURES:</b>			
Cash paid for interest	\$ 1,971	\$ 1,796	\$ 1,801

Edgar Filing: Radius Health, Inc. - Form 10-K

NON-CASH FINANCING ACTIVITIES:

Accretion of dividends on preferred stock	\$ 9,000	\$ 17,471	\$ 13,992
---	----------	-----------	-----------

Reclassification of preferred stock to common stock	\$ 298,063	\$	\$
---	------------	----	----

Fair value of series A-6 convertible preferred stock issued as settlement of liability	\$ 10,109	\$ 23,168	\$
--	-----------	-----------	----

Fair value of warrants issued	\$ 1,552	\$ 1,356	\$ 379
-------------------------------	----------	----------	--------

See accompanying notes to financial statements.

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements**

**1. Nature of Business**

Radius Health, Inc. ("Radius" or the "Company") is a science-driven biopharmaceutical company focused on developing new therapeutics for patients with osteoporosis as well as other serious endocrine-mediated diseases. The Company's lead investigational product candidate is the investigational drug abaloparatide (BA058), a bone anabolic for potential use in the reduction of fracture risk in postmenopausal women with severe osteoporosis delivered via subcutaneous injection, which the Company refers to as abaloparatide-SC and is currently in Phase 3 development. The Company is leveraging its investment in abaloparatide-SC to develop a line extension that is designed to improve patient convenience by enabling administration of abaloparatide through an investigational short-wear-time patch, which the Company refers to as abaloparatide-TD. The Company has recently completed a successful Phase 2 proof of concept study of abaloparatide-TD. The Company also believes that, subject to further research and development, abaloparatide may have potential applications across a variety of skeletal or bone related diseases or medical conditions.

The Company's current clinical product portfolio also includes the investigational drug RAD1901, a selective estrogen receptor down regulator/degrader ("SERD") and RAD140, a nonsteroidal selective androgen receptor modulator ("SARM"). The Company is developing RAD1901 at higher doses for potential use in the treatment of metastatic breast cancer and other estrogen receptor mediated oncology applications. At low doses, RAD1901 acts as a selective estrogen-receptor modulator ("SERM"). Low-dose RAD1901 has shown potential to be effective for the treatment of vasomotor symptoms such as hot flashes in a successful Phase 2 proof of concept study. RAD140 is a nonsteroidal selective androgen receptor modulator, or SARM, that resulted from an internal drug discovery program focused on the androgen receptor pathway which is highly expressed in many breast cancers. Due to its receptor and tissue selectivity, potent oral activity and long duration half-life, RAD140 could have clinical potential in the treatment of breast cancer or possibly other conditions where androgen modulation may offer therapeutic benefit.

The Company is subject to the risks associated with emerging companies with a limited operating history, including dependence on key individuals, a developing business model, the necessity of securing regulatory approval to market its investigational product candidates, market acceptance of the Company's investigational product candidates, competition for its investigational product candidates, and the continued ability to obtain adequate financing to fund the Company's future operations. The Company has incurred losses and expects to continue to incur additional losses for the foreseeable future. As of December 31, 2014, the Company had an accumulated deficit of \$344.2 million, and total cash, cash equivalents and marketable securities of \$105.3 million. On January 28, 2015, the Company completed a public offering whereby the Company sold 4,600,000 shares of common stock at a price of \$36.75 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$158.6 million.

The Company believes that the aggregate proceeds from the offering on January 28, 2015, together with its cash, cash equivalents and marketable securities as of December 31, 2014, will be sufficient to fund its operations into the fourth quarter of 2016. The Company expects to finance the future development costs of abaloparatide-SC, abaloparatide-TD and RAD1901 with its existing cash and cash equivalents and marketable securities, or through strategic financing opportunities, future offerings of our equity, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company fails to obtain additional future capital, it may be unable to

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**1. Nature of Business (Continued)**

complete its planned preclinical and clinical trials and obtain approval of certain investigational product candidates from the U.S. Food and Drug Administration or other foreign regulatory authorities.

**2. Summary of Significant Accounting Policies**

*Initial and Additional Public Offering* On June 11, 2014, the Company completed its initial public offering whereby the Company sold 6,500,000 shares of common stock at a price of \$8.00 per share. The shares began trading on the NASDAQ Global Market on June 6, 2014. In connection with the offering, all outstanding shares of our convertible preferred stock converted into 19,465,132 shares of common stock and 2,862,654 shares of common stock were issued in satisfaction of accumulated dividends accrued on the preferred stock. In addition, all outstanding warrants to purchase shares of A-1 convertible preferred stock and warrants to purchase shares of series B-2 convertible preferred stock were converted into the right to purchase 149,452 shares of common stock and the Company's warrant liability was reclassified to equity.

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

In connection with the completion of its initial public offering, the Company filed an amended and restated certificate of incorporation, which, among other things, changed the number of authorized shares of common stock to 200,000,000 shares.

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

*Reverse Stock Split* On April 24, 2014, the Company effected a reverse stock split of the Company's common stock. The number of authorized shares of the Company's common stock and the par value did not change. Pursuant to the stock split, every 2.28 shares of the Company's issued and outstanding common stock were automatically combined into one issued and outstanding share of the Company's common stock. All shares and per share amounts in the financial statements and accompanying notes have been retroactively adjusted to give effect to the reverse stock split.

*Use of Estimates* The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires the Company's management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued as additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated up to the date of issuance of these financial statements.

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

*Cash Equivalents* The Company considers all highly liquid investment instruments with an original maturity when purchased of three months or less to be cash equivalents. Cash equivalents at December 31, 2014 and 2013 are primarily comprised of money market funds.

*Marketable Securities* All investment instruments with an original maturity date, when purchased, in excess of three months have been classified as current marketable securities. The Company classifies securities that are available to fund current operations as current assets. These marketable securities are classified as available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are included within other comprehensive (loss) income within stockholders' equity (deficit). The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. The Company periodically reviews the portfolio of securities to determine whether an other-than-temporary impairment has occurred. No such losses have occurred to date. There were no realized gains or losses on the sale of securities for the years ended December 31, 2014 and 2013.

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

- Level 1 Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2 Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

*Concentrations of Credit Risk and Off-Balance-Sheet Risk* Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents and available-for-sale marketable securities. The Company mitigates its risk with respect to cash and cash equivalents and marketable securities by maintaining its deposits and investments at high-quality financial institutions. The Company invests any excess cash in money market funds and other securities, and the management of these investments is not discretionary on the part of the financial institution. The Company's credit exposure on its marketable securities is limited by its diversification among United States government and agency debt securities. The Company has no significant off-balance-sheet risks such as foreign exchange contracts, option contracts, or other hedging arrangements.

*Property and Equipment* Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets.

*Research and Development Costs* The Company accounts for research and development costs by expensing such costs to operations as incurred. Research and development costs primarily consist of

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

clinical testing costs, including payments in cash and stock made to contract research organizations, 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.

*Licensing Agreements* Costs associated with licensing early stage technology are expensed as incurred, and are included in research and development expenses.

*Impairment of Long-Lived Assets* The Company evaluates long-lived assets for potential impairment when there is evidence that events or changes in circumstances have occurred that indicate that the carrying amount of a long-lived asset may not be recovered. Recoverability of these assets is assessed based on the undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends, and product development cycles. Impairment in the carrying value of each asset is assessed when the undiscounted expected future cash flows derived from the asset are less than its carrying value.

An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows. No impairment charges have been recognized since the Company's inception.

*Segment Information* Operating segments are defined as components of an enterprise engaged in business activities for which discrete financial information is available and regularly reviewed by the chief decision maker in determining how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating segment and operates in one geographic area.

*Income Taxes* The Company recognizes deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, as well as operating loss and tax credit carry forwards. The Company measures deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which those temporary differences and carryforwards are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect on deferred tax assets and liabilities as a result of a change in tax rates is recognized as income in the period that includes the enactment date.

The Company uses judgment to determine the recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Any material interest and penalties related to unrecognized tax benefits are recognized in income tax expense.

Due to uncertainty surrounding the realization of the favorable tax attributes in future tax returns the Company has recorded a full valuation allowance against otherwise realizable net deferred tax assets as of December 31, 2014 and 2013.

*Financial Instruments Indexed to and Potentially Settled in the Company's Common Stock* The Company evaluates all financial instruments issued in connection with its debt borrowings and equity



Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

offerings when determining the proper accounting treatment for such instruments in the Company's financial statements. The Company considers a number of generally accepted accounting principles to determine such treatment and evaluates the features of the instrument to determine the appropriate accounting treatment. The Company utilizes the Black-Scholes method or other appropriate methods to determine the fair value of its derivative financial instruments. Key valuation factors in determining the fair value include, but are not limited to, the current stock price as of the date of measurement, the exercise price, the remaining contractual life, expected volatility for the instrument and the risk-free interest rate. For financial instruments that are determined to be classified as liabilities on the balance sheet, changes in fair value are recorded as a gain or loss in the Company's statement of operations, with the corresponding amount recorded as an adjustment to the liability on its balance sheet.

*Stock-Based Compensation* The Company measures stock-based compensation cost at the accounting measurement date based on the fair value of the option, and recognizes the expense related to awards to employees on a straight-line basis over the requisite service period of the option, which is typically the vesting period. The Company estimates the fair value of each option using a Black-Scholes option pricing model that takes into account the fair value of its common stock, the exercise price, the expected life of the option, the expected volatility of the Company's common stock, expected dividends on the Company's common stock, and the risk-free interest rate over the expected life of the option. Due to the limited trading history of the Company's common stock since its June 2014 initial public offering, the Company uses 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 Company's 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. The Company has never declared or paid any cash dividends on its common stock and does not expect to do so in the foreseeable future. Accordingly, the Company utilizes 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.

The Company applies an estimated forfeiture rate to current period expense to recognize compensation expense only for those awards expected to vest. Estimated forfeitures are based upon historical data, adjusted for known trends, and will be adjusted 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 for options granted to consultants is also determined based upon the fair value of the options issued, as determined by the Black-Scholes option pricing model and recognized on an accelerated basis. However, the unvested portion of such option grants is re-measured at each reporting period, until such time as the award is fully vested.

