Radius Health, Inc.
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Table of Contents

As filed with the Securities and Exchange Commission on January 18, 2013

Registration No. 333-175091

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

POST EFFECTIVE
AMENDMENT NO. 1
to

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Radius Health, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Michael S. Wyzga
Chief Executive Officer
Radius Health, Inc.
201 Broadway, 6th Floor
Cambridge, Massachusetts 02139
(617) 551-4700

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

Copies To:

Peter N. Handrinos
B. Shayne Kennedy
Latham & Watkins LLP
John Hancock Tower, 20th Floor
200 Clarendon Street
Boston, Massachusetts 02116
(617) 948-6000

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

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ý

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

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

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

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

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

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

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

PROSPECTUS

OFFERING PROSPECTUS
SUBJECT TO COMPLETION, DATED JANUARY 18, 2013

5,320,600 Shares

Common Stock

The selling stockholders identified on pages 136-142 of this prospectus are offering on a resale basis a total of up to 5,320,600 shares of our common stock, $0.0001 par value per share, consisting of (i) 195,552 currently issued shares of our common stock to be offered for resale by certain selling stockholders, (ii) 5,112,120 unissued shares of our common stock to be offered for resale by certain selling stockholders upon the conversion of 511,212 outstanding shares of our convertible preferred stock, $0.0001 par value per share, (iii) 88 unissued shares of our common stock to be offered for resale by certain selling stockholders upon the exercise of outstanding common stock purchase warrants, and (iv) 12,840 unissued shares of our common stock to be offered for resale by certain selling stockholders upon the conversion of 1,284 shares of our preferred stock to be issued upon exercise of outstanding preferred stock purchase warrants.

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

Investing in our common stock involves a high degree of risk. Before buying any shares of our common stock, you should carefully read the discussion of material risks of investing in our common stock in "Risk factors" beginning on page 7 of this prospectus.

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

The date of this prospectus is , 2013.

Table of Contents

EXPLANATORY NOTE

On June 23, 2011, Radius Health, Inc. (the "Company") filed a registration statement with the Securities and Exchange Commission (the "SEC") on Form S-1 (Registration No. 333-175091) (the "Registration Statement").

This Post-Effective Amendment No. 1 to Form S-1 (the "Post Effective Amendment No. 1") is being filed by the registrant to update the prospectus relating to the offering and sale of the shares that were registered for resale on the Registration Statement. No additional securities are being registered under the Post-Effective Amendment No. 1. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

Table of Contents

You should rely only on the information contained in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with additional information or information different from that contained in this prospectus. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

TABLE OF CONTENTS

In this prospectus, references to "dollar" or "$" are to the legal currency of the United States, and references to "euro" or "€" are to the single currency introduced on January 1, 1999 at the start of the third stage of European Economic and Monetary Union, pursuant to the Treaty establishing the European Communities, as amended by the Treaty on European Union and the Treaty of Amsterdam. Unless otherwise indicated, the financial information in this prospectus has been expressed in U.S. dollars. Unless otherwise stated, the U.S. dollar equivalent information translating euros into U.S. dollars has been made, for convenience purposes, on the basis of the noon buying rate published by the Board of Governors of the Federal Reserve as of September 28, 2012, which was €1.00 = $1.2856. 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.

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

Table of Contents

PROSPECTUS SUMMARY

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

Unless the context requires otherwise, the terms "Radius," "Company," "we," "us" and "our" refer to Radius Health, Inc. (f/k/a MPM Acquisition Corp.). See " Our Corporate Information."

SUMMARY OF THE SHARES OFFERED BY THE SELLING STOCKHOLDERS

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

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

Table of Contents

Capital Stock	As of December 31, 2012, there were 867,204 shares of our common stock issued and outstanding. The preferred stock is convertible into common stock at any time at the option of the holder and will automatically convert into common stock upon the listing of our common stock on a national securities exchange. Assuming conversion of all preferred stock outstanding as of December 31, 2012, there would have been 21,622,084 shares of common stock outstanding as of December 31, 2012. These amounts exclude (i) 3,936,748 shares of our common stock issuable upon the exercise of outstanding stock options as of at a weighted average exercise price of $3.11 per share; (ii) 41,582 shares of our common stock reserved for future issuance under our 2011 equity incentive plan; (iii) 147,606 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $8.15 per share; and (iv) 2,519,845 shares of our common stock reserved for issuance in satisfaction of dividends accrued as of December 31, 2012 on our shares of series A-5 convertible preferred stock, which may be issued at any time following the listing of our common stock on a national securities exchange, and additional shares that will accrue quarterly based on the progress of certain preclinical and clinical trials conducted for us by Nordic Bioscience Clinical Development VII A/S, or Nordic, the holder of our series A-5 convertible preferred stock, and are issuable at a price per share equal to the greater of (1) $8.142 or (2) the 20-day average closing trading price of our common stock as of two days prior to the date of accrual.
Use of Proceeds	We will not receive any proceeds from the sale of the common stock offered by the selling stockholders. However, we will generate proceeds in the event of a cash exercise of the warrants by any selling stockholder. We intend to use those proceeds, if any, for general corporate purposes.
Risk Factors	The securities offered hereby involve a high degree of risk. See "Risk Factors" beginning on page 7.
Offering Price	Until our common stock is listed on a national securities exchange, such as the NASDAQ Global Market, or on the OTC Bulletin Board, or the OTCBB, selling stockholders are required to sell the common stock included in this prospectus at a fixed price of $8.142 per share. After our common stock is traded on a national securities exchange or on the OTCBB, all or part of the shares of common stock offered hereby may be sold from time to time in amounts and on terms to be determined by the selling stockholder at the time of sale.
Market for our Shares	There is not now and never has been any market for our securities and an active market may never develop.

Table of Contents

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

- the conversion of all outstanding shares of our convertible preferred stock into 20,754,880 shares of our common stock;
- the issuance of 2,519,845 shares of our common stock to the holders of our series A-1, A-2 and A-3 convertible preferred stock in satisfaction of accumulated dividends, as required by the terms of the series A-1, A-2 and A-3 convertible preferred stock upon listing of the common stock on a national securities exchange, assuming for this purpose that the listing of our common stock on a national securities exchange occurred on December 31, 2012;
- no issuance of the dividends accrued on our series A-5 convertible preferred stock described above; and
- no exercise of the outstanding options or warrants described above.

OUR BUSINESS

We are a biopharmaceutical company focused on developing new therapeutics for the treatment of osteoporosis and other women's health conditions. Our lead product candidate is BA058, a novel synthetic peptide analog of human parathyroid hormone-related protein, or hPTHrP, a naturally-occurring bone building hormone. We are developing BA058 as a treatment for osteoporosis in both injection (with BA058-SC, a subcutaneous injection currently in a Phase 3 clinical study) and transdermal (with BA058-TD, a short wear-time, transdermal patch currently in a Phase 2 clinical study) methods of administration. Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which can lead to an increase in fractures. We believe that BA058 stimulates the rapid formation of new, high-quality bone in patients suffering from osteoporosis and may restore bone mineral density, or BMD, in these patients into the normal reference range.

OUR MARKET OPPORTUNITY

The National Osteoporosis Foundation, or the NOF, has estimated that 10 million people in the United States, comprising eight million women and two million men, have osteoporosis, and another 34 million have low bone mass placing them at increased risk for osteoporosis. In addition, the NOF has estimated that osteoporosis was responsible for more than two million fractures in the United States in 2005 resulting in an estimated $19 billion in costs. The NOF expects that the number of fractures due to osteoporosis will rise to three million by 2025. Worldwide, osteoporosis affects an estimated 200 million women according to the International Osteoporosis Foundation, or the IOF. The IOF has also estimated that 1.6 million hip fractures occur worldwide each year, and by 2050 this number could reach between 4.5 and 6.3 million.

There are two main types of osteoporosis drugs currently available, anti-resorptive agents and anabolic agents. According to industry sources, sales of these drugs in the United States, the five major markets in Europe and Japan exceeded $6 billion in 2011. 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. We believe there is a large unmet need in the market for osteoporosis treatment because existing therapies have shortcomings in efficacy, tolerability and convenience. For example, the current standard of care, bisphosphonates, an anti-resorptive agent, has been associated with infrequent but serious adverse events such as osteonecrosis of the jaw, atrial fibrillation and anomalous fractures, especially of long bones, resulting from "frozen bone." Accordingly, we believe that there is a significant opportunity for a new therapeutic such as BA058, an anabolic agent, that will increase BMD to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis with added advantages in convenience and safety.

Table of Contents

OUR PRODUCT CANDIDATES

In August 2009, we announced positive Phase 2 data which showed that BA058-SC produced faster and greater BMD increases at the spine and the hip with substantially less hypercalcemia than Forteo, the only approved anabolic agent for the treatment of osteoporosis in the United States. Specifically, our study demonstrated that total analyzable hip BMD showed a more than five-fold benefit of BA058 at a dose of 80 µg over Forteo after six months, and BA058 at a dose of 80 µg increased mean lumbar spine BMD by 6.7% at six months, compared to 5.5% with Forteo, and by 12.9% at 12 months, compared to 8.6% with Forteo. In April 2011, we began dosing patients in a pivotal, multinational Phase 3 study designed to show that BA058-SC prevents new vertebral fracture compared to placebo. We expect to report top-line 18-month fracture data from this Phase 3 study in the fourth quarter of 2014. We believe that BA058 has the following potential advantages over the current standard of care:

- greater efficacy;
- faster benefit for building bone;
- shorter treatment duration;
- less hypercalcemia;
- no additional safety risks; and
- no refrigeration required in use.

We are also developing BA058-TD, a short wear time, transdermal form of BA058 that is delivered using a patented microneedle patch technology from 3M Drug Delivery Systems, or 3M. We commenced a Phase 2 clinical study of BA058-TD in the third quarter of 2012, and expect top-line data from this study to be available in the third quarter of 2013. We believe BA058-TD may eliminate the need for daily injections, lead to better treatment compliance for patients and expand the existing market. We reported the following top-line results from a Phase 1b study in December 2011:

- rapid release of BA058 from the microneedle patch;
- peak transdermal drug levels consistent with BA058-SC;
- faster time to peak concentration, and faster elimination in plasma, compared to BA058-SC;
- increase in the bone-formation marker P1NP in serum after seven days of exposure, consistent with bone-building activity; and
- identification of optimal wear time of five minutes or less, and effective sites of application.

We are also developing RAD1901, a selective estrogen receptor modulator, or SERM, for the treatment of vasomotor symptoms, commonly known as hot flashes, in women entering menopause, and RAD140, a selective androgen receptor modulator, or SARM, which is an orally active androgen agonist on muscle and bone and is a potential treatment for age-related muscle loss, frailty, weight loss associated with cancer, cachexia and osteoporosis.

Table of Contents

OUR STRATEGY

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

- completing the pivotal Phase 3 study of BA058-SC for the treatment of osteoporosis and reporting top-line 18-month fracture data in the fourth quarter of 2014;
- pursuing the clinical development of BA058-TD as a follow-on product for the treatment of osteoporosis;
- seeking regulatory approval of BA058-SC and BA058-TD for the treatment of osteoporosis if the clinical trials for these product candidates are successful, initially in the United States and subsequently in Europe;
- potentially collaborating with third parties for the worldwide commercialization of BA058 (except Japan);
- pursuing the potential application of BA058 in the moderate osteoporosis market as well as for the treatment of osteoarthritis;
- potentially collaborating with third parties for the further development and commercialization of RAD1901 and RAD140 on a worldwide basis; and
- building a strong management team and board of directors with significant pharmaceutical development, regulatory and commercial experience.

RISK FACTORS

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

- We will need to raise additional capital immediately in order to continue operating our business. We currently have no product revenues and believe that our existing resourses will not be sufficient to fund our planned operations beyond the first

quarter of 2013. If we fail to secure additional capital immediately we may be unable to continue to operate our business.

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

Table of Contents

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

We have a history of net losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability.

We are heavily dependent on the success of BA058-SC, and BA058-TD as a follow-on product, both of which are under clinical development. We cannot be certain that BA058-SC or BA058-TD will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

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

OUR CORPORATE INFORMATION

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

As of September 30, 2012, we employed fourteen full-time employees and one part-time employee, three of whom held Ph.D. or M.D. degrees. Nine of our employees were engaged in research and development activities and six were engaged in support administration and finance. We intend to use clinical research organizations, or CROs, and third parties to perform our clinical studies and manufacturing.

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

Table of Contents

RISK FACTORS

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

RISKS RELATED TO OUR BUSINESS

Risks related to our financial position and need for capital

We 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 a net loss of $48.4 million for the nine months ended September 30, 2012, $42.5 million for the year ended December 31, 2011 and $14.6 million for the year ended December 31, 2010. As of September 30, 2012, we had an accumulated deficit of $176.8 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. We may not be able to generate these revenues or achieve profitability in the future. 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.

We currently have no product revenues and will need to raise additional capital immediately in order to continue operating our business.

To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Currently, our only product candidates are BA058, RAD1901 and RAD140, and none of these product candidates is approved by the FDA for sale. Therefore, for the foreseeable future, we will have to fund our operations and capital expenditures from cash on hand, borrowings, licensing fees and grants and potentially, future offerings of our securities. We believe that our existing resources will not be sufficient to fund our planned operations beyond the first quarter of 2013. If we fail to obtain additional capital immediately, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities or discontinue our operations entirely. Any additional

Table of Contents

sources of financing 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.