*Net Loss Per Common Share* Net loss per common share is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. Prior to the initial public offering, all of the Company's series of preferred stock contained participation rights in any dividend paid by the Company and were deemed to be participating securities. Net income available to common shareholders and

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

participating preferred shares was allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss.

Diluted net income per share is computed using the more dilutive of (a) the two-class method, or (b) the if-converted method. Prior to the initial public offering, the Company allocated net income first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of common shares outstanding gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and, prior to the Company's initial public offering, potential issuance of stock upon the issuance of the Company's series A-6 convertible preferred stock ("Series A-6") as settlement of the liability to Nordic Bioscience ("Nordic"). Common equivalent shares are excluded from the computation of diluted net income per share if their effect is anti-dilutive.

*Comprehensive (Loss) Income* Comprehensive (loss) income refers to revenues, expenses, gains and losses that are excluded from net income, as these amounts are recorded directly as an adjustment to stockholders' deficit, net of tax. The Company's other comprehensive (loss) income is comprised of unrealized gains (losses) on its available-for-sale securities.

*Recently Adopted Accounting Standards* In July 2013, the Financial Accounting Standards Board ("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 under ASU 2013-11 are effective for interim and annual fiscal periods beginning after December 15, 2013, with early adoption permitted. The adoption of ASU 2013-11 did not have a material impact on the Company's 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 but the amended definition of a public business entity is used in ASU 2014-01 and those that follow. The adoption of ASU 2013-12 did not have a material impact on the Company's results of operations, financial position or cash flows.

*Accounting Standards Updates* In August 2014, the FASB issued Accounting Standards Update No. 2014-15 *Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). ASU 2014-15 provides guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The amendments under ASU 2014-15 are effective for interim and annual fiscal periods beginning after December 15, 2016, with early adoption permitted. The Company plans to adopt ASU 2014-15 on January 1, 2015. The Company does not expect adoption of

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

ASU 2014-15 will have a material impact on the Company's results of operations, financial position or cash flows.

**3. Marketable Securities**

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

	December 31, 2014		
	Amortized	Gross	Gross
	Cost Value	Unrealized	Unrealized
		Gains	Losses
			Fair Value
<b>Cash and cash equivalents:</b>			
Cash	\$ 1,519	\$	\$ 1,519
Money market funds	23,994		23,994
Domestic corporate debt securities	3,005		3,005
<b>Total</b>	<b>\$ 28,518</b>	<b>\$</b>	<b>\$ 28,518</b>

**Marketable securities:**

Domestic corporate debt securities	69,542		(33)	69,509
Domestic corporate commercial paper	7,237	12		7,249
<b>Total</b>	<b>\$ 76,779</b>	<b>\$ 12</b>	<b>\$ (33)</b>	<b>\$ 76,758</b>

There were no debt securities that had been in an unrealized loss position for more than 12 months as of December 31, 2014. There were 34 debt securities in an unrealized loss position for less than 12 months at December 31, 2014. The aggregate unrealized loss on these securities as of December 31, 2014 was less than \$34 thousand and the fair value was \$68.9 million. As it was not more likely than not that the Company would be required to sell these securities before the recovery of their amortized cost basis, which may be maturity, the Company did not consider these investments to be other-than-temporarily impaired as of December 31, 2014.

The contractual term to maturity of all marketable securities held by the Company as of December 31, 2014 is less than one year.

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****4. Property and Equipment**

Property and equipment consists of the following (in thousands):

	Estimated Useful Life (In Years)	December 31,	
		2014	2013
Furniture and fixtures	5	\$ 167	\$ 68
Computer equipment and software	3	230	286
Manufacturing equipment	10	598	
Leasehold improvements	Shorter of useful life or remaining lease term	16	505
		1,011	859
Less accumulated depreciation and amortization		(169)	(783)
Property and equipment, net		\$ 842	\$ 76

During the year ended December 31, 2014, the Company retired \$0.7 million of property and equipment. The retirement was primarily due to the disposal of leasehold improvements and other property as a result of the Company's office relocation. All assets were fully depreciated prior to retirement.

**5. Accrued Expenses and Other Current Liabilities**

Accrued expenses consist of the following (in thousands):

	December 31,	
	2014	2013
Research costs Nordic(1)	\$ 11,536	\$ 17,998
Research costs other	3,336	1,599
Payroll and employee benefits	1,659	1,005
Professional fees	1,304	426
Accrued interest on notes payable	234	852
Other	198	127
Total accrued expenses and other current liabilities	\$ 18,267	\$ 22,007

---

(1) Includes amounts accrued ratably over the estimated per patient treatment period under the Nordic Work Statement NB-1, Work Statement NB-2 and Work Statement NB-3. Amounts do not include pass-through costs which are expensed as incurred or upon delivery. See note 10 for additional information.

**6. Loan and Security Agreement**

On May 23, 2011, the Company entered into a loan and security agreement (the "Loan and Security Agreement") with Oxford Finance LLC and General Electric Capital Corporation (collectively, the "Lender") pursuant to which the Lender agreed to lend the Company up to \$25.0 million. Upon entering into the Loan and Security Agreement, the Company borrowed \$6.3 million from the Lender

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**6. Loan and Security Agreement (Continued)**

on May 23, 2011 ("Term Loan A"), \$6.3 million on November 21, 2011 ("Term Loan B") and an additional \$12.5 million on May 29, 2012 ("Term Loan C"). The Company's obligations under the Loan and Security Agreement are secured by a first priority security interest in substantially all of the assets of the Company.

Interest on the outstanding Term Loan A was payable on a monthly basis through and including December 1, 2011. Principal and interest payments on Term Loan A was payable in 36 equal monthly installments beginning December 1, 2011 through November 1, 2014, with a final balloon payment of \$0.6 million due upon maturity on November 22, 2014. Interest was payable on Term Loan A at an annual interest rate of 10.16%. Interest on the outstanding Term Loan B was payable on a monthly basis through and including June 1, 2012. Principal and interest payments on Term Loan B was payable in 30 equal monthly installments beginning June 1, 2012, through November 1, 2014, with a final balloon payment of \$0.6 million due upon maturity on November 22, 2014. Interest was payable on Term Loan B at an annual interest rate of 10%. Interest on Term Loan C was payable on a monthly basis through, and including, November 1, 2012. Principal and interest payments on Term Loan C was payable in 24 monthly installments beginning December 1, 2012, through November 1, 2014 with a final balloon payment of \$1.3 million upon maturity on November 22, 2014. Interest is payable on Term Loan C at an annual interest rate of 10%.

Per the Loan and Security Agreement, upon the last payment date of the amounts borrowed under the Loan and Security Agreement, whether on the maturity date of one of the Term Loans, on the date of any prepayment or on the date of acceleration in the event of a default, the Company would be required to pay the Lender a final payment fee equal to 3.5% of any of the Term Loans borrowed. In addition, if the Company repaid all or a portion of the Term Loans prior to maturity, it would pay the Lender a prepayment fee of three percent of the total amount prepaid if the prepayment occurs prior to the first anniversary of the funding of the relevant Term Loan, two percent of the total amount prepaid if the prepayment occurs between the first and second anniversary of the funding of the relevant Term Loan, and one percent of the total amount prepaid if the prepayment occurs on or after the second anniversary of the funding of the relevant Term Loan.

In connection with each Term Loan, the Company issued warrants to the Lender to purchase 12,280 shares of the Company's Series A-1 convertible preferred stock (the "Warrants") at an exercise price per share of \$81.42. The Warrants were initially classified as liabilities in the Company's balance sheet and were re-measured at their estimated fair value through completion of the Company's initial public offering. The changes in fair value are recorded as other (expense) income in the statement of operations. Upon the closing of its initial public offering and the automatic conversion of the Series A-1 convertible preferred stock into common stock, the Warrants became exercisable for up to 58,918 shares of common stock. Subsequent to the initial public offering, the Company's warrant liability was reclassified to equity.

The Warrants are immediately exercisable in whole, or in part, and will expire ten years from their issuance.

The initial fair value of the Warrants issued in connection with Term Loan A was \$182.6 thousand and was recorded as a discount to Term Loan A. The Company also paid the Lender a facility fee of \$250.0 thousand and reimbursed the Lender certain costs associated with the Loan and Security Agreement of approximately \$117.0 thousand, both of which were also recorded as a discount to Term Loan A.

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**6. Loan and Security Agreement (Continued)**

The initial fair value of the Warrants issued in connection with Term Loan B was \$177.6 thousand and was recorded as a discount to Term Loan B. The Company also reimbursed the Lender for certain costs associated with Term Loan B of approximately \$18.0 thousand, which was also recorded as a discount to Term Loan B.

The initial fair value of the Warrants issued in connection with Term Loan C was \$379.7 thousand and was recorded as a discount to Term Loan C. The Company also reimbursed the Lender for certain costs associated with the Loan and Security Agreement of approximately \$31.0 thousand, which was also recorded as a discount to Term Loan C.

On May 30, 2014, the Company entered into a Loan and Security Agreement (the "New Credit Facility"), with Solar Capital Ltd. ("Solar"), as collateral agent and a lender, and Oxford Finance LLC ("Oxford"), as a lender (the "New Lenders"), pursuant to which Solar and Oxford agreed to make available to the Company \$30.0 million in the aggregate subject to certain conditions to funding. An initial term loan was made on May 30, 2014 in an aggregate principal amount equal to \$21.0 million ("Initial Term Loan"). The Company used approximately \$9.3 million of the Initial Term Loan to repay all the amounts owed under its Loan and Security Agreement with General Electric Capital Corporation and Oxford.

The Company was initially required to make interest-only payments through June 1, 2015, and beginning on July 1, 2015, it is required to make payments of principal and accrued interest in equal monthly installments over a term of 36 months. However, the Company consummated public stock offerings resulting in the receipt of at least \$65.0 million in aggregate net cash proceeds prior to May 31, 2015. Therefore, it is permitted to make interest-only payments through December 1, 2015 rather than July 1, 2015, and beginning on January 1, 2016, the Company is required to make principal and accrued interest payments in equal monthly installments over a term of 30 months.