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

In May 2011, we entered into our $25.0 million credit facility with General Electric Capital Corporation, or GECC, as agent and lender, and Oxford Finance LLC, as lender. We drew $12.5 million under our credit facility during 2011 and we drew the remaining $12.5 million on May 29, 2012. Our credit facility contains a number of covenants that impose significant operating and financial restrictions on us. These covenants limit our ability to:

dispose of our business or certain assets;

change our business, management, ownership or business locations;

incur additional debt or liens;

make certain investments or declare dividends;

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

engage in transactions with affiliates; or

encumber our intellectual property.

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

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

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

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

Table of Contents

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;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

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

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

Our financial results may fluctuate as a result of a number of factors, many of which are outside of our control. For these reasons, comparing our financial results on a period-to-period basis may not be meaningful, and you should not rely on our past results as an indication of our future performance. Our revenues, if any, may fluctuate from quarter to quarter and our future quarterly and annual expenses as a percentage of our revenues may be significantly different from those we have recorded in the past or which we expect for the future. Our financial results in some quarters may fall below expectations. Any of these events as well as the various risk factors listed in this 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 BA058-SC, and BA058-TD as a follow-on product, both of which are under clinical development. We cannot be certain that BA058-SC or BA058-TD will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

BA058-SC is our only product candidate in late stage clinical development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop marketable drug products. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market BA058-SC in the United States unless and until we receive approval of an NDA from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in such countries. In addition, the approval of BA058-TD as a follow-on product is dependent on the earlier approval of BA058-SC. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. Obtaining approval of an NDA is an extensive,

Table of Contents

lengthy, expensive and uncertain process, and any approval of BA058-SC may be delayed, limited or denied for many reasons, including:

- we may experience delays in the enrollment of patients in our ongoing Phase 3 clinical trial;
- we may not be able to demonstrate that BA058 is safe and effective as a treatment for osteoporosis to the satisfaction of the FDA;
- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the CRO that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA may not find the data from preclinical studies and clinical studies sufficient to demonstrate that BA058's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;
- the FDA may not accept data generated at our clinical study sites;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval; or
- the FDA may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

In addition, the FDA may change its approval policies or adopt new regulations. For example, on February 15, 2012, we received a letter from the FDA stating that, after internal consideration, the agency believes that a minimum of 24-month fracture data are necessary for approval of new products for the treatment of postmenopausal osteoporosis, and our ongoing BA058-SC pivotal Phase 3 clinical study is designed to produce fracture data based on an 18-month primary endpoint. Based on our discussions with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from a 6-month extension of the BA058 80 µg and placebo groups in our Phase 3 study that will receive approved alendronate (generic Fosamax®) therapy for osteoperosis management. We plan to file the NDA with the 18-month fracture data and supplementally provide the 24-month fracture data, when available. We cannot be certain that the FDA will not change this approval policy again, or adopt other approval policies or regulations that adversely affect any NDA that we may submit.

Before we submit an NDA to the FDA for BA058 as a treatment for osteoporosis, we must complete several additional studies, including, but not limited to, our pivotal Phase 3 study based upon 18-month fracture data, a thorough QT Phase 1 study, a Phase 1 pharmacokinetic, or PK, study in renal patients, a Phase 1 PK study in hepatic patients, a Phase 1 absolute bioavailability PK study, a carcinogenicity study in rats, and bone quality studies in rats and monkeys. We have not commenced all of these required studies and the results of these studies will have an

important bearing on the approval of BA058. In addition to fracture and BMD, our pivotal Phase 3 study will measure a number

Table of Contents

of other potential safety indicators, including anti-BA058 antibodies which will have an important bearing on the approval of BA058. At an interim preliminary analysis of histopathology of pre-terminal rats in our rat carcinogenicity study, which includes BA058 and hPTH(1-34), a daily subcutaneous injection of human parathyroid hormone as a positive control, we have observed osteosarcomas in both the BA058 and hPTH(1-34) treated groups. The final results from the rat carcinogenicity study may show that BA058 dosing results in more osteosarcomas than PTH, at similar exposure multiples to the human therapeutic dose, which may have a material adverse bearing on approval of BA058.

If we experience delays in the enrollment of patients in our Phase 3 clinical trial of BA058-SC or any other clinical trial, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for some of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. If we do not enroll patients in our Phase 3 clinical trial of BA058-SC at the rate that we expect, we will not be able to complete the trial in a timely manner and may be required to incur additional expenses in order to seek to accelerate the rate of patient enrollment. 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.

If we do not obtain the necessary United States or foreign regulatory approvals to commercialize any product candidate, we will not be able to sell our product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including BA058, RAD1901 and RAD140, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as 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 indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review, such as the request we received from the FDA with respect to providing a minimum of 24-month fracture data for approval of BA058. 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.

Table of Contents

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.

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

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

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

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

- changes in government regulation, administrative action or changes in FDA policy with respect to clinical trials that change the requirements for approval;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we, the FDA, or other regulatory authorities and ethics committees with jurisdiction over our studies may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or other authorities find deficiencies in our regulatory submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for existing or future clinical trials.

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

Even if our clinical trials are completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical

12

Table of Contents

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

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary or mandatory recall of products and related publicity requirements;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;

refusal to permit the import or export of our products;

product seizure; or

Table of Contents

injunctions or the imposition of civil or criminal penalties.

Physicians and patients may not accept and use our drugs.

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

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

cost-effectiveness of our product relative to competing products;

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

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

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

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

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

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

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

Risks related to our dependence on third parties

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

We depend upon independent researchers, investigators and collaborators, such as Nordic, to conduct our preclinical and clinical trials under agreements with us. These third parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These third parties may not assign as great a priority to our programs or pursue them as diligently as

Table of Contents

we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist competitors at our expense, our competitive position would be harmed.

If a regulatory or governmental authority determines that a financial interest in the outcome of the Phase 3 study of BA058-SC by any of the entities managing our Phase 3 study affected the reliability of the data from the Phase 3 study, 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 study of BA058-SC is 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 this Phase 3 study, we 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 both €41.2 million ($52.9 million) and $3.2 million. 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 $525,000. These shares of our series A-5 convertible preferred stock will automatically convert into 64,430 shares of our common stock upon the listing of our common stock on a national securities exchange. Pursuant to the terms of our agreements with Nordic, we will also issue to Nordic additional shares of common stock with an aggregate value of up to €36.8 million ($47.3 million). These additional shares of common stock accrue at a quarterly rate based on the progress of the Phase 3 clinical study and are issuable at a price per share equal to the greater of $8.142 or the 20-day average of the closing price of our common stock at any time after our common stock is publicly traded.

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 common stock that we will issue to Nordic in consideration of Nordic's management of the Phase 3 study may be less than the full value contemplated under our agreements with Nordic. As a result, the total consideration that Nordic will receive in cash and common stock may be viewed to be below the market price paid by other companies for comparable clinical trial services.

Table of Contents

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

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 BA058-SC for use in clinical trial activities. These contract manufacturers are currently our only source for the production and formulation of BA058. We currently do not have sufficient clinical supplies of BA058 to complete the Phase 3 study for BA058-SC but believe that our contract manufacturers will be able to produce sufficient supply of BA058 to complete all of the planned BA058 clinical studies. However, if our contract manufacturers are unable to produce, in a timely manner, adequate clinical supplies to meet the needs of our clinical studies, we would be required to seek new contract manufacturers that may require us to modify our finished product formulation and modify or terminate our clinical studies for BA058. Any modification of our finished product or modification or termination of our Phase 3 clinical study could adversely affect our ability to obtain necessary regulatory approvals and significantly delay or prevent the commercial launch of the product, which would materially harm our business and impair our ability to raise capital.

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

While we are currently in discussions, to date, neither we nor our collaborators have entered into a long-term agreement with Lonza, Vetter or 3M, each of whom currently produce BA058 or related components on a purchase order basis for us. Accordingly, Lonza, Vetter and 3M could terminate their relationship with us at any time and for any reason. We may not be able to negotiate long-term agreements on acceptable terms, or at all. If our relationship with any of these contract manufacturers is terminated, or if they are unable to produce BA058 or related components in required quantities, on a timely basis or at all, or if we are forced to accept unfavorable terms for our future relationship, our business and financial condition would be materially harmed. If any of our current product candidates or any product candidates we may develop or acquire in the future receive FDA approval, we will rely on one or more third-party contractors to manufacture our drugs or related components. Our

Table of Contents

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, and corresponding state agencies to ensure strict compliance with good manufacturing practice, or GMP, and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

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

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

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

Table of Contents

Risks related to marketing and sale of our products

We have no experience selling, marketing or distributing products and no internal capability to do so.

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

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

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

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have 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 BA058, RAD1901 and RAD140 will have to compete with existing therapies. In addition, a large

Table of Contents

number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, 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.

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 part on the extent to which coverage and reimbursement will be available from:

government and health administration authorities;

private health maintenance organizations and health insurers; and

other healthcare payers.

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

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

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

Risks related to our intellectual property

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

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

Table of Contents

If our efforts to protect our intellectual property related to BA058, RAD1901 and/or RAD140 fail to adequately protect these assets, we may suffer the loss of the ability to license or successfully commercialize one or more of these candidates.

Our commercial success is significantly dependent on intellectual property related to our product portfolio. We are either the licensee or assignee of numerous issued and pending patent applications that cover various aspects of our assets, including BA058, RAD1901 and RAD140.

Patents covering BA058 as a composition of matter have been issued in the United States (US Patent No. 5,969,095), Europe and several additional countries. Because the BA058 composition of matter patent was filed in 1996, it is expected to have a normal expiration in approximately 2016 in the United States (this date does not include the possibility of Hatch-Waxman patent term extension which could extend the expiration in the United States into the first quarter of 2021 if an application for extension is made and the maximum extension is granted by the United States Patent and Trademark Office, or USPTO) and additional countries where it has issued.

We and Ipsen Pharma SAS, or Ipsen, are also co-assignees to US Patent No. 7,803,770 that we believe provides exclusivity until 2028 in the United States (absent any Hatch-Waxman patent term extensions) for the method of treating osteoporosis with the intended therapeutic dose for BA058-SC. We and Ipsen are also co-assignees to US Patent No. 8,148,333 that we believe provides exclusivity until 2027 in the United States (absent any Hatch-Waxman patent term extensions) for the intended therapeutic formulation for BA058-SC.

We and 3M are co-assignees to an international patent application and a corresponding U.S. patent application filed in 2012 (claiming priority to 2011) which cover various aspects of BA058 for microneedle application. Any issued claims resulting from these applications will expire no earlier than 2032. However, pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of claimed inventions are not always predictable. Additional intellectual property covering BA058-TD technology exists in the form of proprietary information contained by trade secrets. These can be accidentally disclosed to, independently derived by or misappropriated by competitors, possibly reducing or eliminating the exclusivity advantages of this form of intellectual property, thereby allowing those competitors more rapid entry into the marketplace with a competitive product thus reducing our marketing advantage of BA058-TD. In addition, trade secrets may in some instances become publicly available required disclosures in regulatory files. Alternatively, competitors may sometimes reverse engineer a product once it becomes available on the market. Even where a competitor does not use an identical technology for the delivery of BA058, it is possible that they could achieve an equivalent or even superior result using another technology. Such occurrences could lead to either one or more alternative competitor products available on the market and/or one or more generic competitor products on the market with a corresponding decrease in market share and/or price for BA058-TD. See "Business Patents relating to BA058."

Patents covering RAD1901 as a composition of matter have been issued in the United States, Canada and Australia and are pending in Europe and India. The RAD1901 composition of matter patent in the United States expires in 2026 (not including any Hatch-Waxman extension). Additional patent applications relating to methods of treating vasomotor symptoms, clinical dosage strengths and combination treatment modalities 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 that patent office are not always predictable. As a result, we could encounter challenges or difficulties in building, maintaining and/or defending our intellectual property both in the United States and abroad. See "Business Patents relating to RAD1901."

Table of Contents

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

Patent applications covering RAD140 and other SARM compounds that are part of the SARM portfolio have been granted in the United States, Mexico and Australia, and are pending in the United States and elsewhere. The RAD140 composition of matter case expires in 2029 in the United States (this does not include the possibility of any Hatch-Waxman extension) and additional countries if and when it issues. Since patents are both highly technical and legal documents that are frequently subject to intense litigation pressure, there is risk that even if one or more RAD140 patents does issue and is asserted that the patent(s) will be found invalid, unenforceable and/or not infringed when subject to said litigation. Finally, the intellectual property laws and practices can vary considerably from one country to another and also can change with time. As a result, we could encounter challenges or difficulties in building, maintaining and defending our intellectual property both in the United States and abroad. See "Business Patents relating to RAD140."

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

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

Table of Contents

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. Assuming the other requirements for patentability are met, in the United States, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. We may become involved in opposition or interference proceedings challenging our patent rights or the patent rights of others. 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. Such 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 patent portfolio 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 the product portfolio.

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

If we 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 them, such as our employees, corporate

Table of Contents

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. In addition, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such 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 and which could result in a substantial diversion of our financial and management resources.

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

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

Table of Contents

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. 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. Such litigation or 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 such litigation or proceedings. Some of our competitors may be able to sustain the costs of such 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 certain branded prescription drugs and biologics, beginning in 2011, and increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program. In addition, among other things, PPACA also establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research. Congress has proposed a number of legislative initiatives to alter PPACA, including possible repeal of PPACA. At this time, it remains unclear whether there will be any changes made to certain provisions of PPACA or its entirety. In addition, other legislative changes have been proposed and adopted since PPACA was enacted. Most recently, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which may result in such changes as aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, starting in 2013. The full impact on our business of PPACA and the Budget Control Act is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the pharmaceutical industry generally.

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

Risks related to employee matters and managing growth

We may not successfully manage our growth.

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

Table of Contents

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;
- potential unknown liabilities and expenses;
- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

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

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

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

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

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

RISKS RELATING TO OUR COMMON STOCK AND THIS OFFERING

There is not now and never has been any market for our securities and an active market may never develop. You may therefore be unable to re-sell shares of our securities at times and at prices that you believe are appropriate.

There is no market active or otherwise for our common stock or our preferred stock and neither is eligible for listing or quotation on any securities exchange, automated quotation system or any other over-the-counter market, such as the OTC Bulletin Board, or the OTCBB, or the Pink Sheets. Even if we are successful in obtaining approval to have our common stock quoted on the

Table of Contents

OTCBB, it is unlikely that an active market for our common stock will develop any time soon thereafter. Accordingly, our common stock is highly illiquid. Because of this illiquidity, you will likely experience difficulty in re-selling such shares at times and prices that you may desire.

There is no assurance that our common stock will be listed on a national securities exchange or quoted on an automated quotation system.

We plan to seek listing of our common stock on a national securities exchange or quotation of our common stock on the OTCBB, as soon as practicable. However, there is no assurance we will be able to meet the initial listing standards of any stock exchange or automated quotation systems, or that we will be able to maintain a listing of our common stock on any stock exchange or automated quotation system. An investor may find it more difficult to dispose of shares or obtain accurate quotations as to the market value of our common stock while our common stock is listed on the OTCBB. If our common stock is listed on the OTCBB, we would be subject to an SEC rule that, if it failed to meet the criteria set forth in such rule, imposes various practice requirements on broker-dealers who sell securities governed by the rule to persons other than established customers and accredited investors. Consequently, such rule may deter broker-dealers from recommending or selling our common stock, which may further limit its liquidity. This would also make it more difficult for us to raise additional capital.

Because we became an operating company by means of a reverse merger, we may not be able to attract the attention of major brokerage firms.

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

The resale of shares covered by this resale registration statement could adversely affect the market price of our common stock in the public market, should one develop, which result would in turn negatively affect our ability to raise additional equity capital.

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

Table of Contents

We are subject to Sarbanes-Oxley and the reporting requirements of federal securities laws, which can be expensive.

As a public reporting company, we are subject to the Sarbanes-Oxley Act, as well as the information and reporting requirements of the Exchange Act and other federal securities laws. The costs of compliance with the Sarbanes-Oxley Act and of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC, and furnishing audited reports to stockholders, will cause our expenses to be higher than they would be if we were privately held. We were not currently subject to Section 404 of the Sarbanes-Oxley Act, but may be subject to Section 404 in the future. Section 404 may require us, on an annual basis, to review and evaluate our internal controls, and may require our independent auditors to attest to the effectiveness of our internal controls. Any failure by us to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

For so long as shares of our preferred stock remain outstanding, if we are sold in a transaction yielding less than the liquidation preference payable in the aggregate to holders of outstanding preferred stock, holders of our common stock may not receive any proceeds from such transaction and may lose their investment entirely.

As of December 31, 2012, we had outstanding 867,204 shares of common stock; 939,612 shares of series A-1 preferred stock; 983,208 shares of series A-2 preferred stock; 142,227 shares of series A-3 preferred stock; 3,998 shares of series A-4 preferred stock; 6,443 shares of series A-5 preferred stock; warrants to acquire 14,734 shares of series A-1 preferred stock; and warrants to acquire 266 shares of common stock. As more fully described herein and in our Certificate of Incorporation, holders of shares of our preferred stock outstanding at the time of a sale or liquidation will have a right to receive proceeds, if any, from any such transactions, before any payments are made to holders of our common stock. In the event that there are not enough proceeds to satisfy the entire liquidation preference of our preferred stock, holders of our common stock will receive nothing in respect of their equity holdings.

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act we may be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm at such time as we no longer qualify as a smaller reporting company. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue

Table of Contents

steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Our directors, executive officers and principal stockholders have substantial control over us and could delay or prevent a change in corporate control.

As of September 30, 2012, our directors, executive officers and holders of more than five percent of our common stock, together with their affiliates, own, in the aggregate, substantially all of our outstanding voting stock. As a result, these stockholders, acting together, have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Certain provisions in our charter documents and Delaware law could discourage takeover attempts and lead to management entrenchment.

Our certificate of incorporation and bylaws contain provisions that could have the effect of delaying or preventing changes in control or changes in our management without the consent of our board of directors. These provisions include:

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to determine to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; and
- the requirement that a special meeting of stockholders may be called only by the directors or any officer instructed by the directors to call the meeting, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors.

We are also subject to certain anti-takeover provisions under Delaware law. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction by which such holder acquired the stock.

Table of Contents

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

As of December 31, 2011, we had $128.3 million of federal and $109.7 million of state net operating loss carryforwards available to offset future taxable income. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code has previously occurred or will occur as a result of this offering. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this prospectus, including the sections titled "Prospectus summary," "Risk factors," Managements's discussion and analysis of financial condition and results of operations" and "Business," contains forward-looking statements. In some cases, we may use words such as "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "continue," "should," "would," "could," "potentially," "will," "may" or similar words and expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements in this prospectus may include, among other things, statements about:

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

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

we discuss in this prospectus under the caption "Risk factors." You should read these factors and the other cautionary statements made in this prospectus as being applicable to all related forward-looking statements wherever they appear in this prospectus.

Before you decide to invest in our common stock, you should carefully consider these risk factors, together with the other information contained in this prospectus, including our financial statements and the related notes and the information set forth under the heading "Management's discussion and analysis of financial condition and results of operations."

Table of Contents

USE OF PROCEEDS

We will not receive any proceeds from the resale of any of the shares offered by this prospectus by the selling stockholders. With respect to the underlying shares being offered hereby, we would receive gross proceeds of approximately $105,863 assuming the exercise of all warrants and options for cash. To the extent any of these warrants are exercised, we intend to use the proceeds for general working capital and administrative functions. The warrant holders are not required to exercise the warrants, accordingly, there is no guarantee that we will receive any cash from the exercise of warrants.

DIVIDEND POLICY

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

Our ability to pay cash dividends is restricted pursuant to the terms of our credit facility. See "Management's discussion and analysis of financial condition and results of operations Liquidity and Capital Resources Financings."

DETERMINATION OF OFFERING PRICE

All shares being offered will be sold by existing stockholders without our involvement, consequently the actual price of the stock will be $8.142 until our common stock is eligible for trading on a national securities exchange, such as the NASDAQ Global Market, or on the OTCBB. At and after such time, the actual price of the stock will be determined by prevailing market prices at the time of sale or by private transactions negotiated by the selling stockholders and the independent decisions of the selling stockholders.

Table of Contents

SELECTED FINANCIAL DATA

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

We derived the statements of operations data for the years ended December 31, 2009, 2010 and 2011 and the balance sheets data as of December 31, 2011 from our audited financial statements included elsewhere in this prospectus. We derived the statement of operations data for the nine months ended September 30, 2011 and 2012 and the balance sheet data as of September 30, 2012 from our unaudited financial statements for period ended September 30, 2012 included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future.

SEC rules require that the most recently filed annual financial statements be recast in this prospectus to reflect any subsequent changes in accounting principles or presentation that are being applied retrospectively. As a result, we have recast certain financial information presented in our Annual Report on Form 10-K to reflect the adoption of Accounting Standards Update No. 2011-05, *Presentation of Comprehensive Income*. These changes were previously reflected in our most recent quarterly report on Form 10-Q. Except as related to the matters that have led to the recast financial information presented herein, the disclosures contained in our Annual Report on Form 10-K have not otherwise been updated from those disclosures contained in our 2011 Form 10-K.

	Years ended December 31,			Nine months ended September 30,	
Statements of Operations and Comprehensive Loss Data:	**2011**	**2010**	**2009**	**2012**	**2011**
		(in thousands, except share and per share amounts)			
Revenue:					
Option fee revenue	$	$	$ 1,616	$	$
Operating expenses:					
Research and development	36,179	11,692	14,519	38,539	28,336
General and administrative	5,330	3,630	2,668	6,209	3,062
Restructuring		217			
Loss from operations	(41,509)	(15,539)	(15,571)	(44,748)	(31,398)
Other (expense) income, net	(236)	824	(7)	(1,788)	(279)
Interest (expense) income, net	(731)	85	489	(1,827)	(344)
Net loss	$ (42,476)	$ (14,630)	$ (15,089)	$ (48,363)	$ (32,021)
Other comprehensive loss, net of tax:					
Unrealized gain (loss) from available-for-sale securities	8	(18)	(232)	(2)	3
Comprehensive loss	$ (42,468)	$ (14,648)	$ (15,321)	$ (48,365)	$ (32,018)
Earnings (loss) attributable to common stockholders basic and diluted	$ 253	$ (26,773)	$ (26,494)	$ (58,733)	$ 713
Earnings (loss) per share basic	$ 0.51	$ (83.42)	$ (82.68)	$ (70.76)	$ 1.53
Earnings (loss) per share diluted	$ 0.07	$ (83.42)	$ (82.68)	$ (70.76)	$ 0.21
Weighted average shares basic	499,944	320,942	320,424	830,068	467,488
Weighted average shares diluted	3,454,276	320,942	320,424	830,068	3,406,615

Table of Contents

Balance Sheet Data:	As of December 31, 2011	2010	As of September 30, 2012
		(in thousands)	
Cash and cash equivalents	$ 25,128	$ 10,582	$20,449
Marketable securities	31,580	7,969	14,755
Working capital	56,607	15,448	27,276
Total assets	63,637	18,969	39,569
Note payable, net of current portion and discount	8,886		15,206
Total liabilities, convertible preferred stock, redeemable convertible preferred stock and stockholders' deficit	63,637	18,969	39,569

Table of Contents

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

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

OVERVIEW

We are a biopharmaceutical company focused on developing new therapeutics for the treatment of osteoporosis and other women's health conditions. We have three product candidates in development, the most advanced of which is BA058. We have begun dosing subjects in a pivotal Phase 3 clinical study of BA058-SC for the prevention of fractures in women suffering from osteoporosis. We are also developing BA058-TD, a short wear time, transdermal form of BA058 that is based on a microneedle technology from 3M, which has completed a Phase 1b clinical study. We believe that BA058-TD may eliminate the need for injections and lead to better treatment compliance for patients. Our second clinical-stage product candidate is RAD1901, which has completed an initial Phase 2a clinical study for the treatment of vasomotor symptoms, commonly known as hot flashes, in women entering menopause. Our third product candidate, RAD140, is in preclinical development and is a potential treatment for age-related muscle loss, frailty, weight loss associated with cancer cachexia and osteoporosis.

BA058 is a novel synthetic peptide analog of hPTHrP we are developing as a bone anabolic treatment for osteoporosis. hPTHrP is a critical cytokine for the regulation of bone formation, able to rebuild bone with low associated risk of inducing hypercalcemia as a side effect. In August 2009, we announced positive Phase 2 data that showed BA058-SC produced faster and greater BMD increases at the spine and the hip after six months and 12 months of treatment than did Forteo, which was a comparator in our study. Key findings were that the highest dose of BA058 tested of 80 micrograms (μg) increased mean lumbar spine BMD at six months and 12 months by 6.7% and 12.9% compared to the increases seen with Forteo trial arms of 5.5% and 8.6%, respectively. BA058 also produced increases in mean femoral neck BMD at the hip at six months and 12 months of 3.1% and 4.1% compared to increases for Forteo of 1.1% and 2.2%, respectively. We believe there is a strong correlation between an increased level of BMD and a reduction in the risk of fracture for patients with osteoporosis. BA058 was generally safe and well tolerated in this study, with adverse events similar between BA058, placebo and Forteo groups. In addition, the occurrence of hypercalcemia as a side effect for the 80 μg dose of BA058 was half that seen with Forteo. In April 2011, we began the dosing of subjects in a pivotal Phase 3 clinical study managed by Nordic and expect to report top-line 18-month fracture data from this study in the fourth quarter of 2014. We designed this planned Phase 3 study to enroll a total of 2,400 patients to be randomized equally to receive daily doses of one of the following: 80 μg of BA058, a matching placebo or the approved dose of 20 μg of Forteo for 18 months. The study will also include a 6-month extension period in order to obtain 24-month fracture data requested by the FDA. We plan to file the NDA with the 18-month fracture data and supplementally provide the 24-month fracture data, when available. The study is powered to show that BA058 is superior to placebo for prevention of vertebral fracture. The study is also powered to show that BA058 is superior to Forteo for greater BMD improvement at major skeletal sites and for a lower occurrence of hypercalcemia, a condition in which the calcium level in a patient's blood is above normal.