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

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

On July 10, 2014, the Company entered into a first amendment to the New Credit Facility ("First Amendment"). Pursuant to the terms of the First Amendment, a second term loan of \$4.0 million was drawn on July 10, 2014. The terms of the First Amendment, among other things,

provide the Company with, subject to certain customary funding conditions, additional term loans in an aggregate principal amount of \$4.0 million upon the closing of the First Amendment (the "Modified Term B Loan"). All other terms applicable to the Original Term B Loan remain applicable to the Modified Term B Loan. The Original Term B Loan is replaced by the Modified Term B Loan. The Company borrowed the full amount of the Modified Term B Loan on July 10, 2014.

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****6. Loan and Security Agreement (Continued)**

provide the Company the ability to borrow additional term loans in an aggregate amount of \$5.0 million (the "Term C Loan") at any time through December 31, 2014. In order to draw the Term C Loan, the Company must, in addition to other customary conditions, either (a) close public or private stock offerings, equity raises or strategic partner arrangements resulting in \$13.0 million in aggregate net proceeds after the closing of the First Amendment, or (b) as it relates specifically to RAD1901, complete both the maximum tolerable dose trial and enroll the first patient in the breast cancer brain metastasis trial.

Although the Company closed a public offering resulting in over \$13.0 million in aggregate net proceeds after the closing of the First Amendment, it did not exercise our right to draw the Term C Loan prior to December 31, 2014.

The future principal payments under the New Credit Facility, as amended, are as follows, as of December 31, 2014 (in thousands):

<b>Years ending December 31,</b>	<b>Principal Payments</b>
2015	\$
2016	10,000
2017	10,000
2018	5,000
	\$ 25,000

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

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

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



Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****7. Convertible Preferred Stock**

Below is a summary of the rights, preferences, and privileges of the Series B convertible preferred stock ("Series B"), Series B-2 convertible preferred stock ("Series B-2"), Series A-1 convertible preferred stock ("Series A-1"), Series A-2 convertible preferred stock ("Series A-2"), Series A-3 convertible preferred stock ("Series A-3"), Series A-4 convertible preferred stock ("Series A-4"), Series A-5 convertible preferred stock ("Series A-5") and Series A-6 convertible preferred stock ("Series A-6") (the Series A-1, Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6, collectively, the "Series A Preferred Stock") prior to the conversion of all outstanding convertible preferred stock into common stock upon completion of the Company's initial public offering on June 11, 2014.

On April 23, 2013, the Company entered into a Series B Convertible Preferred Stock and Warrant Purchase Agreement (the "Series B Purchase Agreement"), pursuant to which the Company could raise, at any time on or prior to May 10, 2013, up to approximately \$60.0 million through the issuance of (1) up to 980,000 shares of its new Series B preferred stock (the "New Series B") and (2) warrants to acquire up to approximately 1,075,000 shares of its common stock with an exercise price of \$14.004 per share. On April 23, 2013, the Company consummated a first closing under the Series B Purchase Agreement, whereby in exchange for aggregate proceeds of approximately \$43.0 million, it issued 700,098 shares of New Series B and warrants to purchase up to a total of 767,651 shares of its common stock. On May 10, 2013, the Company consummated a second closing under the Series B Purchase Agreement, whereby in exchange for aggregate proceeds of approximately \$0.1 million, it issued 1,137 shares of New Series B and warrants to purchase up to a total of 1,246 shares of its common stock. The warrants can be exercised at any time prior to the fifth anniversary of their issuance.

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

*Conversion* Any holder of the Company's preferred stock had the right, at any time or from time to time, to convert any or all of its shares of preferred stock into fully paid and non-assessable shares of the Company's common stock for each share of preferred stock converted based upon the then in effect Conversion Price ("Conversion Feature"). If the Company issued or sold any shares of its Common Stock (as defined by the Company's certificate of incorporation) or options to purchase or other rights to subscribe for such convertible or exchangeable securities, in each case other than Excluded Stock (as defined by the Company's certificate of incorporation), for a consideration per share less than the then in effect conversion price ("Dilutive Issuance") of the Company's Series A-1, A-2, A-3, B, or B-2 preferred stock, respectively, the Conversion Price for such series in effect immediately prior to each such Dilutive Issuance would automatically be reduced in accordance with the provisions set forth in the Certificate of Designations. Upon issuance of each series of the Company's preferred stock, the respective Conversion Prices were greater than the fair value of the Company's common stock at the respective commitment dates. Therefore, the Conversion Feature was

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**7. Convertible Preferred Stock (Continued)**

not considered to be a beneficial conversion feature that would require the Company to record a deemed dividend on the preferred stock. Each holder of Series B and Series B-2 shares had the right, at their option at any time, to convert any such shares of preferred stock into such number of fully paid shares of common stock as determined by dividing the original purchase price of \$61.42 by the conversion price ("Series B Optional Conversion"). The conversion price of the Series B and Series B-2 as of June 6, 2014 was \$14.004 per share and \$8.00 per share, respectively, (the "Series B Conversion Price"), which represented a conversion ratio of one share of Series B or Series B-2 into approximately 4.386 and 7.678 shares of common stock, respectively.

Each holder of Series A-1, Series A-2 and Series A-3 had the right, at their option at any time, to convert any such shares of preferred stock into such number of fully paid shares of common stock as determined by dividing the original purchase price of \$81.42 by the conversion price ("Optional Conversion"). The original conversion price of the Series A-1, Series A-2 and Series A-3 was \$18.564 per share (the "Conversion Price"), which represented a conversion ratio of one share of Series A-1, Series A-2 or Series A-3 into approximately 4.386 shares of common stock. The issuance of the Series B in April and May of 2013 and the Series B-2 in February and March of 2014 resulted in an adjustment to the Conversion Price of the Series A-1, Series A-2 and Series A-3 (the "Anti-Dilution Adjustment"). As a result of the Anti-Dilution Adjustment, the conversion price of each share of Series A-1, Series A-2 and Series A-3 was reduced to \$16.970, which represented a conversion ratio of one share of Series A-1, Series A-2 or Series A-3 into approximately 4.798 shares of common stock. This reduction of the Conversion Price did not create a beneficial conversion feature that would require the Company to record a deemed dividend on the Series A-1, Series A-2 or Series A-3 preferred stock.

Each holder of Series A-4, Series A-5 and Series A-6 had the right, at their option at any time, to convert any such shares of preferred stock into such number of fully paid shares of common stock as determined by dividing the original purchase price of \$81.42 by the conversion price. The Conversion Price of the Series A-4, Series A-5 and Series A-6 as of June 6, 2014 was \$18.564 per share, which represented a conversion ratio of one share of Series A-4, Series A-5 or Series A-6 into approximately 4.386 shares of common stock.

Upon an optional conversion, the holders of the converted Series B-2, Series B and Series A Preferred Stock were entitled to payment of all accrued, whether or not declared, but unpaid dividends in shares of the common stock of the Company at the then effective Conversion Price.

Each share of the Series B, Series B-2 and Series A Preferred Stock was automatically convertible into fully paid and non-assessable shares of common stock at the applicable conversion price (as described above) in effect upon, in the case of the Series A and Series B Preferred Stock, upon (1) a vote of the holders of at least 70% of the outstanding shares of Series B, Series B-2, Series A-1, Series A-2 and Series A-3 to convert all shares of Series B, Series B-2 and Series A Preferred Stock or (2) the common stock becoming listed for trading on a national stock exchange, and in the case of the Series B-2 Preferred Stock, upon (1) a vote of the holders of at least 70% of the outstanding shares of Series B-2 to convert all shares of Series B-2 Preferred Stock, (2) the closing of a firm commitment underwritten public offering on or prior to June 30, 2014 or (3) after June 30, 2014, the common stock becoming listed for trading on a national stock exchange ("Special Mandatory Conversion"). Upon a Special Mandatory Conversion, all accrued, whether or not declared, but unpaid dividends were to be

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**7. Convertible Preferred Stock (Continued)**

paid in cash or shares of common stock (calculated based on the then effective conversion price) at the discretion of the Company's Board of Directors.

In the event of a conversion upon the closing of a firm commitment underwritten public offering on or prior to June 30, 2014 in which the public offering price per share was less than the Series B-2 Conversion Price, then the Series B-2 Conversion Price was automatically reduced to the price equal to the public offering price.

*Redemption* Unless redemption was waived by a requisite stockholder vote or consent, the shares of Series B, Series B-2 and Series A Preferred Stock were automatically redeemable upon an event of sale of the Company. The shares of Series B, Series B-2 and Series A Preferred Stock were not redeemable at the option of the holder.

*Dividends* Holders of shares of Series B and Series B-2 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrued on a daily basis commencing on the date of issuance of the shares of Series B and Series B-2. Dividends were payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series B and Series B-2 were also entitled to dividends declared or paid on any shares of common stock.

Following payment in full of required dividends to the holders of Series B and Series B-2, holders of shares of Series A-1 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrued on a daily basis commencing on the date of issuance of the shares of Series A-1. Dividends were payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series A-1 were also entitled to dividends declared or paid on any shares of common stock.

Following payment in full of required dividends to the holders of Series B, Series B-2 and Series A-1, holders of Series A-2 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrued on a daily basis commencing on the date of issuance of the shares of Series A-2. Dividends were payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series A-2 were also entitled to dividends declared or paid on any shares of common stock.

Following payment in full of required dividends to the holders of Series B, Series B-2, Series A-1 and Series A-2, holders of Series A-3 were entitled to receive dividends at a rate of 8% per annum, compounding annually, which accrued on a daily basis commencing on the date of issuance of the shares of Series A-3. Dividends were payable, as accrued, upon liquidation, event of sale and conversion to common stock, as described above. The holders of shares of Series A-3 were also entitled to dividends declared or paid on any shares of common stock.

Without regard to the payment of required dividends to the holders of Series B, Series B-2, Series A-1, Series A-2 and Series A-3, holders of Series A-5 were entitled to receive the Series A-5 Special Accruing Dividend (as defined in the Company's certificate of incorporation) paid in shares of Series A-6 as described in note 10. Dividends were payable, as accrued, upon liquidation, event of sale and conversion to common stock, as described above. The holders of shares of Series A-5 were also entitled to dividends declared or paid on any shares of common stock.