On May 17, 2011, the Former Operating Company merged with a subsidiary of ours and the surviving corporation of such merger was merged into us. Our efforts and resources are focused primarily on developing BA058 and our other pharmaceutical product candidates, raising capital and recruiting personnel. We have no product sales to date and we will not receive any revenue from

Table of Contents

product sales unless and until we receive approval for BA058-SC from the FDA, or equivalent foreign regulatory bodies. However, developing pharmaceutical products is a lengthy and very expensive process. Assuming we do not encounter any unforeseen delays during the course of developing BA058, we do not expect to complete development and file the NDA submission for BA058-SC until approximately mid-2015 and/or BA058-TD until approximately mid-2017. Accordingly, our success depends not only on the safety and efficacy of BA058, but also on our ability to finance the development of these products, which will require substantial additional funding to complete development and file for marketing approval. Our ability to raise this additional financing will depend on our ability to execute on the BA058 development plan, complete patient enrollment in clinical studies in a timely fashion, manage and coordinate on a cost-effective basis all the required components of the NDA submission for BA058-SC and scale-up BA058-SC and BA058-TD manufacturing capacity, as well as overall capital market conditions for companies with limited operating histories.

In addition, we currently have no sales, marketing or distribution capabilities and thus our ability to market BA058 will depend 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. Our ability to secure collaborators for BA058 will depend on the strength of our clinical data. However, we believe that there are certain favorable trends that will interest third parties to collaborate on BA058, including increasing prevalence of osteoporosis due to an increase in the elderly population in most developed countries, increased availability and reimbursement of diagnostic facilities, growing physician and patient awareness regarding the importance of treating osteoporosis, and concerns regarding the long-term safety profiles of the bisphosphonates prompting physicians to be interested in new therapies for osteoporosis. We are also evaluating strategic alternatives with respect to collaborating with third parties for the future development of RAD1901 and RAD140. Our ability to further develop these product candidates will be dependent upon the outcome of our collaboration strategy.

We currently have no product revenues and we believe our existing resources will not be sufficient to fund our planned operations beyond the first quarter of 2013. As a result, we need to obtain additional capital immediately in order to continue our operations. Any additional sources of financing will likely involve issuances of additional equity securities, which will have a dilutive effect on our stockholders. We are currently exploring various financing alternatives to address our capital needs.

FINANCIAL OVERVIEW

Research and development expenses

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

None of the research and development expenses in relation to our product candidates are currently borne by third parties. Our lead product candidate is BA058 and it represents the largest portion of our research and development expenses for our product candidates. We began tracking program expenses for BA058-SC in 2005, and program expenses from inception to September 30, 2012 were approximately $85.0 million. We began tracking program expenses for BA058-TD in 2007, and program expenses from inception to September 30, 2012 were approximately $15.7 million. We began tracking program expenses for RAD1901 in 2006, and program expenses from inception to September 30, 2012 were approximately $15.4 million. We began tracking program expenses for

Table of Contents

RAD140 in 2008, and program expenses from inception to September 30, 2012 were approximately $5.2 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs. Costs related to facilities, depreciation, share-based compensation and research and development support services are not directly charged to programs as they benefit multiple research programs that share resources.

We expect that future development costs related to BA058-SC and BA058-TD programs will increase significantly through possible marketing approval in the United States for BA058-SC in mid-2016 and for BA058-TD in mid-2017. For BA058-SC, we estimate that future development costs may exceed $120.0 million, including $92.0 million for clinical costs, $18.0 million for license and milestone payments and NDA filing fees, $4.0 million for preclinical costs and $6.0 million for manufacturing costs. For BA058-TD, we estimate that future development costs may exceed $46.0 million, including $31.0 million for clinical costs, $13.0 million for manufacturing costs, $2.0 million for preclinical costs and NDA filing fees. We expect to finance these future development costs of BA058 with our existing cash and cash equivalents and marketable securities and future offerings of our common stock or preferred stock. In addition, our current strategy is to collaborate with third parties for the further development and commercialization of RAD1901 and RAD140. Therefore, we do not expect that we will incur substantial future costs for these programs because we expect these costs to be borne by third parties. Our ability to further develop these product candidates will be dependent upon our ability to secure third-party collaborators, and it is not possible to project the future development costs for RAD1901 and RAD140 or possible marketing approval timeline at this time.

The successful development of BA058-SC and BA058-TD is subject to numerous risks and uncertainties associated with developing drugs, including the variables listed below. A change in the outcome of any of these variables with respect to the development of any of our product candidates could mean a significant change in the costs and timing associated with the development of that product candidate.

BA058-SC is our only product candidate in late stage development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop marketable drug products. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. Obtaining approval of an NDA is an extensive, lengthy, expensive and uncertain process, and any approval of BA058-SC may be delayed, limited or denied for many reasons, including:

- we may experience delays in the enrollment of patients in our ongoing Phase 3 clinical trial;
- we may not be able to demonstrate that BA058 is safe and effective as a treatment for osteoporosis to the satisfaction of the FDA;
- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the CRO that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA may not find the data from preclinical studies and clinical studies sufficient to demonstrate that BA058's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;

Table of Contents

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

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

the FDA may require development of a REMS as a condition of approval; or

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

In addition, the FDA may change its approval policies or adopt new regulations. For example, on February 15, 2012, we received a letter from the FDA stating that, after internal consideration, the agency believes that a minimum of 24-month fracture data are necessary for approval of new products for the treatment of postmenopausal osteoporosis, and our ongoing BA058-SC pivotal Phase 3 clinical study is designed to produce fracture data based on an 18-month primary endpoint. Based on our discussions with the agency, 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 BA058 80 µg and placebo groups in our Phase 3 clinical study that will receive approved alendronate (generic Fosamax®) therapy for osteoporosis management. We plan to file the NDA with the 18-month fracture data and supplementally provide the 24-month fracture data, when available. We cannot be certain that the FDA will not change this approval policy again, or adopt other approval policies or regulations that adversely affect any NDA that we may submit.

We are unable to determine the duration and costs to be incurred by us to continue development of RAD1901 and RAD140 until such time as we are able to secure a third party to collaborate on the further development and commercialization of these product candidates. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, progress on securing third-party collaborators, as well as ongoing assessments of such product candidate's commercial potential and our ability to fund such product development. If we are unable to continue to fund the development of RAD1901 and/or RAD140 and are unable to secure third-party collaborators for these product candidates, our business will be adversely affected and we will depend solely on the successful development, regulatory approval and commercialization of BA058-SC and BA058-TD.

The following table sets forth our research and development expenses related to BA058-SC, BA058-TD, RAD1901 and RAD140 for the years ended December 31, 2011, 2010 and 2009 and for the nine-months ended September 30, 2012 and 2011:

	Year ended December 31,			Nine months ended September 30,	
	2011	2010	2009	2012	2011
	(In thousands)				
BA058-SC	$ 27,046	$ 4,664	$ 3,671	$ 31,601	$ 21,825
BA058-TD	6,369	1,863	2,819	3,771	4,743
RAD1901	70	1,654	2,185	8	20
RAD140	23	313	2,031	18	23

General and administrative expenses

General and administrative expenses consist primarily of salaries and related expense for executive, finance and other administrative personnel, professional fees, business insurance, rent, general legal

Table of Contents

activities, including costs of maintaining our intellectual property portfolio, and other corporate expenses. We expect our general and administrative expenses to increase as a result of higher costs associated with being a public reporting company and any listing of our securities on a national securities exchange.

Our results also include non-cash compensation expense as a result of the issuance of stock and stock option grants to employees and consultants. 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 a previous credit facility under which we made the final payment in 2009, and interest due under our current credit facility, which we entered into on May 23, 2011 and pursuant to which we borrowed an aggregate of $12.5 million during the year ended December 31, 2011 and $12.5 million during the nine months ended September 30, 2012. See "Financings."

Other income and other expense

For the year ended December 31, 2011 and the nine months ended September 30, 2012, other expense primarily reflects changes in the fair value of the series A-6 preferred stock liability from the date of the initial accrual to the reporting date as discussed in Note 16 to our financial statements for the year ended December 31, 2011 and in Note 12 to our condensed quarterly financial statements for the period ended September 30, 2012.

Accretion of preferred stock

Accretion of preferred stock reflects the periodic accretions of issuance costs, dividends and the investor rights/obligations on the Former Operating Company's Series B and C redeemable convertible preferred stock and accretion of dividends on our series A-1, A-2 and A-3 convertible preferred stock.

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

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

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

Table of Contents

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.

In 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 these service providers. However, we may be required to estimate the cost of these services based on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

Research and development expenses

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

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts will be 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 a Black-Scholes option pricing model that takes into account the fair value of our common stock, the exercise price, the expected life of the option, the expected volatility of our common stock, expected dividends on our common stock, and the risk-free interest rate over the expected life of the option. Due to our limited history, we use the simplified method described in the SEC's Staff Accounting Bulletin No. 107, Share-Based Payment to determine the expected life of the option grants. We estimate expected volatility 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 utilize an expected dividend yield of zero. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. These assumptions are highly subjective and changes in them could significantly impact the value of the option and hence the compensation expense.

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

Stock-based compensation expense for options granted to consultants is also determined based upon the fair value of the options issued, but the unvested portion of such option grants is remeasured at each reporting period.

Table of Contents

The following table presents the grant dates and related exercise prices of stock options granted from January 1, 2011 to September 30, 2012.

Date of issuance	Nature of issuance	Number of shares	Exercise or purchase price per share	Per share estimated fair value of common stock(1)	Per share weighted average estimated fair value of options(2)
November 7, 2011	Option grant	849,709	$ 3.22	$ 3.22	$ 1.80
December 15, 2011	Option grant	1,981,700	$ 3.89	$ 3.89	$ 2.19
April 11, 2012	Option grant	188,000	$ 4.21	$ 4.21	$ 2.36
May 24, 2012	Option grant	10,000	$ 4.21	$ 4.21	$ 2.36
August 27, 2012	Option grant	20,000	$ 4.27	$ 4.27	$ 2.35

(1) The per share estimated fair value of common stock represents the determination by our board of directors of the fair value of our common stock as of the date of grant, taking into account various objective and subjective factors and including the results, if applicable, of valuations of our common stock as discussed below.

(2) Our estimate of the per share weighted average fair value for stock option grants was computed based upon the Black-Scholes-Merton option-pricing model with the assumptions through September 30, 2012 as disclosed in our financial statements included elsewhere in this Report.

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

- the prices at which we sold shares of convertible preferred stock;
- the superior rights and preferences of securities senior to our common stock at the time of each grant;
- the likelihood of achieving a liquidity event such as a public offering or sale of our company;
- our historical operating and financial performance and the status of our research and product development efforts; and
- the achievement of enterprise milestones, including our entering into collaboration and license agreements.

Our board of directors also considered valuations provided by management in determining the fair value of our common stock. Such valuations were prepared as of September 30, 2011, November 28, 2011, March 31, 2012 and June 30, 2012 and valued our common stock at $3.22, $3.89, $4.21 and $4.27 per share, respectively. The valuations have been used to estimate the fair value of our common stock as of each option grant date listed above and in calculating stock-based compensation expense. Our board of directors has consistently used the most recent valuation provided by management for determining the fair value of our common stock unless a specific event occurs that necessitates an interim valuation.

The valuations were based on the guidance from the *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or Practice Aid, that was developed by staff of the American Institute of Certified Public Accountants and a task force comprising representatives from the appraisal, preparer, public accounting, venture capital and academic communities. The option-pricing method was selected to value our common stock based on our stage of development and the degree of uncertainty surrounding the future success of clinical trials for our product candidates.

41

Table of Contents

For the valuations prepared as of September 30, 2011, November 28, 2011, March 31, 2012 and June 30, 2012, we utilized the probability-weighted expected return method, or PWERM, as outlined in the Practice Aid, which considers the value of preferred and common stock based upon the probability-weighted present value of expected future net cash flows, considering each of the possible future events, as well as the rights and preferences of each share class. PWERM is complex as it requires numerous assumptions relating to potential future outcomes of equity, hence, the use of this method can be applied: (i) when possible future outcomes can be predicted with reasonable certainty; and (ii) when there is a complex capital structure (i.e., several classes of preferred and common stock). We utilized the fair value of common stock derived from the September 30, 2011 valuation for purposes of the November 7, 2011 option grants, the fair value of common stock derived from the November 28, 2011 valuation for purposes of the December 15, 2011 option grants and the fair value of common stock derived from the March 31, 2012 valuation for purposes of the April 11, 2012 and May 24, 2012 option grants. We concluded, for purposes of the November 7, 2011 grants, that there were no significant changes to the assumptions used in the PWERM model between September 30, 2011 and November 7, 2011 that would impact the fair value of our common stock. We concluded, for purposes of the December 15, 2011 grants, that there were no significant changes to the assumptions used in the PWERM model between November 28, 2011 and December 15, 2011 that would impact the fair value of our common stock. We concluded, for purposes of the April 11, 2012 and May 24, 2012 grants, that there were no significant changes to the assumptions used in the PWERM model between March 31, 2012 and April 11, 2012 and May 24, 2012 that would impact the fair value of the common stock. We concluded, for purposes of the August 27, 2012 grant, that there were no significant changes to the assumptions used in the PWERM model between June 30, 2012 and August 27, 2012 that would impact the fair value of the common stock. We also used this methodology to estimate the fair value of our preferred stock, which we used in the preferred stock extinguishment, discussed in Note 4 to our financial statements for the year ended December 31, 2011, and to determine the fair value of shares of series A-6 convertible preferred stock due to Nordic at December 31, 2011, as discussed in Note 16 to our financial statements for the year ended December 31, 2011.

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 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.

Table of Contents

Our financial assets are classified as Level 1, Level 2 and Level 3 assets as of December 31, 2011 and 2010 and September 30, 2012. The carrying amounts of our financial instruments, which include cash equivalents, marketable securities, accounts payable and accrued expenses, approximate their estimated fair values as of December 31, 2011 and 2010 and September 30, 2012. Money market funds are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized as Level 1. Assets utilizing Level 2 inputs include government agency securities, including direct issuance bonds, and corporate bonds. These assets 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. Our assets utilizing Level 3 inputs are valued based upon the fair value of our series A-6 preferred stock.

Fair value for Level 1 is based on quoted market prices. Fair value for Level 2 is based on 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. Fair value for Level 3 is based upon the fair values determined using PWERM, as discussed above.

We have assets and liabilities that are estimated based upon the fair value of our common and preferred stock, as determined using PWERM, as described above. These assets and liabilities require Level 3 inputs. As of September 30, 2012, we have a stock dividend asset of approximately $2.7 million, a warrant liability of approximately $0.8 million, and an other liability ("stock liability") of approximately $21.1 million; the fair value for each of which is determined by Level 3 inputs being the fair value of our common and preferred stock, as discussed in Note 7 to our financial statements for the year ended December 31, 2011 and in Note 6 to our condensed quarterly financial statements for the period ended September 30, 2012.

The stock dividend asset represents the prepaid balance of the accrued stock dividend ("other liability" or "stock liability") to issue shares of series A-6 to Nordic, as discussed in Note 16 to our financial statements for the year ended December 31, 2011, and the amount of research and development expense related to stock dividend amounts being recognized ratably over the estimated per patient treatment period. The fair value of the stock liability is based upon the fair value of the series A-6 shares as determined using the PWERM as discussed above. As such the valuation of the stock dividend and other current asset was determined to be a Level 3 valuation.

The warrant liability represents the liability for the warrants issued to the placement agent in connection with the series A-1 financings, as discussed in Note 4 to our financial statements for the year ended December 31, 2011, and to the lenders in connection with our credit facility, as discussed in Note 4 to our financial statements for the year ended December 31, 2011. The warrant liability is calculated using the Black-Scholes-Merton option pricing method. This method of valuation includes using inputs such as the valuation of our various classes of preferred stock, historical volatility, the term of the warrant and risk-free interest rates. The fair value of our shares of common and preferred stock was estimated using PWERM, as described above. As such the valuation of the warrant liability was determined to be a Level 3 valuation.

The other liability represents the liability to issue shares of series A-6 preferred stock to Nordic for services rendered in connection with the Phase 3 clinical study of BA058-SC, as discussed in Note 16 to our financial statements for the year ended December 31, 2011. The liability is calculated based upon the number of shares earned by Nordic through the performance of clinical trial services multiplied by the estimated fair value of our series A-6 preferred stock at each reporting date. The estimated fair value of our series A-6 preferred stock is determined using PWERM, as described above. As such the valuation of the other liability was determined to be a Level 3 valuation.

Table of Contents

As of December 31, 2011, Level 3 assets and Level 3 liabilities represent approximately 5% and 17% of our total assets, respectively. As of September 30, 2012, Level 3 assets and Level 3 liabilities represent approximately 7% and 55% of our total assets, respectively. The other liability ("stock liability") balance will continue to increase until we issue the accrued shares of series A-6 to Nordic, as discussed in Note 16 to our financial statements for the year ended December 31, 2011 and Note 12 to our condensed quarterly financial statements for the period ended September 30, 2012. The stock dividend and other current asset balance will fluctuate with the stock liability and amount of research and development expense related to stock dividend amounts being recognized ratably over the estimated per patient treatment period. Increases and decreases in the aggregate fair value of these assets and liabilities will affect net loss as changes in fair value are recognized as other income (expense), but the changes will not significantly impact our liquidity and capital resources.

RESULTS OF OPERATIONS

The discussion under "Results of Operations" discusses results for the year ended December 31, 2011 in comparison with the years ended December 31, 2010 and 2009 and the nine months ended September 30, 2012 in comparison with the nine months ended September 30, 2011. The results for the years ended December 31, 2010 and 2009 and the nine months ended September 30, 2011 are the results of the Former Operating Company. The results for the year ended December 31, 2011 include our pre- and post-Merger results. The results for the nine months ended September 30, 2012 are post-Merger results.

	Years ended December 31,			Nine months ended September 30,	
	2011	2010	2009	2012	2011
Revenue:					
Option Fee	$	$	$ 1,616	$	$
Operating expenses:					
Research and development	36,179	11,692	14,519	38,539	28,336
General and administrative	5,330	3,630	2,668	6,209	3,062
Restructuring		217			
Loss from operations	(41,509)	(15,539)	(15,571)	(44,748)	(31,398)
Other (expense) income:					
Other (expense) income, net	(236)	824	(7)	(1,788)	(279)
Interest (expense) income, net	(731)	85	489	(1,827)	(344)
Net loss	$ (42,476)	$ (14,630)	$ (15,089)	$ (48,363)	$ (32,021)

Nine months ended September 30, 2012 and 2011

	Nine months ended September 30,		Change	
	2012	2011	$	%
	(In thousands)			
Operating expenses:				
Research and development	$ 38,539	$ 28,336	$ 10,203	36%
General and administrative	6,209	3,062	3,147	103%
			44	

Table of Contents

Research and development expenses: For the nine months ended September 30, 2012, research and development expense was $38.5 million, compared to $28.3 million for the nine months ended September 30, 2011, an increase of $10.2 million, or 36%. For the nine months ended September 30, 2012, we incurred professional contract services associated with the development of BA058-SC and BA058-TD of $35.4 million compared to $26.6 million for the nine months ended September 30, 2011. The increase was primarily the result of expenses incurred for continuing enrollment of patients in our Phase 3 study of BA058-SC, which began with the dosing of patients in April 2011, partially offset by lower contract services costs associated with the development of the BA058-TD in 2012. We expect that BA058-SC expenses will be maintained or increase over the course of the Phase 3 study. We expect that the BA058-TD expenses will to increase as we commenced a Phase 2 clinical study during the quarter ended September 30, 2012, with top-line data expected to be available in the third quarter of 2013. However, there will be variability from quarter to quarter in the costs for both BA058-SC and BA058-TD, driven primarily by the rate of patient enrollment, the euro/dollar exchange rate, and fluctuations in the value of our stock issued to Nordic under a stock issuance agreement between us and Nordic, or the Stock Issuance Agreement.

General and administrative expenses: For the nine months ended September 30, 2012, general and administrative expense was $6.2 million, compared to $3.1 million for the nine months ended September 30, 2011, an increase of $3.1 million, or 103%. The increase is primarily the result of incremental employee-related costs, increased legal fees, including costs associated with maintaining our intellectual property portfolio, and costs associated with being a public company.

Other (expense) income: For the nine months ended September 30, 2012, other expense, net of other income, was $1.8 million. Other expense, net of other income, primarily reflects changes in the fair value of the stock dividend liability from the date of the initial accrual to the reporting date as discussed in note 12 to our condensed quarterly financial statements for the period ended September 30, 2012.

Interest (expense) income: For the nine months ended September 30, 2012, interest expense, net of interest income was $1.8 million. Interest expense reflects interest due on our loan and security agreement with Oxford Finance and GECC, which was effective on May 23, 2011.

Years ended December 31, 2011 and 2010

	Years ended December 31,		Change	
	2011	2010	$	%
	(dollars in thousands)			
Operating expenses:				
Research and development	$ 36,179	$ 11,692	$ 24,487	209%
General and administrative	5,330	3,630	1,700	47%
Restructuring		217	(217)	(100)%

Revenue: There was no revenue for the years ended December 31, 2011 or 2010.

Research and development expenses: For the year ended December 31, 2011, research and development expense was $36.2 million compared to $11.7 million for the year ended December 31, 2010, an increase of $24.5 million or 209%. For the year ended December 31, 2011, we incurred professional contract services associated with the development of BA058-SC of $27.0 million compared to $4.7 million for the year ended December 31, 2010. The increase was primarily the result of expenses incurred in connection with the initiation of our Phase 3 study of BA058-SC, which began with the dosing of patients in April 2011. We expect this higher level of BA058-SC expenses to be maintained or increase over the course of the Phase 3 study, for which we expect to report top-line 18-month fracture data in the fourth quarter of 2014. However, there will be variability from year to

Table of Contents

year driven primarily by the rate of patient enrollment, the euro/dollar exchange rate and fluctuations in the value of our stock issued to Nordic under the Stock Issuance Agreement. Additionally, for the year ended December 31, 2011, as compared to the year ended December 31, 2010, we incurred $4.5 million more in contract services associated with the development of BA058-TD in relation to the manufacture of toxicology and Phase 2 clinical supplies. These increases during the year ended December 31, 2011 were offset by a reduction of $290,000 on RAD140 spending, and a reduction of $1.6 million in professional contract services associated with the development of RAD1901 due to the completion of the Phase 2a study of RAD1901 in early 2010. We also had reductions in facilities expenses of approximately $436,000 for the year ended December 31, 2011 compared to the year ended December 31, 2010. These reductions were attributable to the closure of a laboratory facility in September 2010.

General and administrative expenses: For the year ended December 31, 2011, general and administrative expense was $5.3 million compared to $3.6 million for the year ended December 31, 2010, an increase of $1.7 million or 47%. The increase is primarily the result of increased legal, accounting, and marketing costs, as well as business insurance, related to public company reporting.

Restructuring expenses: We incurred restructuring costs of approximately $217,000 in the year ended December 31, 2010, primarily related to lease termination costs associated with vacating our laboratory space. No similar costs were incurred in the year ended December 31, 2011.

Other income (expense), net: For the year ended December 31, 2011, other expense, net of other income, was $236,000, which primarily reflects changes in the fair value of the series A-6 preferred stock liability from the date of the initial accrual to the reporting date as discussed in Note 16 to our financial statements for the period ended December 31, 2011. No similar costs were incurred in the year ended December 31, 2010. For the year ended December 31, 2010, we had other income, net of other expense, of $824,000, which was primarily comprised of approximately $733,000 of grant proceeds from the Internal Revenue Service pursuant to the qualifying therapeutic discovery grant program and approximately $149,000 in proceeds from the sale of equipment. We did not receive grant proceeds or sell equipment during the year ended December 31, 2011.

Interest income (expense), net: For the year ended December 31, 2011, interest expense, net of interest income, was $731,000 compared to interest income, net of interest expense, of $85,000 for the year ended December 31, 2010. Interest expense for the year ended December 31, 2011 reflects interest accrued on our credit facility.

Years ended December 31, 2010 and 2009

Revenue: For the year ended December 31, 2010, revenue was $0 compared to $1.6 million for the year ended December 31, 2009. The revenue in 2009 relates solely to an option agreement signed with Novartis in 2007 pursuant to which Novartis obtained an option to license the exclusive worldwide rights (except Japan) to all formulations of BA058. Revenue was recognized ratably over the option period based on criteria specified in the agreement. The period of option exclusivity expired in 2009 without exercise by Novartis.

	Years ended December 31,		Change	
	2010	2009	$	%
	(dollars in thousands)			
Operating expenses:				
Research and development	$ 11,692	$ 14,519	$ (2,827)	(19)%
General and administrative	3,630	2,668	962	36%
Restructuring	217		217	100%
			46	

Table of Contents

Research and development expenses: For the year ended December 31, 2010, research and development expense was $11.7 million compared to $14.5 million for the year ended December 31, 2009, a decrease of $2.8 million or 19%. For the year ended December 31, 2010, we incurred professional contract services associated with the development of BA058-SC of approximately $4.6 million compared to approximately $3.7 million for the year ended December 31, 2009. The increase is attributable to a $1.0 million up-front payment to Nordic for Phase 3 study expenses. Offsetting these increases, we incurred $1.0 million less in contract services associated with the development of BA058-TD. The decrease was mainly the result of the completion of the feasibility agreement with 3M for BA058-TD in 2009. Additionally, we spent $1.7 million less on RAD140 and $531,000 less on RAD1901 for professional contract services in the year ended December 31, 2010 compared to the year ended December 31, 2009 as we evaluated strategic options of the further development of these programs. Lastly, we experienced reductions in stock-based and other compensation of approximately $125,000, professional fees of approximately $234,000, and facility and other miscellaneous costs of approximately $256,000, for the year ended December 30, 2010 compared to the year ended December 31, 2009. The reduction in compensation was the result of the achievement of certain milestones that generated higher stock-based compensation in 2009. The reduction in professional fees, facilities, and miscellaneous other costs was related to the curtailment of costs for the RAD140 and RAD1901 programs.

General and administrative expenses: For the year ended December 31, 2010, general and administrative expense was $3.6 million compared to $2.7 million for the year ended December 31, 2009, an increase of approximately $1.0 million or 36%. The increase was attributable to an increase in compensation of approximately $279,000 and professional fees of approximately $715,000. The increase in compensation consisted mainly of management bonuses which were higher in 2010 than in 2009. The increase in professional fees included legal and accounting fees. These increases were offset by reductions in other individually insignificant accounts.