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**7. Convertible Preferred Stock (Continued)**

Following payment in full of required dividends to the holders of Series B, Series B-2, Series A-1, Series A-2, Series A-3 and Series A-5, holders of Series A-4 and Series A-6 were entitled to receive, when, if and as declared by the Board of Directors, dividends on any shares of Series A-4 Stock or Series A-6 Stock, as the case may be, out of funds legally available for that purpose, at a rate to be determined by the Board of Directors if and when they may so declare any dividend on the Series A-4 Stock or A-6 Stock, as the case may be. Dividends were payable, as accrued, upon liquidation, event of sale, and conversion to common stock, as described above. The holders of shares of Series A-4 and Series A-6 were also entitled to dividends declared or paid on any shares of common stock.

As of June 6, 2014, the Company had accrued dividends of \$3.9 million, \$18.1 million, \$21.2 million and \$3.1 million on Series B, Series A-1, Series A-2 and Series A-3, respectively. As of June 11, 2014 the Company had accrued dividends of \$0.7 million on Series B-2. Upon completion of the Company's initial public offering, all accrued dividends were paid in shares of common stock at the then effective Conversion Price.

*Voting* The holders of Series B, Series B-2 and Series A Preferred Stock were entitled to vote together with the holders of the common stock as one class on an as-if converted basis. In addition, as long as the shares of Series A-1 were outstanding, the holders of Series A-1, voting as a separate class, had the right to elect two members of the Company's Board of Directors.

*Liquidation* The shares of Series B and Series B-2 ranked equally to other shares of Series B and Series B-2, and ranked senior to the Series A-1 and all other classes of Series A Preferred Stock. The shares of Series A-1 ranked senior to all other classes of Series A Preferred Stock. Series A-2 ranked junior to Series A-1 and senior to Series A-3, Series A-4, Series A-5 and Series A-6. Series A-3, Series A-5 and Series A-6 ranked equally but junior to Series A-1 and Series A-2 and senior to Series A-4. Series A-4 ranked senior to the Company's common stock.

In the event of a liquidation, dissolution, or winding-up of the Company, the holders of Series B and Series B-2 were entitled to be paid first out of the assets available for distribution, before any payment is made to the Series A Preferred Stock. Payment to the holders of Series B was to consist of two (2) times the original purchase price of \$61.42, plus all accrued but unpaid dividends. Payment to the holders of Series B-2 was to consist of one and a half (1.5) times the original purchase price of \$61.42, plus all accrued but unpaid dividends. After such distribution to the holders of Series B and Series B-2, the holders of Series A-1 would have been entitled to be paid out of the remaining assets available for distribution, before any payment is made to the Series A-2, Series A-3, Series A-4, Series A-5 and Series A-6. Payment to the holders of Series A-1 was to consist of the original purchase price of \$81.42, plus all accrued but unpaid dividends. After the distribution to the holders of Series A-1, the holders of Series A-2 would have been entitled to receive an amount per share equal to the original purchase price per share of \$81.42, plus any accrued but unpaid dividends. After the distribution to the holders Series A-1 and Series A-2, the holders of Series A-3, Series A-5 and Series A-6, would have been entitled to receive an amount per share equal to the original purchase price per share of \$81.42, plus any accrued but unpaid or declared and unpaid dividends, as appropriate. After the distribution to the holders Series A-1, Series A-2, Series A-3, Series A-5 and Series A-6, the holders of Series A-4 would have been entitled to receive an amount per share equal to the original purchase price per share of \$81.42, plus any declared and unpaid dividends. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series B, the assets would have been distributed ratably among the holders of Series B in proportion to their

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****7. Convertible Preferred Stock (Continued)**

aggregate liquidation preference amounts. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series A-1, the assets would have been distributed ratably among the holders of Series A-1 in proportion to their aggregate liquidation preference amounts. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series A-2, the assets would have been distributed ratably among the holders of Series A-2 in proportion to their aggregate liquidation preference amounts. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series A-3, Series A-5 and Series A-6, the assets would have been distributed ratably among the holders of Series A-3, Series A-5 and Series A-6 in proportion to their aggregate liquidation preference amounts. If the assets of the Company were insufficient to pay the full preferential amounts to the holders of Series A-4, the assets would have been distributed ratably among the holders of Series A-4 in proportion to their aggregate liquidation preference amounts. After all liquidation preference payments have been made to the holders of the Series B, Series B-2 and Series A Preferred Stock, the holders of the Series B, Series B-2 and Series A-1, Series A-2 and Series A-3 were to participate in the distribution of the remaining assets with the holders of the Company's common stock on an as-if converted basis.

In the event of, and simultaneously with, the closing of an event of sale of the Company (as defined in the Company's Amended Certificate of Incorporation), the Company was to redeem all of the shares of Series B, Series B-2 and Series A Preferred Stock then outstanding at the Special Liquidation Price, as defined. If the event of sale involved consideration other than cash, the Special Liquidation Price could have been paid with such consideration having a value equal to the Special Liquidation Price. The Special Liquidation Price was to be equal to an amount per share, which would be received by each holder of the Preferred Stock if, in connection with the event of sale, all the consideration paid in exchange for the assets or the shares of capital stock of the Company was actually paid to and received by the Company, and the Company was immediately liquidated thereafter and its assets distributed pursuant to the liquidation terms above.

**8. Fair Value Measurements**

The following tables summarize the financial assets and liabilities measured at fair value on a recurring basis in the accompanying balance sheets as of December 31, 2014 and 2013 (in thousands):

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

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****8. Fair Value Measurements (Continued)**

	As of December 31, 2013			
	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Cash and cash equivalents:				
Cash	\$ 2,710	\$	\$	\$ 2,710
Money market funds(1)	9,593			9,593
	\$ 12,303	\$	\$	\$ 12,303
<b>Liabilities</b>				
Warrant liability(3)	\$	\$	\$ 1,945	\$ 1,945
Stock Liability(3)			5,328	5,328
	\$	\$	\$ 7,273	\$ 7,273

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

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

(3) Fair value is determined using the probability-weighted expected return model ("PWERM"), as discussed below. Changes in the fair value of the Level 3 assets and liabilities are recorded as other (expense) income in the statement of operations.

The stock liability represents the accrued balance of the research and development expense related to the stock dividends that were issuable to Nordic Bioscience Clinical Development VII A/S ("Nordic") in shares of Series A-6 (or in shares of common stock upon listing the Company's common stock on a national exchange) as of December 31, 2013, for services rendered which is being recognized ratably over the estimated per patient treatment period under the three work statements executed with Nordic (the "Nordic Work Statements") (see note 10). The fair value of the stock liability was based upon the fair value of the Series A-6 as determined using PWERM, which considered the value of the Company's various classes of preferred stock. The fair value of the Company's various classes of preferred stock was determined through an analysis of the future values for equity assuming various future outcomes. Accordingly, share value was based upon the probability weighted present value of expected future net cash flows, considering each of the possible future events, discount rate as determined using the capital asset pricing model, 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. Accordingly, the valuation of the Company's stock liability was determined using Level 3 inputs. Upon completion of the Company's initial public offering, any payments owed by the Company to Nordic in relation to the Nordic Work Statements

## Edgar Filing: Radius Health, Inc. - Form 10-K

were changed from the right to receive shares of Series A-6 to the right to receive a total cash payment from the Company of \$4.3 million.

The warrant liability as of December 31, 2013, represents the liability for the warrants issued to the placement agent in connection with the Company's Series A-1 financing, to the investors in the Series B financing in April and May 2013, and to the lenders in connection with the Company's Loan and Security Agreement executed with Oxford and General Electric Capital Corporation in May 2011. The warrant liability was calculated using the Black-Scholes option pricing method. This method of

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****8. Fair Value Measurements (Continued)**

valuation includes using inputs such as the fair value of the Company's common stock or preferred stock, historical volatility, the term of the warrant and risk free interest rates. Prior to its initial public offering, the fair value of the Company's shares of common stock and preferred stock is estimated using PWERM, as described above. Accordingly, the valuation of the warrant liability at December 31, 2013, was determined using Level 3 inputs. Upon completion of the Company's initial public offering, the outstanding warrants to purchase shares of A-1 convertible preferred stock were converted into the right to purchase shares of common stock and the Company's warrant liability was reclassified to equity.

The following table provides a roll forward of the fair value of the assets, where fair value is determined using Level 3 inputs (in thousands):

Balance at December 31, 2013	\$	
Issuance of shares of Series A-6 prepayment		1,220
Nordic amendment		(1,220)
Balance at December 31, 2014	\$	

The following table provides a roll forward of the fair value of the liabilities, where fair value is determined using Level 3 inputs (in thousands):

Balance at December 31, 2013	\$	7,273
Issuance of shares of Series A-6		(8,889)
Additions accrued shares of Series A-6		2,717
Additions warrants		1,511
Change in fair value		505
Warrant liability reclassified to equity		(3,117)
Balance at December 31, 2014	\$	

Additions represent the value of the asset or liability for additional accrued shares of stock that were issuable to Nordic for services rendered in connection with the Company's Phase 3 clinical trial of abaloparatide-SC (see note 10), as well as the value of any new warrants issued during the period. The issuance of shares of Series A-6 represents the release of the quarterly stock dividends of Series A-6 accrued under the Nordic Work Statements (see note 10). The Nordic amendment represents amounts that were originally payable in shares of Series A-6, but converted to the right to receive cash upon completion of the Company's initial public offering and no longer require fair value measurement at December 31, 2014 (see note 10).

The fair value of the Company's note payable is determined using current applicable rates for similar instruments as of the balance sheet date. The carrying value of the Company's note payable approximated its fair value as of December 31, 2014, as the Company's interest rate is near current market rates. The fair value of the Company's notes payable was determined using Level 3 inputs.