Restructuring: We incurred restructuring costs of approximately $217,000 in the year ended December 31, 2010 related to lease termination costs associated with vacating our laboratory space. No similar costs were incurred in the year ended December 31, 2009.

Other income (expense), net: Other income, net of other expense, of $824,000 at December 31, 2010 was primarily comprised of approximately $733,000 of grant proceeds from the Internal Revenue Service pursuant to the qualifying therapeutic discovery grant program and approximately $149,000 in proceeds from the sale of equipment.

Interest income (expense), net: Interest income decreased approximately $404,000 from $489,000 in the year ended December 31, 2009 to $85,000 in the year ended December 31, 2010. The decrease is attributable to a lower average cash equivalents and marketable securities balance in 2010.

LIQUIDITY AND CAPITAL RESOURCES

From inception to September 30, 2012, we have incurred an accumulated deficit of $176.8 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and expenses supporting those activities.

We have financed our operations since inception primarily through the private sale of preferred stock as well as the receipt of $5.0 million in fees associated with an option agreement. We have also borrowed $25.0 million under our credit facility in three term loans. See "Financings." Our total cash, cash equivalents and marketable securities balance was $35.2 million as of September 30, 2012.

Table of Contents

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

	Year ended December 31,			Nine months ended September 30,	
	2011	2010	2009	2012	2011
			(In thousands)		
Net cash provided by (used in):					
Operating activities	$ (35,896)	$ (12,986)	$ (18,293)	$ (32,032)	$ (24,627)
Investing activities	(23,800)	15,670	17,623	16,770	7,906
Financing activities	74,242	2	(8)	10,583	26,078
Net increase (decrease) in cash and cash equivalents	$ 14,546	$ 2,686	$ (678)	$ (4,679)	$ 9,357

Cash flows from operating activities

Net cash used in operations for the nine months ended September 30, 2012 was $32.0 million, an increase of $7.4 million, or 30% from the nine months ended September 30, 2011. The increase of $7.4 million in net cash used in operations for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily attributed to a $10.2 million increase in research and development expense, offset by adjustments to reconcile net loss to net cash used in operations, including stock-based compensation expense and non-cash expenses for research and development expenses to be settled in stock.

Net cash used in operations for the year ended December 31, 2011 was $35.9 million, an increase of $22.9 million or 176% from the year ended December 31, 2010. The increase of $22.9 million in net cash used in operations for the year ended December 31, 2011 compared to the year ended December 31, 2010 was primarily associated with an increase in net loss and net changes in working capital related to expenses incurred in connection with the initiation of the Phase 3 clinical study for BA058-SC, offset by adjustments to reconcile net loss to net cash used in operations, including non-cash expenses of $10.3 million and $1.4 million for research and development expenses to be settled in stock and a milestone payment settled with stock, respectively. The changes in working capital included a $6.5 million increase in prepaid expenses, a $301,000 decrease in accounts payable offset by an $819,000 increase in accrued expenses, all of which were attributable due to the timing of payments made in connection with our Phase 3 clinical study for BA058-SC.

Net cash used in operations for the year ended December 31, 2010 was $13.0 million, a decrease of $5.3 million or 29% from the year ended December 31, 2009. The decrease of $5.3 million in net cash used in operations for the year ended December 31, 2010 compared to the year ended December 31, 2009 was primarily associated with a $459,000 decrease in net loss and net changes in working capital, including a $1.5 million increase in accrued expenses related to preparations to initiate the Phase 3 clinical study for BA058-SC, a $94,000 decrease in the accounts payable in comparison with a $1.1 million decrease for the year ended December 31, 2009, and no change to deferred revenue in comparison with a decrease of $1.6 million in deferred revenue due to the expiration of the Novartis option agreement in the year ended December 31, 2009.

Table of Contents

Cash flows from investing activities

Net cash provided by investing activities increased $8.9 million for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. The increase was the result of a increase in cash proceeds from the sales and maturities of short-term investments, net of purchases, in the nine months ended September 30, 2012.

Net cash provided by investing activities decreased by $39.5 million for the year ended December 31, 2011 compared to the year ended December 31, 2010. The decrease was primarily a result of a $39.2 million decrease in cash proceeds from the maturities of investments, net of purchases, in the year ended December 31, 2011.

Net cash provided by investing activities decreased by $2.0 million for the year ended December 31, 2010 compared to the year ended December 31, 2009. The decrease was primarily a result of a $2.1 million decrease in net cash proceeds from the sales and maturities of investments, net of purchases, in the year ended December 31, 2010, offset by $149,000 in proceeds from the sale of equipment.

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

Our financing activities provided cash of $10.6 million and $26.1 million for the nine months ended September 30, 2012 and September 30, 2011, respectively. The cash provided by financing activities for the nine months ended September 30, 2012 consists of $12.5 million of net proceeds from our note payable and $0.3 million of net proceeds from stock option exercises, offset by $2.2 million of payments on our notes payable. The cash provided by financing activities for the nine months ended September 30, 2011 consists of $20.1 million of net proceeds from the issuance of preferred stock, $5.9 million of net proceeds from our note payable and $0.2 million of net proceeds from stock option exercises.

Cash flows from financing activities for the year ended December 31, 2011 included $62.1 million of proceeds, net of issuance costs, from the series A-1 and series A-5 financings, $12.1 million of proceeds, net of issuance costs, from our credit facility and $204,000 of net proceeds from stock option exercises, offset by $156,000 of payments under our credit facility. We did not have significant cash flows from financing activities for the years ended December 31, 2010 and 2009.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing and potential collaboration agreements. Through September 30, 2012, almost all of our financing has been through private placements of preferred stock and borrowings under our credit facility. We will seek to continue to fund operations from cash on hand and through additional equity and/or debt financing and potential collaboration agreements. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. We believe that our existing resources will not be sufficient to fund our planned operations beyond the first quarter of 2013. We need to raise additional capital immediately in order to continue operating our business, including to allow us to conduct clinical and non-clinical studies, seek regulatory approvals and, subject to such approvals, commercially launch our product candidates. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies. We may also need additional funds for possible future strategic acquisitions of businesses, products or technologies

Table of Contents

complementary to our business. If additional funds are required, we may raise such funds from time to time through public or private sales of equity or from borrowings. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition and results of operations. Additional equity financing may be dilutive to the holders of our common stock and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business. We are currently exploring various financing alternatives to address our capital needs.

Financings

Through September 30, 2012, we received aggregate net cash proceeds of $168.0 million from the sale of shares of our preferred stock as follows:

Issue	Year	No. of shares(1)	Net proceeds (in thousands)
Series B redeemable convertible preferred stock	2003, 2004, 2005	1,599,997	$ 23,775
Series C redeemable convertible preferred stock	2006, 2007, 2008	10,146,629	82,096
Series A-1 convertible preferred stock	2011	9,223,041	61,591
Series A-5 convertible preferred stock	2011	64,430	525
Total		21,034,097	$ 167,987

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

On May 11, 2011, accredited investors in a series A-1 convertible preferred stock financing, or the Series A-1 Private Placement, entered into an irrevocable legally binding commitment to purchase approximately $64.3 million of series A-1 preferred stock in three closings. The first closing, or the Stage I Closing, of the Series A-1 Private Placement occurred on May 17, 2011 and resulted in gross proceeds of approximately $21.4 million through the sale of 2,631,845 shares of the Former Operating Company's series A-1 convertible preferred stock. Those shares were exchanged in the Merger for an aggregate of 263,177 shares of series A-1 preferred stock. Each share of the series A-1 preferred stock is convertible into ten shares of our common stock. The second closing, or Stage II Closing, occurred on November 18, 2011, and we received gross proceeds of approximately $21.4 million through the sale of 263,178 shares of series A-1 preferred stock. The third closing, or Stage III Closing, occurred on December 14, 2011, and we received gross proceeds of approximately $21.4 million through the sale of 263,180 shares of series A-1 preferred stock. In connection with the consummation of the Stage I Closing, Stage II Closing and the Stage III Closing, Leerink Swann LLC received, on May 17, 2011, November 18, 2011 and December 14, 2011, warrants, which are currently exercisable at any time and expiring five (5) years from the date of issuance, at a purchase price of $81.42 per share, for up to a total of 2,454 shares of series A-1 preferred stock. After the automatic conversion of the preferred stock upon the listing of our common stock on a national securities exchange, these warrants will be exercisable for a total of 24,540 shares of common stock at a purchase price of $8.142 per share.

Concurrently with the Stage I Closing, the Former Operating Company issued 64,430 shares of series A-5 preferred stock to Nordic for gross proceeds of approximately $525,000. These shares were exchanged in the Merger for 6,443 shares of our series A-5 convertible preferred stock, which shares will convert automatically upon the listing of the common stock on a national securities exchange into 64,430 shares of common stock.

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

Table of Contents

bears interest at 10.16% per year. We drew $6.3 million under the second term loan on November 21, 2011. The second term loan is repayable over a term of 36 months, including an approximately six-month interest-only period, and bears interest at 10.0% per year. We drew $12.5 million under the third term loan on May 29, 2012. The third term loan is repayable over a term of 30 months, including an approximated six-month interest-only period, and bears interest at 10.0% per year. On each of May 23, 2011, November 21, 2011 and May 29, 2012, we issued warrants to GECC and Oxford Finance LLC for the purchase of up to a total 12,280 shares of series A-1 preferred stock, which will become exercisable for 122,800 shares of common stock at a purchase price of $8.142 per share after the listing of our common stock on a national securities exchange. The exercise period of each warrant is 10 years from the date of issuance.

Research and development agreements

BA058-SC Phase 3 Clinical Study. On March 29, 2011, we and Nordic entered into a Clinical Trial Services Agreement, a Work Statement NB-1, or the Work Statement NB-1, under such Clinical Trial Services Agreement and a related Stock Issuance Agreement. Pursuant to the Work Statement NB-1, Nordic is managing the Phase 3 clinical study, or the Phase 3 Clinical Study, of BA058-SC and Nordic will be compensated for such services in a combination of cash and shares of stock.

In December 2011, we entered into an amendment to the Work Statement NB-1, or the First Amendment. Pursuant to the original terms of the Work Statement NB-1, the study was to be conducted in 10 countries at a specified number of sites within each country. The terms of the First Amendment (1) provided for two additional countries (the United States and India) in which the study will be conducted, (2) specified a certain number of sites within each such additional country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect the addition of such countries and sites within the study's parameters. Payments to be made by us to Nordic under the First Amendment in connection with the conduct of the study in such additional countries are denominated in both euros and U.S. dollars and total up to both €717,700 ($922,675) and $289,663, respectively, for the 15 additional study sites in India contemplated by the First Amendment and up to both €1.2 million ($1.6 million) and $143,369, respectively, for the five additional study sites in the United States contemplated by the First Amendment.

In June 2012, we entered into a second amendment to the Work Statement NB-1, or the Second Amendment. Pursuant to the original terms of the Work Statement NB-1, as amended by the First Amendment, the study was to be conducted in 12 countries at a specified number of sites within each country. The terms of the Second Amendment (1) increased the overall number of sites by adding sites in Europe, Brazil and Argentina and removing other sites, (2) specified a certain number of sites within each country for the conduct of the study, and (3) amended various terms and provisions of the Work Statement NB-1 to reflect additional services provided at existing sites and the addition of the new study sites within the study's parameters. The Second Amendment also provided that cash payments to Nordic under the Clinical Trial Services Agreement as well as the payment of shares of stock under the related Stock Issuance Agreement will each be reduced by an amount of €11,941 ($15,351) per subject for any subjects enrolled in India or the United States. Such reductions shall be applied in pro rata monthly installments. Payments to be made by us to Nordic under the Second Amendment in connection with the extra services provided at existing sites and the conduct of the study at the new study sites are denominated in both euros and U.S. dollars and total €3.7 million ($4.8 million) and $205,540, respectively.

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 Study 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 Study schedule may alter the timing, but not the aggregate amounts, of the payments. The

Table of Contents

Work Statement NB-1, as amended on December 9, 2011 and June 18, 2012, provides for a total of up to approximately €41.2 million ($52.9 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 Study.

Pursuant to the Stock Issuance Agreement, as amended, Nordic agreed to purchase the equivalent of €371,864 of Series A-5 preferred stock at $8.142 per share, and we sold 64,430 shares of Series A-5 preferred stock to Nordic on May 17, 2011 for proceeds of $525,154 to the Former Operating Company. These shares were exchanged in the Merger for an aggregate of 6,443 shares of Series A-5 preferred stock.

The Stock Issuance Agreement provides that Nordic is entitled to receive quarterly stock dividends, payable in shares of Series A-6 preferred stock prior to the conversion of the Company's preferred stock into common stock, and shares of common stock after our preferred stock has been converted into common stock in accordance with our certificate of incorporation, having an aggregate value of up to €36.8 million ($47.3 million), or the Nordic Accruing Dividend. This right to receive the Nordic Accruing Dividend is non-transferrable and will remain with Nordic in the event it sells the shares of Series A-5 preferred stock or in the event the shares of Series A-5 preferred stock are converted into common stock in accordance with our amended certificate of incorporation. As of September 30, 2012, 277,049 shares of Series A-6 preferred stock are due to Nordic, or after the automatic conversion into common stock of our convertible preferred stock, 2,770,490 shares of common stock.

We recorded $8.5 million and $20.3 million of research and development expense in the three and nine months ended September 30, 2012 for per-patient costs incurred for patients that had enrolled in the Phase 3 Clinical Study as of September 30, 2012. As of September 30, 2012, in addition to the $20.6 million liability that is reflected in other liabilities on the condensed balance sheet for the Nordic Accruing Dividend, as noted above, we have (1) an asset of $2.2 million reflected in prepaid expenses and other current assets on the condensed balance sheet resulting from services provided by Nordic which are payable in the form of a stock dividend, the fair value of which exceeds the services provided by Nordic as of September 30, 2012, and (2) a liability of $1.5 million that is reflected in accrued expenses on the condensed balance sheet resulting from services provided by Nordic which are payable in cash.

BA058-TD Phase 2 Clinical Study. On July 26, 2012, we entered into a Letter of Intent with Nordic, or the Letter of Intent, which provides that we and Nordic will, subject to compliance by us with certain requirements of its Certificate of Incorporation and applicable securities laws, negotiate in good faith to enter into (1) a Work Statement NB-2, or the Work Statement NB-2, a draft of which is attached to the Letter of Intent, and (2) an amendment to the Amended and Restated Stock Issuance Agreement. The Work Statement NB-2 is contemplated by the terms of the Clinical Trial Services Agreement.

The Letter of Intent further provides that Nordic will begin providing clinical trial services relating to the Phase 2 clinical study of the Company's BA058-TD product, or the Phase 2 Clinical Study, as contemplated by the Services Agreement and the draft Work Statement NB-2. Payments in cash to be made by us to Nordic under the Letter of Intent in connection with the services to be provided are denominated in both euros and U.S. dollars and total up to €3.5 million ($4.5 million) and $257,856, respectively. In addition, we will issue to Nordic, subject to the execution of the Work Statement NB-2 and the Stock Issuance Agreement Amendment, shares of our Series A-6 preferred stock having a value of at least $2.9 million, as additional payment for services to be provided under the Work Statement NB-2 and the Services Agreement.

Table of Contents

The Letter of Intent will terminate on the earlier of (1) the date on which we entered into the Work Statement NB-2 and the Stock Issuance Agreement Amendment and (2) November 15, 2012 (pursuant to an extension mutually agreed to by us and Nordic).

The Stock Issuance Agreement provides that, beginning with the quarter ended December 31, 2012, Nordic is entitled to receive quarterly stock dividends, payable in shares of Series A-6 preferred stock, or shares of common stock if our preferred stock has been automatically converted into common stock in accordance with our certificate of incorporation, having an aggregate value of up to $2.9 million. This right to receive the Nordic Accruing Dividend is non-transferrable and will remain with Nordic in the event it sells the shares of series A-5 preferred stock or in the event the shares of Series A-5 preferred stock are converted into common stock in accordance with our amended certificate of incorporation.

We recorded less than $0.1 million of research and development expense in the three and nine months ended September 30, 2012 for per-patient costs incurred for patients that had enrolled in the Phase 2 Clinical Study as of September 30, 2012. As of September 30, 2012, in addition to the $0.5 million liability that is reflected in other liabilities on the condensed balance sheet that will be settled in shares of stock, as noted above, we have an asset of $0.5 million reflected in prepaid expenses and other current assets on the condensed balance sheet resulting from services provided by Nordic which are payable in the form of a stock dividend, the fair value of which exceeds the services provided by Nordic as of September 30, 2012.

We are also responsible for certain pass through costs in connection with the Phase 3 Clinical Study and Phase 2 Clinical Study. We recognized research and development expense of $0.5 million and $5.4 million for pass through costs in the three and nine months ended September 30, 2012.

License agreement obligations

BA058. In September 2005, we exclusively licensed the worldwide rights (except Japan) to BA058 and analogs from Ipsen, including US Patent No. 5,969,095, (effective filing date March 29, 1996, statutory term expires March 29, 2016) entitled "Analogs of Parathyroid Hormone" that claims BA058 and US Patent No. 6,544,949 (effective filing date March 29, 1996, statutory term expires March 29, 2016) entitled "Analogs of Parathyroid Hormone" that claims methods of treating osteoporosis using BA058 and pharmaceutical compositions comprising BA058, and the corresponding foreign patents and continuing patent applications. In addition, we have rights to joint intellectual property related to BA058, including rights to the jointly derived intellectual property contained in US Patent No. 7,803,770 (effective filing date October 3, 2007, statutory term extended to March 26, 2028 with 175 days of patent term adjustment due to delays in patent prosecution by the USPTO), US Patent No. 8,148,333 (effective filing date October 3, 2007, statutory term extended to November 8, 2027 with 36 days of patent term adjustment due to delays in patent prosecution by the USPTO) and related patents and patent applications both in the United States and worldwide that cover the method of treating osteoporosis using the Phase 3 clinical study dosage strength and form. In consideration for the rights to BA058 and in recognition of certain milestones having been met as of December 31, 2011, 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 ($12.9 million to $46.3 million). Should BA058 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 BA058 patents, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense BA058 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

Table of Contents

is in the low double-digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, we will be obligated to pay to Ipsen a fixed low single-digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of our patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country. Effective May 11, 2011, Ipsen agreed to accept shares of series A-1 preferred stock in lieu of a cash milestone payment of €1.0 million. We issued 173,263 shares of series A-1 preferred stock to Ipsen on May 17, 2011 to settle the liability. These shares were exchanged in the Merger for an aggregate of 17,326 shares of series A-1 convertible preferred stock and upon the listing of our common stock on a national securities exchange will convert automatically into 173,260 shares of common stock. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

RAD1901. In June 2006, we exclusively licensed the worldwide rights (except Japan) to RAD1901 from Eisai Co. Ltd., or Eisai. In particular, we have licensed US Patent No. 7,612,114 (effective filing date December 25, 2003, statutory term extended to August 18, 2026 with 967 days of patent term adjustment due to delays by the USPTO). In consideration for the rights to RAD1901 and in recognition of certain milestones having been met to date, we have paid to Eisai an aggregate amount of $1.5 million. The range of milestone payments that could be paid under the agreement is $1.0 million to $20.0 million. The license agreement further requires us to make payments upon the achievement of certain future clinical and regulatory milestones. Should RAD1901 become commercialized, we will be obligated to pay to Eisai a royalty in a variable mid-single digit range based on net sales of the product on a country by country basis for a period that expires on the later of (i) 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 (ii) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated. The latest valid claim is expected to expire, barring any extension thereof, on August 18, 2026. The royalty rate shall then be subject to reduction and the royalty obligation will expire at such time as sales of lawful generic version of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound. We were also granted the right to sublicense with prior written approval from Eisai, but subject to a right of first negotiation held by Eisai if we seek to grant sublicenses limited to particular Asian countries. If we sublicense RAD1901 to a third party, we will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees we receive from such sublicensee and royalties in a variable mid-single digit range based on net sales of the sublicensee. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

NET OPERATING LOSS CARRYFORWARDS

As of December 31, 2011, we had federal and state net operating loss carryforwards of approximately $128.3 million and $109.7 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2023 and 2012 for federal and state purposes, respectively.

Under Section 382 of the Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be utilized 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. Private placements and other transactions that have occurred since our inception, may have triggered an ownership change pursuant to Section 382, which could limit the amount of net operating loss carryforwards that could be utilized

Table of Contents

annually in the future to offset taxable income, if any. Any such limitation, whether as the result of 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.

NEW ACCOUNTING STANDARDS

In December 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*, or ASU No. 2011-11, which will require disclosures for entities with financial instruments and derivatives that are either offset on the balance sheet in accordance with ASC 210-20-45 or ASC 815-10-45, or subject to a master netting arrangement. ASU No. 2011-11 is effective for interim and annual periods beginning on or after January 1, 2013. We have not completed our review of ASU No. 2011-11, but we do not expect its adoption to have a material impact on our results of operations, financial position or cash flows.

In June 2011, FASB issued Accounting Standard Update No. 2011-05, *Presentation of Comprehensive Income*, or ASU No. 2011-05, which will require companies to present the components of net income and other comprehensive income, or OCI, either as one continuous statement or as two consecutive statements. ASU No. 2011-05 eliminates the option to present components of OCI as part of the statement of changes in stockholders' equity. The update does not change the items which must be reported in OCI, how such items are measured or when they must be reclassified to net income. We adopted ASU No. 2011-12 on January 1, 2012. Its adoption did not have a material impact on our financial statements or results of operations.

In May 2011, FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 82) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU No. 2011-04. The amendments in this update will ensure that fair value has the same meaning in U.S. GAAP and in IFRS and that their respective fair value measurement and disclosure requirements are the same. This update is effective prospectively for interim and annual periods beginning after December 15, 2011. We adopted ASU No. 2011-04 on January 1, 2012. Its adoption did not have a material impact on our results of operations, financial position or cash flows.

Table of Contents

BUSINESS

OVERVIEW

We are a biopharmaceutical company focused on developing new therapeutics for the treatment of osteoporosis and other women's health conditions. Our lead product candidate is BA058, a novel synthetic peptide analog of hPTHrP, a naturally-occurring bone building hormone. We are developing BA058 as a potential best-in-disease treatment for osteoporosis in both injection and transdermal methods of administration. Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which can lead to an increase in fractures. We believe that BA058 stimulates the rapid formation of new, high-quality bone in patients suffering from osteoporosis and may restore BMD in these patients into the normal reference range.

In August 2009, we announced positive Phase 2 data that showed BA058-SC produced faster and greater BMD increases at the spine and the hip with substantially less hypercalcemia than did Forteo, the only approved anabolic agent for the treatment of osteoporosis in the United States. Specifically, our study demonstrated that total analyzable hip BMD showed a more than five-fold benefit of BA058 at a dose of 80μg over Forteo after six months, and BA058 at a dose of 80μg increased mean lumbar spine BMD by 6.7% at six months, compared to 5.5% with Forteo, and by 12.9% at 12 months, compared to 8.6% with Forteo. In April 2011, we began dosing patients in a pivotal, multinational Phase 3 study designed to show that BA058-SC prevents new vertebral fracture compared to placebo. We expect to report top-line 18-month fracture data from this Phase 3 study in the fourth quarter of 2014. We believe that BA058 has the following potential advantages:

- greater efficacy;
- faster benefit for building bone;
- shorter treatment duration;
- less hypercalcemia;
- no additional safety risks; and
- no refrigeration required in use.

We are also developing BA058-TD, a short wear time, transdermal form of BA058 that is delivered using a microneedle patch technology from 3M. We believe BA058-TD may eliminate the need for daily injections, lead to better treatment compliance for patients and expand the existing market. We reported the following top-line results from a Phase 1b study in December 2011:

- rapid release of BA058 from the microneedle patch;
- peak transdermal drug levels consistent with BA058-SC;
- faster time to peak concentration, and faster elimination in plasma, compared to BA058-SC;
- increase in the bone-formation marker procollagen type 1N-terminal propeptide, or P1NP, in serum after seven days of exposure, consistent with bone-building activity; and

identification of optimal wear time of five minutes or less, and effective sites of application.

We commenced a Phase 2 clinical study of BA058-TD during the third quarter of 2012, and expect top-line data from this study to be available in the third quarter of 2013.

The NOF has estimated that 10 million people in the United States, comprising eight million women and two million men, are already diagnosed with osteoporosis, and another 34 million have low bone mass placing them at increased risk for osteoporosis. In addition, the NOF has estimated that osteoporosis was responsible for more than two million fractures in the United States in 2005 resulting

Table of Contents

in an estimated $19 billion in costs. The NOF expects that the number of fractures due to osteoporosis will rise to three million by 2025.

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. We believe there is a large unmet need in the market for osteoporosis treatment because existing therapies have shortcomings in efficacy, tolerability and convenience. For example, the current standard of care, biophosphonates, an anti-resorptive agent, has been associated with infrequent but serious adverse events such as osteonecrosis of the jaw, atrial fibrillation and anomalous fractures, especially of long bones, resulting from "frozen bone." These atypical fractures have created increasing concern with physicians and patients. Many physicians are seeking alternatives to current anti-resorptive therapies, which we believe will drive greater demand for bone anabolic agents in the future. We believe there is a significant opportunity for a new anabolic agent, such as BA058, that will increase BMD to a greater degree and at a faster rate than other approved drugs for the treatment of osteoporosis with added advantages in convenience and safety.

We are also developing RAD1901, a SERM, which we license from Eisai in 2006. We previously completed an initial one month Phase 2a clinical study for the treatment of vasomotor symptoms, commonly known as hot flashes, in women entering menopause. Our third product candidate, RAD140, is in preclinical development. RAD140, a SARM, is an orally-active androgen agonist on muscle and bone and is a potential treatment for age-related muscle loss, frailty, weight loss associated with cancer cachexia and osteoporosis.

OUR PRODUCT CANDIDATES

OUR STRATEGY

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

- completing the pivotal Phase 3 study of BA058-SC for the treatment of osteoporosis and reporting top-line 18-month fracture data in the fourth quarter of 2014;

- pursuing the clinical development of BA058-TD as a follow-on product for the treatment of osteoporosis;

Table of Contents

seeking regulatory approval of BA058-SC and BA058-TD for the treatment of osteoporosis if the clinical trials for these product candidates are successful, initially in the United States and subsequently in Europe;

potentially collaborating with third parties for the worldwide commercialization of BA058 (except Japan);

pursuing the potential application of BA058 in the moderate osteoporosis market as well as for the treatment of osteoarthritis;

potentially collaborating with third parties for the further development and commercialization of RAD1901 and RAD140 on a worldwide basis; and

building a strong management team and board of directors with significant pharmaceutical development, regulatory and commercial experience.