**9. License Agreements**

On September 27, 2005, the Company entered into a license agreement (the "Ipsen Agreement"), as amended, with SCRAS S.A.S, a French corporation on behalf of itself and its affiliates (collectively, "Ipsen"). Under the Ipsen Agreement, Ipsen granted to the Company an exclusive right and license





Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****9. License Agreements (Continued)**

under certain Ipsen compound technology and related patents to research, develop, manufacture and commercialize certain compounds and related products in all countries, except Japan and (subject to certain co-marketing and co-promotion rights retained by Ipsen) France. With respect to France, if Ipsen exercises its co-marketing and co-promotion rights, then Ipsen may elect to receive a percentage of the aggregate revenue from the sale of products by both parties in France (subject to a mid-double digit percentage cap) and Ipsen shall bear a corresponding percentage of the costs and expenses incurred by both parties with respect to such marketing and promotion efforts in France; Ipsen shall also pay Radius a mid-single digit royalty on Ipsen's allocable portion of aggregate revenue from the sale of products by both parties in France. Abaloparatide (the Company's investigational bone growth drug) is subject to the Ipsen Agreement. Ipsen also granted the Company an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen also granted the Company an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling the Company to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan and (subject to certain co-marketing and co-promotion rights retained by Ipsen) France. In consideration for these licenses, the Company made a nonrefundable, non-creditable payment of \$250.0 thousand to Ipsen, which was expensed during 2005. The Ipsen Agreement provides for further payments in the range of €10.0 million to €36.0 million (\$12.1 million to \$43.6 million) to Ipsen upon the achievement of certain development and commercialization milestones specified in the Ipsen Agreement, and for the payment of fixed 5% royalties on net sales of any product by the Company or our sublicensees on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country of any product that includes the compound licensed from Ipsen or any analog thereof.

If the Company sublicenses the rights licensed from Ipsen, then the Company will also be required to pay Ipsen a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double digit range. In addition, if the Company or its sublicensees commercialize a product that includes a compound discovered by it based on or derived from confidential Ipsen know-how, it will be obligated to pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of its patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country. In connection with the Ipsen Agreement, the Company recorded approximately \$0.5 million, \$0.2 million and \$0.7 million in research and developments costs in the years ended December 31, 2014, 2013 and 2012, respectively. The costs were incurred by Ipsen and charged to the Company for the manufacture of the clinical supply of the licensed compound.

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

In addition, should a product covered by the licensed technology be commercialized, the Company will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****9. License Agreements (Continued)**

product on a country-by-country basis until the later of the last to expire of the licensed patents or the expiration of data protection clauses covering such product in such country; the royalty rate shall then be subject to reduction and the royalty obligation will expire at such time as sales of lawful generic version of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. The latest patent to expire, barring any extension thereof, is expected on August 18, 2026.

The Eisai Agreement also grants the Company the right to sublicense with prior written approval from Eisai. If the Company sublicenses the licensed technology to a third party, the Company will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees received from such sublicensee and royalties in low single digit range based on net sales of the sublicensee. The license agreement expires on a country-by-country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the product is not covered by data protection clauses, and the sales of lawful generic version of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated. During the years ended December 31, 2014, 2013 and 2012, the Company did not incur any expense related to the Eisai Agreement.

**10. Research Agreements**

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

Pursuant to the Work Statement NB-1, the Company is 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. In addition, the Company agreed to pay to Nordic an additional performance incentive (each a "Performance Incentive Payment") of \$500,000 for every 50 patients that, subsequent to March 28, 2014, complete all end-of-study procedures, up to a maximum aggregate amount of additional payments equal to \$5.0 million. The Work Statement NB-1, provides for a total of up to approximately €41.2 million (\$49.8 million) of euro-denominated payments and a total of up to approximately \$3.2 million of U.S. dollar-denominated payments over the course of the Phase 3 Clinical Trial, plus Performance Incentive Payments. These payments may be adjusted based upon actual sites opened, work performed or number of patients enrolled. In addition, payments are due to Nordic in connection with the Work Statement NB-1 pursuant to the Stock Issuance Agreement, as discussed below.

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**10. Research Agreements (Continued)**

The Company recognizes research and development expense for the amounts due to Nordic under the Work Statement NB-1 ratably over the estimated per patient treatment period beginning upon enrollment in the Phase 3 Clinical Trial, or a twenty-month period. The Company recognizes research and development expense for the amounts due to Nordic under the fourth amendment to the Work Statement NB-1, which is recognized on a per patient basis when the end-of-study visit and all other required procedures are completed. The Company recorded \$8.2 million, \$31.6 million, and \$30.8 million of research and development expense during the years ended December 31, 2014, 2013, and 2012, respectively, for per patient costs incurred for patients that had enrolled in the Phase 3 Clinical Trial.

As of December 31, 2014, the Company had a liability of \$5.6 million 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* On February 21, 2013, the Company entered into a Work Statement NB-3, as amended on March 4, 2014 (the "Work Statement NB-3"). Pursuant to the Work Statement NB-3, Nordic will perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial, and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management ("the Extension Study").

Payments in cash to be made to Nordic under the Work Statement NB-3 are denominated in both euros and U.S. dollars and total up to €7.5 million (\$9.1 million) and \$1.1 million, respectively. In addition, payments are due to Nordic in connection with the Work Statement NB-3 pursuant to the Stock Issuance Agreement, as discussed below.

The Company recognizes research and development expense for the amounts due to Nordic under the 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. The Company recorded \$9.6 million and \$4.5 million of research and development expense during the years ended December 31, 2014 and 2013, respectively, for per patient costs incurred for patients that had enrolled in the Extension Study and Second Extension.

As of December 31, 2014, the Company had a liability of \$5.9 million reflected in accrued expenses and other current liabilities on the balance sheet resulting from services provided by Nordic, which are payable in cash.

*Stock Issuance Agreement* Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase 6,443 shares of the Company's Series A-5 and to receive quarterly stock dividends, payable in shares of the Company's Series A-6. In connection with the Work Statement NB-1, the Stock Issuance Agreement provided that Nordic was entitled to receive stock dividends, having an aggregate value of up to €36.8 million (\$44.5 million) (the "NB-1 Accruing Dividend"). In connection with Work Statement NB-3, the Stock Issuance Agreement provided that, beginning with the quarter ended March 31, 2013, Nordic was entitled to receive stock dividends having an aggregate value of up to €7.5 million (\$9.1 million) and \$0.8 million (the "NB-3 Accruing Dividend" and together with the "NB-1 Accruing Dividend," the "Nordic Accruing Dividend"). On March 28, 2014, the Company entered into the second amendment to the Stock Issuance Agreement (the "Second Stock Issuance Agreement Amendment"). The Second Stock Issuance Agreement Amendment required that the

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**10. Research Agreements (Continued)**

Company's Board of Directors declare, as soon as reasonably practical, a stock dividend of twenty-nine (29) shares of its Series A-6 for each share of the Company's then-outstanding Series A-5, all of which were held by Nordic, for a total of 186,847 shares of Series A-6, in full satisfaction of all stock dividends payable in 2014 under the terms of the Stock Issuance Agreement in connection with Work Statement NB-1 and Work Statement NB-3. In March 2014, Nordic requested that all 186,847 shares of Series A-6 be issued. Accordingly, the Company's Board of Directors declared and issued a dividend to Nordic of all 186,847 shares on March 31, 2014. The Second Stock Issuance Agreement Amendment further provided that in the event an initial public offering of the Company's common stock occurred prior to May 31, 2014, any payments owed by the Company to Nordic in relation to Work Statement NB-1 and Work Statement NB-3, excluding Performance Incentive Payments, for all periods of time after 2014, would be changed from the right to receive stock to the right to receive a total cash payment from the Company of \$4.3 million payable in ten equal monthly installments of \$430,000 beginning on March 31, 2015. On May 19, 2014, the Company entered into the third amendment to the Stock Issuance Agreement, which amended the date prior to which an initial public offering must occur to June 30, 2014. The Second Stock Issuance Agreement Amendment also stipulated that all consideration to be paid to Nordic pursuant to the Stock Issuance Agreement at any time after the consummation of an initial public offering be payable in cash. As the Company completed an initial public offering on June 11, 2014, Nordic no longer has the right to receive stock from the Company and has been paid in cash for all periods after June 11, 2014.

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

*Abaloparatide-TD Phase 2 Clinical Trial* On July 26, 2012, the Company entered into a Letter of Intent, (the "Phase 2 Letter of Intent with Nordic"), which provided that the Company and Nordic would, subject to the Company's compliance with certain requirements of the certificate of incorporation and applicable securities law, negotiate in good faith to enter into a Work Statement NB-2, (the "Work Statement NB-2"), and an amendment to the Amended and Restated Stock Issuance Agreement.

On February 21, 2013, the Company entered into Work Statement NB-2. Pursuant to the Work Statement NB-2, Nordic provided clinical trial services relating to the Phase 2 clinical trial of abaloparatide-TD (the "Phase 2 Clinical Trial"). Payments in cash to be made by the Company to Nordic under the Work Statement NB-2 were denominated in both euros and U.S. dollars and totaled up to €3.6 million (\$4.4 million) and \$0.3 million, respectively. In addition, pursuant to the Stock Issuance Agreement, Nordic was entitled to shares of Series A-6 payable as dividends upon the shares of Series A-5 held by Nordic, having an aggregate value of up to \$2.9 million.

As of December 31, 2013, 32,215 shares of Series A-6 were due to Nordic under Work Statement NB-2. In December 2013, Nordic requested that all 32,215 shares of Series A-6 accrued as of December 31, 2013 under Work Statement NB-2 be issued. Accordingly, the Company's Board of Directors declared a dividend to Nordic of all 32,215 shares of Series A-6 accrued under Work Statement NB-2 on December 31, 2013, which constituted all shares of Series A-6 due under Work Statement NB-2.

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**10. Research Agreements (Continued)**

The Company recognized 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. The Company recorded nil, \$4.1 million, and \$1.4 million of research and development expense during the years ended December 31, 2014, 2013, and 2012, respectively, for per patient costs incurred for patients that had enrolled in the Phase 2 Clinical Study. Additionally, the Company recorded approximately \$0.9 million of research and development expense associated with the costs incurred for preparatory and other start-up costs to initiate the Phase 2 Clinical Study during the year ended December 31, 2012. As of December 31, 2014, all obligations due to Nordic under Work Statement NB-2 had been paid.

The Company is also responsible for certain pass-through costs in connection with the Phase 3 Clinical Trial, Extension Study and Phase 2 Clinical Study. Pass through costs are expensed as incurred or upon delivery. The Company recognized research and development expense of \$1.3 million, \$3.9 million, and \$6.0 million for pass-through costs during the years ended December 31, 2014, 2013, and 2012, respectively.

**11. Stock-based Compensation**

The Company has the following stock-based compensation plans as of December 31, 2014, under which equity awards have been granted to employees, directors and consultants:

2003 Long-Term Incentive Plan; and

2011 Equity Incentive Plan.

The 2011 Equity Incentive Plan replaced the 2003 Long-Term Incentive Plan when the board of directors approved the new plan on November 7, 2011. As of December 31, 2014, an aggregate of approximately 4,560,000 shares have been authorized for issuance under the Company's stock-based compensation plans, with approximately 3,220,000 options outstanding. The number of common shares available for granting of future awards under these plans was approximately 981,000 at December 31, 2014.

*2003 Long-Term Incentive Plan* The Company's 2003 Long-Term Incentive Plan (the "Incentive Plan") provides for the granting of incentive stock options and nonqualified options to key employees, directors and consultants of the Company. The exercise price of the incentive stock options, as determined by the board of directors, must be at least 100% (110% in the case of incentive stock options granted to a stockholder owning in excess of 10% of the Company's common stock) of the common stock fair value as of the date of the grant. The provisions of the Incentive Plan limit the exercise of incentive stock options, but in no case may the exercise period extend beyond ten years from the date of grant (five years in the case of incentive stock options granted to a stockholder owning in excess of 10% of the Company's common stock). Stock options generally vest over a four-year period. Certain options contain explicit performance conditions. The Company authorized approximately 884,000 shares of common stock for issuance under the Incentive Plan.

*2011 Equity Incentive Plan* The Company's 2011 Equity Incentive Plan (the "Equity Plan") provides for the granting of incentive stock options and nonqualified options to key employees, directors and consultants of the Company. The exercise price of the incentive stock options, as determined by the board of directors, must be at least 100% (110% in the case of incentive stock

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****11. Stock-based Compensation (Continued)**

options granted to a stockholder owning in excess of 10% of the Company's common stock) of the common stock fair value as of the date of the grant. The provisions of the Equity Plan limit the exercise of incentive stock options, but in no case may the exercise period extend beyond ten years from the date of grant (five years in the case of incentive stock options granted to a stockholder owning in excess of 10% of the Company's common stock). Stock options generally vest over a four-year period. During 2014, the Company also issued stock options to certain members of its board of directors which vested immediately. Certain options contain explicit performance conditions. The Company has authorized approximately 3,676,000 shares of common stock for issuance under the Equity Plan. In addition, the shares remaining available for issuance under the Incentive Plan were assumed as shares authorized under the Equity Plan.

The Company has historically granted stock options at exercise prices no less than the fair value of its common stock as determined by its board of directors, with input from management. Prior to the Company's initial public offering, the Company's board of directors has historically determined, with input from management, the estimated fair value of the Company's common stock on the date of grant based on a number of objective and subjective factors, including:

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

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

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

the Company's historical operating and financial performance and the status of its research and product development efforts;  
and

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

Subsequent to the Company's initial public offering, exercise prices in the case of non-qualified and incentive stock options are not less than the fair value of the underlying common stock on the date of grant.

The Company uses the Black-Scholes option-pricing model to estimate the grant date fair value of its employee stock options. The weighted-average grant-date fair value per share of options granted during 2014, 2013 and 2012 was \$8.26, \$4.67 and \$5.38, respectively. The weighted-average assumptions used in the Black-Scholes option-pricing model were as follows:

	<b>Years Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Expected term (years)	6.06	6.25	6.25
Volatility	59%	62%	60%
Expected dividend yield	0%	0%	0%
Risk-free interest rates	2.06%	2.45%	1.10%

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****11. Stock-based Compensation (Continued)**

A summary of stock option activity for the year ended December 31, 2014 is as follows (in thousands, except for per share and weighted-average contractual life amounts):

	Shares	Weighted-Average Exercise Price (in dollars per share)	Weighted-Average Contractual Life (In Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2013	1,667	\$ 7.05		
Granted	2,785	15.20		
Exercised	(49)	3.45		
Cancelled	(1,182)	8.63		
Expired	(1)	3.42		
Options outstanding at December 31, 2014	3,220	\$ 13.58	8.57	\$ 81,584
Options exercisable at December 31, 2014	1,323	\$ 9.98	7.27	\$ 38,266
Options vested or expected to vest at December 31, 2014	3,114	\$ 13.49	8.54	\$ 79,158

The aggregate intrinsic value of options exercised (i.e., the difference between the market price at exercise and the price paid by employees to exercise the option) during the years ended December 31, 2014 and 2013 was \$0.7 million and \$0.02 million, respectively.

The following table summarizes stock-based compensation expense by financial statement line (in thousands):

	Years Ended December 31,		
	2014	2013	2012
Research and development	\$ 1,953	\$ 302	\$ 338
General and administrative	5,117	1,206	1,457
Share-based compensation expense included in operating expenses	\$ 7,070	\$ 1,508	\$ 1,795

As of December 31, 2014, there was approximately \$16.0 million of total unrecognized compensation expense related to unvested share-based compensation arrangements, which is expected to be recognized over a weighted- average period of approximately 3 years.



Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****12. Net Loss Per Share**

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

	Year Ended December 31,		
	2014	2013	2012
<b>Numerator:</b>			
Net loss	\$ (62,479)	\$ (60,690)	\$ (69,128)
Accretion of preferred stock	(9,000)	(17,471)	(13,992)
Loss attributable to common stockholders basic	(71,479)	(78,161)	(83,120)
Effect of dilutive convertible preferred stock			
Loss attributable to common stockholders diluted	\$ (71,479)	\$ (78,161)	\$ (83,120)
<b>Denominator:</b>			
Weighted-average number of common shares used in loss per share diluted	17,699,487	383,310	368,261
Loss per share basic and diluted	\$ (4.04)	\$ (203.91)	\$ (225.71)

The following potentially dilutive securities, prior to the use of the treasury stock method, have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive. For the years ended December 31, 2014, 2013, and 2012, all convertible preferred stock, options to purchase common stock and warrants outstanding were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Year Ended December 31		
	2014	2013	2012
Convertible preferred stock	3,857,664	6,617,686	3,412,898
Options to purchase common stock	2,466,492	1,743,890	1,706,539
Warrants	1,271,520	545,797	15,000

**13. Income Taxes**

As of December 31, 2014 the Company had federal and state net operating loss ("NOL") carryforwards of approximately \$319.7 million and \$246.5 million, respectively, which may be used to offset future taxable income. The Company also had federal and state tax credits of \$4.5 million and \$0.5 million, respectively, to offset future tax liabilities. The NOL and tax credit carryforwards will expire at various dates through 2034, and are subject to review and possible adjustment by federal and state tax authorities. The Internal Revenue Code contains provision that may limit the NOL and tax credit carryforwards available to be used in any given year in the event of certain changes in the ownership interests of significant stockholders under Section 382 of the Internal Revenue Code.

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****13. Income Taxes (Continued)**

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Income tax benefit using U.S. federal statutory rate	\$ (21,243)	\$ (20,635)	\$ (23,504)
State income taxes, net of federal benefit	(2,494)	(2,255)	(2,774)
Stock-based compensation	149	92	72
Research and development tax credits	(499)	(1,277)	(55)
Change in the valuation allowance	23,186	27,194	25,175
Permanent items	910	(3,085)	709
Other	(9)	(34)	377
	\$	\$	\$

The Company is subject to Massachusetts net worth taxes, not based on income, which is largely offset by allowable tax credits and recorded as a component of operating expenses.

The principal components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2014	2013
<b>Current assets:</b>		
Accrued expenses	\$ 671	\$ 351
Deferred rent		9
Gross current deferred tax assets	671	360
Valuation allowance	(671)	(360)
Net current deferred tax assets	\$	\$
<b>Non-current assets:</b>		
Net operating loss carryforwards	\$ 121,278	\$ 100,284
Capitalized research and development	356	662
Research and development credits	4,844	4,345
Depreciation and amortization	(47)	110
Other	3,158	1,313
Gross non-current deferred tax assets	129,589	106,714
Valuation allowance	(129,589)	(106,714)
Net non-current deferred tax assets	\$	\$

The Company has recorded a valuation allowance against its deferred tax assets in each of the years ended December 31, 2014 and 2013, because the Company's management believes that it is more likely than not that these assets will not be realized. The increase in the valuation allowance in 2014 primarily relates to the net loss incurred by the Company.

Table of Contents

**Radius Health, Inc.**

**Notes to Financial Statements (Continued)**

**13. Income Taxes (Continued)**

As of December 31, 2014, the Company has no unrecognized tax benefits or related interest and penalties accrued. The Company has not, as yet, conducted a study of research and development credit carryforwards. In addition, the Company has not, as yet, conducted an Internal Revenue Code Section 382 study, which could impact its ability to utilize available NOL and tax credit carryforwards. These studies may result in adjustments to the Company's research and development credit carryforwards and NOL carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and net operating loss carryforward and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment were required. The Company would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company has not recorded any interest or penalties on any unrecognized benefits since inception.

The statute of limitations for assessment by the Internal Revenue Service ("IRS") and state tax authorities remains open for all tax years. The Company files income tax returns in the United States, Colorado, Connecticut, Florida, Pennsylvania, New Jersey, New York and Massachusetts. There are currently no federal or state audits in progress.

**14. Commitments and Contingencies**

*Litigation* The Company may be exposed to certain claims or assessments in the ordinary course of business. In the opinion of management, the outcome of these matters is not likely to have any material effect on the financial position, results of operations, or cash flows of the Company.

*Commitments* On July 15, 2011, the Company entered into an operating lease agreement for office space in Cambridge, Massachusetts. The term of the lease was August 1, 2011 through July 31, 2014.

On May 14, 2014, the Company entered into an operating lease for office space in Waltham, Massachusetts. The term of the lease is August 1, 2014 through July 31, 2019. The Company has the option to extend the lease once for an additional 5-year period.

On July 3, 2014, the Company entered into an operating lease for office space in Morristown, New Jersey. The term of the lease is August 1, 2014 through January 31, 2015. On October 31, 2014, the Company executed an agreement to extend the term of the rental agreement through July 31, 2015.

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****14. Commitments and Contingencies (Continued)**

The Company is obligated to make monthly rent payments pursuant to these agreements as set forth below:

Years ended December 31,	Future Lease Commitments
2015	\$ 328
2016	296
2017	305
2018	313
2019	186
 Total minimum lease payments	 \$ 1,428

Rent expense for the years ended December 31, 2014, 2013 and 2012 was \$0.2 million, \$0.2 million and \$0.2 million, respectively.

**15. Related Party Transactions**

On July 24, 2013, the Company entered into a Consulting Agreement with Morana Jovan-Embiricos, Ph.D. (the "Consulting Agreement"), a member of the Company's board of directors. Pursuant to the Consulting Agreement, Dr. Jovan-Embiricos agreed to provide financial and strategic consulting services as may be requested by the Company, and such other consulting services as may be reasonably requested by the Company, from time to time from July 1, 2013 until June 30, 2014. The Company agreed to pay Dr. Jovan-Embiricos an aggregate consulting fee in cash of \$160,000, of which \$80,000 was paid on July 30, 2013 and the remaining \$80,000 was paid on October 2, 2013.

On January 23, 2014, the Company entered into a consulting agreement with Orbit Advisors Limited (the "Orbit Agreement"), a Swiss company ("Orbit"), and Morana Jovan-Embiricos, Ph.D and an agreement terminating the Consulting Agreement dated July 24, 2013. The Orbit Agreement was effective as of January 22, 2014 and would continue in effect until December 31, 2014 or until the earlier termination thereof in accordance with its terms (the "Term"). Pursuant to the Orbit Agreement, Orbit had agreed to provide financial and strategic consulting services as may be requested by the Company, and such other consulting services as may have been reasonably requested by the Company, from time to time during the Term. The Company agreed to pay Orbit an aggregate consulting fee in cash of \$400,000 in four equal installments of \$100,000 on each of January 31, 2014, June 30, 2014, September 30, 2014 and December 31, 2014. The Orbit Agreement contained customary provisions, applicable to both Orbit and Dr. Jovan-Embiricos, as Orbit's representative under the Orbit Agreement, regarding the treatment of the Company's confidential information and assignment of inventions, as well as an obligation of Orbit and Dr. Jovan-Embiricos to not solicit, during the Term and for a period of one year thereafter, any person or entity engaged by the Company as an employee, customer or supplier of, or consultant or advisor to, the Company to terminate such party's relationship with the Company. On February 27, 2014, the Company entered into a letter agreement terminating the Orbit Agreement.

Table of Contents**Radius Health, Inc.****Notes to Financial Statements (Continued)****16. Selected Quarterly Financial Data (Unaudited)**

Selected quarterly financial data for the years ended December 31, 2014 and 2013 is as follows (in thousands, except for share and per share data):

	Three Months Ended			
	March 31,	June 30,	September 30,	December 31,
<b>2014:</b>				
Net loss	\$ (14,488)	\$ (12,609)	\$ (17,420)	\$ (17,962)
Net loss applicable to common stock	(19,457)	(16,640)	(17,420)	(17,962)
Net loss per share basic and diluted	(50.45)	(2.22)	(0.59)	(0.55)
Weighted-average common shares outstanding basic and diluted	385,664	7,500,148	29,746,426	32,678,459
<b>2013:</b>				
Net loss	\$ (8,305)	\$ (19,512)	\$ (20,342)	\$ (12,531)
Net loss applicable to common stock	(11,887)	(23,880)	(25,090)	(17,304)
Net loss per share basic and diluted	(31.25)	(62.59)	(65.05)	(44.87)
Weighted-average common shares outstanding basic and diluted	380,352	381,525	385,688	385,688

**17. Subsequent Events**

On January 28, 2015, the Company completed a public offering of 4,000,000 shares of its common stock at a price of \$36.75 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately \$137.8 million. On January 28, 2015, the underwriters purchased an additional 600,000 shares by exercising an option to purchase additional shares that was granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the underwriters' option, the Company received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately \$158.6 million.

On March 9, 2015, the Company entered into an amendment to the Eisai Agreement (the "Eisai Amendment") in which Eisai granted to the Company an exclusive right and license to research, develop, manufacture and commercialize RAD1901 in Japan. In consideration for the rights to RAD1901 in Japan, the Company paid Eisai an initial license fee of \$0.4 million upon execution of the contract. The Eisai Amendment also provides for additional payments, payable upon the achievement of certain clinical and regulatory milestones in Japan.

Table of Contents

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**ITEM 9A. CONTROLS AND PROCEDURES.**

**Limitations on Effectiveness of Controls and Procedures**

In designing and evaluating our disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2014.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2014, based on the criteria set forth in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on that assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2014.

The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is contained in Item 9A of this Annual Report on Form 10-K.

**Changes in Internal Control Over Financial Reporting**

There was no change in our internal control over financial reporting during the quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of Radius Health, Inc.

We have audited Radius Health, Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Radius Health, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Radius Health, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Radius Health, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2014 of Radius Health, Inc. and our report dated March 10, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 10, 2015



Table of Contents

**ITEM 9B. OTHER INFORMATION.**

On March 9, 2015, we entered into an Amendment, effective as of February 26, 2015, or the Eisai Amendment, to the License Agreement, dated June 29, 2006, or the Eisai Agreement, between us and Eisai Co., Ltd., or Eisai. The Eisai Agreement granted a license to the Company for the right to research, develop, manufacture and commercialize the compound used in our investigational drug product candidate RAD1901, covering a worldwide territory excluding Japan. The Eisai Amendment amends the Eisai Agreement to include Japan in the territory covered by the license. In consideration for the rights to RAD1901 in Japan, we paid Eisai an upfront fee of \$0.4 million upon execution of the Eisai Amendment. The Eisai Amendment also provides for additional payments, payable upon the achievement of certain clinical and regulatory milestones in Japan. The Eisai Agreement also obligated us to first negotiate with Eisai if we decided to sublicense the licensed technology to a collaborator in particular countries in Asia. The Eisai Amendment eliminates this obligation.

None.

Table of Contents**PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

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

<b>Name</b>	<b>Age</b>	<b>Position</b>
Robert E. Ward	57	President, Chief Executive Officer and Director
B. Nicholas Harvey	54	Senior Vice President, Chief Financial Officer, Treasurer and Secretary
Gary Hattersley, Ph.D.	48	Senior Vice President, Chief Scientific Officer
Alan G. Harris, M.D., Ph.D	63	Chief Medical Officer
Gregory Williams, Ph.D.	55	Chief Development Officer
Alan H. Auerbach(2)(3)	45	Director
Willard H. Dere, M.D.	61	Director
Ansbert K. Gadicke, M.D.(2)(3)	56	Director
Kurt C. Graves(2)(3)	47	Chairman of the Board
Owen Hughes(1)	40	Director
Martin Münchbach, Ph.D.(1)(3)	44	Director
Anthony Rosenberg	61	Director
Elizabeth Stoner, M.D.(1)	64	Director

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

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

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

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

Table of Contents

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

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

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

**Alan H. Auerbach** has served on our Board of Directors since May 2011 and served as a member of the Board of Directors of the Former Operating Company from October 2010 until the Merger. Mr. Auerbach is currently the Founder, Chief Executive Officer, President and Chairman of the Board of Puma Biotechnology, Inc., a company dedicated to in-licensing and developing drugs for the treatment of cancer and founded in 2010. Previously, Mr. Auerbach founded Cougar Biotechnology in May 2003 and served as the company's Chief Executive Officer, President and as a member of its Board of Directors until July 2009. From July 2009 until January 2010, Mr. Auerbach served as the Co-Chairman of the Integration Steering Committee at Cougar (as part of Johnson & Johnson). Mr. Auerbach received a B.S. in Biomedical Engineering from Boston University and an M.S. in Biomedical Engineering from the University of Southern California. We believe Mr. Auerbach is qualified to serve as a member of our Board of Directors because of his business and professional experience, including his leadership of Cougar Biotechnology in drug development, private and public financings and a successful sale of the business.

**Willard H. Dere, M.D.** has served on our Board of Directors since November 2014. Dr. Dere has been Executive Director of Personalized Health at the University of Utah Health Sciences Center, and a Professor of Medicine in the School of Medicine since November 2014. Prior to that, he served as the Senior Vice President, Global Development from December 2004 to June 2007, and from April 2014 to October 2014, and as Chief Medical Officer from January 2007 to April 2014 at Amgen, Inc., a biopharmaceutical company, from December 2004 to October 2014. Before he joined Amgen in 2003, Dr. Dere served as Vice President of Endocrine, Bone and General Medicine Research and Development at Eli Lilly and Company, a biopharmaceutical company, where he also held various

Table of Contents

other roles in clinical pharmacology, regulatory affairs, and both early-stage translational, and late-stage clinical research. Dr. Dere received B.A. degrees in history and zoology and a M.D. degree from the University of California, Davis. We believe Mr. Dere is qualified to serve as a member of our Board of Directors because of his strong medical background and extensive experience in the pharmaceutical industry.

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

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

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

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

Table of Contents

our Board of Directors because of his extensive business and professional experience, including his experience in the venture capital industry, membership on various other boards of directors and scientific background.

**Anthony Rosenberg** has served on our Board of Directors since March 2015. From January 2013 to February 2015, Mr. Rosenberg served as Corporate Head of M&A and Licensing at Novartis International, a pharmaceutical company. From March 2005 to December 2012, he served as Global Head of Business Development and Licensing at Novartis Pharmaceuticals. Prior to that, Mr. Rosenberg was Global Head of the Transplant and Immunology Business Unit at Novartis Pharmaceuticals from 2000 to 2005. Mr. Rosenberg initially joined Sandoz, a predecessor to Novartis, in 1980. Mr. Rosenberg served as a director of Idenix Pharmaceuticals, Inc. from June 2009 to March 2012 and from December 2012 to March 2013. Mr. Rosenberg holds a B.Sc from the University of Leicester and an M.Sc in physiology from the University of London. We believe Mr. Rosenberg is qualified to serve as a member of our Board of Directors due to his extensive experience in mergers and acquisitions and licensing in the pharmaceutical sector.

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

**Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics is available on our website at [www.radiuspharm.com](http://www.radiuspharm.com). Any amendments to the code, or any waivers of its requirements, will be disclosed on our website. Information contained on or accessible through our website is not incorporated by reference into this report, and you should not consider information contained on or accessible through our website to be part of this report.

The remainder of the response to this item is contained in our definitive Proxy Statement for our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required to be disclosed by this item is contained in our definitive Proxy Statement for our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The information required to be disclosed by this item is contained in our definitive Proxy Statement for our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Table of Contents

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**

The information required to be disclosed by this item is contained in our definitive Proxy Statement for our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.**

The information required to be disclosed by this item is contained in our definitive Proxy Statement for our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Table of Contents

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.**

**(a) Financial Statements**

The following financial statements and supplementary data are included in Part II of Item 8 filed of this Annual Report on Form 10-K:

<u>Report of Independent Registered Public Accounting Firm</u>	<u>106</u>
<u>Balance Sheets as of December 31, 2014 and 2013</u>	<u>107</u>
<u>Statements of Operations and Comprehensive Loss for the years ended December 31, 2014, 2013 and 2012</u>	<u>108</u>
<u>Statements of Convertible Preferred Stock, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2014, 2013 and 2012</u>	<u>109</u>
<u>Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012</u>	<u>111</u>
<u>Notes to Financial Statements</u>	<u>112</u>

**(b) Financial Statement Schedules**

All financial statement schedules have been omitted because they are not applicable or are not required, or because the information required to be set forth therein is included in the consolidated financial statements or notes thereto.

**(c) Exhibits**

The Exhibit Index follows the signature pages hereof and is incorporated herein by reference.





Edgar Filing: Radius Health, Inc. - Form 10-K

Table of Contents

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<hr/> <i>/s/ MARTIN MÜNCHBACH</i> Martin Münchbach	Director	March 10, 2015
<hr/> <i>/s/ ANTHONY ROSENBERG</i> Anthony Rosenberg	Director	March 10, 2015
<hr/> <i>/s/ ELIZABETH STONER</i> Elizabeth Stoner	Director	March 10, 2015

Table of Contents**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed/ Furnished Herewith</b>
3.1	Restated Certificate of Incorporation, filed on June 11, 2014	8-K	001-35726	3.1	6/13/14	
3.2	Amended and Restated By-Laws	8-K	001-35726	3.2	6/13/14	
4.1	Fifth Amended and Restated Stockholders' Agreement, dated April 24, 2014, by and among the Company and the stockholders party thereto	S-1/A	333-194150	4.2	4/25/14	
10.1	Loan and Security Agreement, dated May 30, 2014, by and among the Company, Solar Capital Ltd. and Oxford Finance LLC	8-K	001-35726	10.1	6/2/14	
10.1(a)	First Amendment to Loan and Security Agreement, dated July 10, 2014, by and among Radius Health, Inc., Solar Capital Ltd., and Oxford Finance LLC	8-K	001-35726	10.3	7/11/14	
10.2	Form of Warrant to Purchase Shares of Common Stock in connection with the Series B Convertible Preferred Stock and Warrant Purchase Agreement, issued by the Company to certain investors and attached schedule with details	8-K	001-35726	10.2	4/25/13	
10.3	Form of Warrant to Purchase Shares of Common Stock in connection with the Series B-2 Convertible Preferred Stock and Warrant Purchase Agreement, issued by the Company to certain investors and attached schedule with details	8-K	001-35726	10.2	2/21/14	
10.4	Form of Warrant to Purchase Series A-1 Convertible Preferred Stock, issued by the Company, as successor to Radius Health, Inc., and Leerink Swann LLC					*
10.5	Form of Warrant to Purchase Shares of Series A-1 Convertible Preferred Stock issued by the Company to GE Capital Equity Investments and Oxford Finance LLC					*
10.6	Warrant to Purchase Stock, dated May 30, 2014, issued by the Company to Oxford Finance LLC	8-K	001-35726	10.2	6/2/14	
10.7	Warrant to Purchase Stock, dated May 30, 2014, issued by the Company to Oxford Finance LLC	8-K	001-35726	10.3	6/2/14	

## Edgar Filing: Radius Health, Inc. - Form 10-K

### Table of Contents

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.8	Warrant to Purchase Stock, dated July 10, 2014, issued by the Company to Oxford Finance LLC	8-K	001-35726	10.2	7/11/14	
10.9	Warrant to Purchase Stock, dated July, 10, 2014, issued by the Company to Solar Capital Ltd.	8-K	001-35726	10.1	7/11/14	
10.10 <sup>^</sup>	Clinical Trial Services Agreement, dated March 29, 2011, by and between the Company, as successor to Radius Health, Inc., and Nordic BioScience Clinical Development VII A/S	8-K/A	000-53173	10.1	10/24/11	
10.11 <sup>^</sup>	Work Statement NB-1, dated March 29, 2011, by and between the Company and Nordic Bioscience Clinical Development VII A/S, as amended on December 9, 2011, June 18, 2012, November 6, 2013, March 28, 2014, May 19, 2014 and July 22, 2014					*
10.12 <sup>^</sup>	Work Statement NB-2, dated February 21, 2013, by and between the Company and Nordic Bioscience Clinical Development VII/AS, as amended on November 6, 2013					*
10.13 <sup>^</sup>	Work Statement NB-3, dated February 21, 2013, by and between the Company and Nordic Bioscience Clinical Development VII/AS, as amended on February 28, 2014					*
10.14	Amended and Restated Stock Issuance Agreement, dated May 16, 2011, by and between the Company, as successor to Radius Health, Inc., and Nordic BioScience Clinical Development VII A/S, as amended on February 21, 2013, March 28, 2014 and May 19, 2014					*
10.15 <sup>^</sup>	License Agreement, dated September 27, 2005, by and between the Company, as successor to Nuvios, Inc., and Ipsen Pharma SAS (f/k/a SCRAS S.A.S.) on behalf of itself and its affiliates, as amended on September 12, 2007 and May 11, 2011					*

## Edgar Filing: Radius Health, Inc. - Form 10-K

### Table of Contents

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.16 <sup>^</sup>	Pharmaceutical Development Agreement, dated January 2, 2006, by and between the Company, as successor to Radius Health, Inc., and Beaufour Ipsen Industrie SAS, as amended on January 1, 2007, January 1, 2009, June 16, 2010 and January 2, 2011					*
10.17 <sup>^</sup>	Development and Manufacturing Services Agreement, dated October 16, 2007, by and between the Company, as successor to Radius Health, Inc., and LONZA Sales Ltd., as amended on May 19, 2011 and January 30, 2014, and Work Orders thereunder through March 9, 2015					*
10.18 <sup>^</sup>	Development and Clinical Supplies Agreement, dated June 19, 2009, by and among the Company, as successor to Radius Health, Inc., and 3M Co. and 3M Innovative Properties Co., as amended on December 31, 2009, September 16, 2010, September 29, 2010, March 2, 2011 and November 30, 2012 and Change Order Forms thereunder through March 9, 2015					*
10.19 <sup>^</sup>	License Agreement, dated June 29, 2006, by and between the Company, as successor to Radius Health, Inc., and Eisai Co., Ltd.	8-K/A	000-53173	10.25	10/24/11	
10.20	Radius Health, Inc. (f/k/a Nuvios, Inc.) 2003 Long-Term Incentive Plan, assumed in the Merger (As Amended)					*
10.21	Radius Health, Inc. (f/k/a Nuvios, Inc.) 2003 Long-Term Incentive Plan Form of Stock Option Agreement	8-K	000-53173	10.32	5/23/11	
10.22	Radius Health, Inc. 2011 Equity Incentive Plan (As Amended)	S-1/A	333-194150	10.84	4/21/14	
10.23	Form of Radius Health, Inc. 2011 Equity Incentive Plan Stock Option Agreement	S-1/A	333-175091	10.83	11/7/11	
10.24	Radius Health, Inc. Non-Employee Director Compensation Program					*
10.25	Employment Letter Agreement, November 14, 2003, by and between the Company, as successor to Nuvios, Inc., and Gary Hattersley	8-K	000-53173	10.49	5/23/11	

Edgar Filing: Radius Health, Inc. - Form 10-K

Table of Contents

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed/ Furnished Herewith</b>
10.26	Employment Letter Agreement, dated November 15, 2006, by and between the Company, as successor to Radius Health, Inc., and B. Nicholas Harvey	8-K	000-53173	10.51	5/23/11	
10.27	Executive Employment Agreement, dated as of December 12, 2013, by and between the Company and Robert Ward	8-K	001-35726	10.1	12/17/13	
10.28	Employment Letter Agreement, dated January 3, 2014, by and between the Company and Greg Williams	S-1/A	333-194150	10.141	4/3/14	
10.29	Employment Letter Agreement, dated February 21, 2014, by and between the Company and Alan Harris	S-1/A	333-194150	10.142	4/3/14	
10.30	Form of Indemnification Agreement by and between the Company and the individuals listed on Schedule A thereto					*
10.31	Lease, dated May 14, 2014, by and between the Company and BP Bay Colony LLC	8-K	001-35726	10.1	5/20/14	
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm					*
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

# Edgar Filing: Radius Health, Inc. - Form 10-K

## Table of Contents

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed/ Furnished Herewith *</b>
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*

---

^

Confidential treatment has been granted with respect to redacted portions of this exhibit. Redacted portions of this exhibit have been filed separately with the SEC.

A management contract or compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 15(a)(3) of Form 10-K.

\*

Filed herewith.

\*\*

Furnished herewith.