BACKGROUND ON OSTEOPOROSIS

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

Worldwide, osteoporosis affects an estimated 200 million women according to the IOF and is an important cause of morbidity and mortality. Many individuals may have osteoporosis but do not know it. The Office of the Surgeon General of the United States has said that based on survey results by The National Health and Nutrition Examination Survey, or NHANES, testing at the hip showed that four times as many men (four percent) and 2.5 times as many women (26%) actually had osteoporosis than reported that they had the disease. All bones become more fragile and susceptible to fracture as the disease progresses. People tend to be unaware that their bones are getting weaker, and a person with osteoporosis can fracture a bone from even a minor fall.

Fractures due to osteoporosis are most likely to occur in the hip, spine and wrist. In 2000, there were an estimated 9 million new osteoporotic fractures, of which 1.6 million were at the hip, 1.7 million were at the forearm and 1.4 million were clinical vertebral fractures. According to the IOF, hip fractures cause the most morbidity among types of osteoporotic fractures and can lead to lasting immobility. The IOF has estimated that by 2050 the number of hip fractures could reach between 4.5 and 6.3 million. According to the NOF:

osteoporosis was responsible for more than two million fractures in the United States in 2005;

vertebral (spinal) fractures may result in severe back pain, loss of height or spinal deformities;

there were approximately 293,000 Americans age 45 and over admitted to hospitals in 2005 with a fracture of the femoral neck, a common type of hip fracture that is associated with osteoporosis;

a women's lifetime risk of a hip fracture is equal to her combined risk of breast, uterine and ovarian cancer;

approximately 50% of women and 20% of men will have an osteoporotic facture after age 50; and

Table of Contents

an average of 24% of hip fracture patients aged 50 and over die in the year following their fracture (15-20% excess mortality risk), while an additional 20% of patients who were ambulatory before their hip fracture require long-term care (with a 50% chance of added permanent disability).

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 risk of subsequent fractures increases by 86% for those with a fracture. The NOF has estimated that osteoporosis-related fractures were responsible for $19 billion in costs in the United States in 2005.

The prevalence of osteoporosis is growing and, according to the NOF, is significantly under-recognized and under-treated in the population. While the aging of the population is a primary driver of an increase in cases, osteoporosis is also increasing from the use of drugs that induce bone loss, such as chronic use of glucocorticoids, aromatase inhibitors that are increasingly used for breast cancer and the hormone therapies used for prostate cancer.

The range of treatment and prevention options for osteoporosis has expanded in recent years from anti-resorptive drugs that act to prevent bone loss by blocking bone resorption, which is the process by which bone is broken down in the body and the resulting minerals, including calcium, are released into the blood, to include bisphosphonates, SERMs, calcitonins, and most recently in 2010, a genetic-based therapy known as receptor activator of nuclear factor kappa-B ligand, known as a RANKL inhibitor. Bisphosphonates remain the current standard of care, led by Actonel, Boniva, and Fosamax. Generic versions of Fosamax (alendronate) became available in the United States in 2008 and have now gained market share from branded oral bisphosphonates.

The only anabolic drug approved in the United States for osteoporosis is Forteo, which was approved by the FDA in December 2002. In 2011, the medical journal, Osteoporosis International, published results of a study indicating that patients' preferences for osteoporosis medications are strongly influenced by the mode of administration. In particular, when given the choice of subcutaneously injected Forteo versus other therapies, patients preferred the alternative drugs over Forteo, which requires once-daily, self-administered injections and must be refrigerated for storage between uses. We believe that this research suggests that there is a substantial opportunity to optimize patient outcomes and expand the market by improved treatment compliance with a bone anabolic drug that offers an alternative to daily injection, is stable at room temperature and requires a shorter treatment duration, such as BA058-TD. Forteo had worldwide sales of $594 million in 2006 and $950 million in 2011.

BA058

Overview

BA058 is a novel synthetic peptide analog of hPTHrP that we are developing as a bone anabolic treatment for osteoporosis. hPTHrP is critical in the formation of the embryonic skeleton, is involved in the regulation of bone formation and is able to rebuild bone with low associated risk of inducing the presence of too much calcium in the blood, known as hypercalcemia, as a side effect. Human PTHrP (a protein of 139 to 173 amino acids) is different to hPTH (a protein of 84 amino acids) in its structure and role. In 2009, the medical journal, Nature Chemical Biology, published results of a study indicating that PTH (which primarily regulates calcium homeostasis and bone resorption) and PTHrP activate the same PTHR1 receptor but produce divergent effects in bone due to differences in downstream cell signaling. We believe that BA058 is the most advanced hPTHrP analog in clinical development for the treatment of osteoporosis. We acquired and maintain exclusive worldwide rights, excluding Japan, to certain patents, data and technical information related to BA058 through a license agreement with an affiliate of Ipsen.

Table of Contents

BA058-SC

In August 2009, we announced positive Phase 2 data that showed BA058-SC produced faster and greater BMD increases at the spine and the hip after six months and 12 months of treatment than Forteo, which was a comparator in our study. Key findings were that the highest dose of BA058, which was 80 µg, increased mean lumbar spine BMD at six months and 12 months by 6.7% and 12.9% compared to the increases seen with Forteo in the study of 5.5% and 8.6%, respectively. BA058-SC also produced increases in mean femoral neck BMD at the hip at six months and 12 months of 3.1% and 4.1% compared to increases for Forteo of 1.1% and 2.2%, respectively. We believe there to be a strong correlation between an increased level of BMD and a reduction in the risk of fracture for patients with osteoporosis. BA058 was generally safe and well tolerated in this study, with adverse events similar between BA058, placebo and Forteo groups. In addition, the occurrence of hypercalcemia as a side effect was half that seen with Forteo for the 80 µg dose of BA058. We expect that the Phase 2 data for BA058-SC will be published by a third-party publication in 2013.

In March 2011, we entered into an agreement with Nordic to manage the Phase 3 study of BA058-SC. The study is being conducted in 10 countries at up to 27 centers operated by CCBR, as well as other medical centers. We expect to report top-line data from the Phase 3 study of BA058-SC in the fourth quarter of 2014. Before we submit an NDA to the FDA for BA058 as a treatment for osteoporosis, we must complete several additional studies, including, but not limited to, our pivotal Phase 3 study based upon 18-month fracture data, a thorough QT Phase 1 study, which is a study designed to assess the potential arrhythmia liability of a drug by measuring the effect on the start to finish time of the ventricular main part of the cardiac contraction, also known as the QT interval, a Phase 1 PK study in renal patients, a Phase 1 PK study in hepatic patients, a carcinogenicity study in rats, and bone quality studies in rats and monkeys.

Our ongoing Phase 3 study, which commenced in April 2011, is targeting enrollment of a total of 2,400 subjects to be randomized equally to receive daily doses of one of the following: 80 µg of BA058, a matching placebo, or the approved dose of 20 µg of Forteo for 18 months. The study is designed to support, or not, our belief that BA058 is superior to placebo for prevention of vertebral fracture and Forteo for greater BMD improvement at major skeletal sites and for a lower occurrence of hypercalcemia. We believe the study will also show that BMD gains for BA058 patients will occur earlier than for Forteo patients. The study will also include a 6-month extension period in order to obtain 24-month fracture data requested by the FDA. An interim safety analysis was performed by the independent Data Safety Monitoring Board, or DSMB, as part of its routine oversight of the Phase 3 study. At the latest meeting in November 2012, the DSMB reviewed accumulated safety data on more than 75 percent of the planned 2,400 subjects and recommended that the trial continue unmodified. As part of this DSMB review, a blinded analysis was performed on safety reports of clinical, non-vertebral fractures occurring in the study. The blinded (BA058/Placebo) versus open label (Forteo) arm has shown a lower non-vertebral fracture rate (1.2 percent in the blinded BA058/Placebo arm versus 1.9 percent in the Forteo arm). There have been no significant (serious) adverse events, or SAEs, to date attributed to BA058-SC.

Based upon new guidance we received from the FDA earlier this year, we believe that a successful, single pivotal placebo-controlled, comparative Phase 3 fracture study will be sufficient to support registration of BA058-SC for the treatment of osteoporosis in the United States. Phase 3 studies with similar size, design and endpoints as our Phase 3 fracture study have been sufficient to support registration with the European Medicines Agency, or the EMA, for other bone anabolic drugs used to treat women with osteoporosis in the European Union, or EU. In December 2012, we met with the Swedish Medical Products Agency, or MPA, to review the design and the overall progress of the Phase 3 study. The MPA confirmed that the program, based on the current single pivotal trial design, would support the submission and potential approval of an MAA in the EU, pending the results of the Phase 3 study.

Table of Contents

Assuming we do not encounter any unforeseen delays during the course of developing BA058-SC, we expect to present the 18-month data in the fourth quarter of 2014. We plan to file the NDA submission for BA058-SC in approximately mid-2015 with the 18-month fracture data and supplementally provide the 24-month fracture data, when available. We expect commercial launch to follow in the United States, if and when the FDA approves the NDA for BA058-SC, and in the EU if and when the marketing authorization application for BA058-SC is approved. In the fourth quarter of 2014, we expect to begin hiring additional personnel in preparation for this commercial launch.

BA058-TD

We successfully completed combined single-day and seven-day repeat-dose Phase 1b clinical studies of BA058-TD in healthy subjects. We commenced the Phase 2 BA058-TD clinical study in the third quarter of 2012 and expect top-line data to be available in the third quarter of 2013. Our Phase 2 clinical study compares multiple daily doses of BA058-TD to placebo and BA058-SC using lumbar spine BMD at six months as the primary endpoint. If BA058-SC is already approved by the FDA, we believe that we will only need to conduct a single non-inferiority Phase 3 clinical study comparing the change in lumbar spine BMD at 12 months for patients dosed with BA058-TD to patients dosed with BA058-SC to show that the effect of BA058-TD treatment is not worse than that of BA058-SC. In 2014, we expect that the Phase 2 data for BA058-TD will be published by a third-party publication. In addition, we expect to commence our Phase 3 clinical study for BA058-TD in 2014.

We believe that development costs for BA058-TD will be lower than the injectable version as we currently do not intend to conduct an additional pivotal fracture study for this follow-on product. As a result of the compressed pathway, if our clinical trials of BA058-SC and BA058-TD are successful, we expect that marketing approval of BA058-TD can occur soon after BA058-SC. Therefore, the FDA approval, and the timing of any such approval, is dependent upon the approval of BA058-SC. As a result, BA058-TD is not likely to receive FDA approval, if ever, until at least two years following approval of BA058-SC.

Clinical Development Program

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

Ongoing BA058-SC Phase 3 Study

The Phase 3 study for BA058-SC (Study BA058-05-003) was submitted as a draft protocol to investigational new drug, or IND, 73,176 on December 18, 2009, and was the subject of a Type B End of Phase 2 Meeting conducted with the FDA on January 21, 2010. The protocol was subsequently revised and submitted to the FDA on December 17, 2010. In April 2011, we began dosing patients in this study. The study is planned to enroll 2,400 patients at up to 27 medical centers in 10 countries in the United States, Europe, Latin America, India and Asia.

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 BA058-SC pivotal Phase 3 clinical study is designed to produce fracture data based on an 18-month primary endpoint. The FDA's

Table of Contents

letter solicited a meeting to review the status of our Phase 3 clinical study and discuss options for fulfilling the FDA's new request for 24-month fracture data in the context of the ongoing Phase 3 study. We subsequently met with the FDA on March 21, 2012 to discuss satisfying the 24-month data request while preserving the current 18-month primary endpoint. Based upon our discussion with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from a 6-month extension of the BA058 80 µg and placebo groups in our Phase 3 study that will receive approved alendronate (generic Fosamax®) therapy for osteoporosis management. We intend to file the NDA with the 18-month fracture data and supplementally provide the 24-month fracture data, when available.

Study objectives. The primary objective of this study is to determine the safety and efficacy of BA058-SC at a dose of 80 µg when compared to a matching placebo for prevention of vertebral fracture in otherwise healthy ambulatory postmenopausal women at risk of fracture from severe osteoporosis. Patients, investigators and independent assessors will be blinded as to treatment for that outcome. The secondary objectives of this study are to determine the safety and efficacy of BA058 at a dose of 80 µg when compared to placebo for prevention of non-vertebral fractures and for change in vertical height. Additional key secondary efficacy outcomes include BMD of spine, hip and femoral neck and frequency of hypercalcemia when compared to Forteo.

Study population. The study will enroll otherwise healthy ambulatory women who have been postmenopausal for at least five years aged 50 to 85 (inclusive), meet the study entry criteria and have provided written informed consent. The women will have a BMD t-score ≤-2.5 and > -5.0 at the lumbar spine or hip (femoral neck) by DXA and radiological evidence of two or more mild or one or more moderate lumbar or thoracic vertebral fractures, or history of low trauma forearm, humerus, sacral, pelvic, hip, femoral or tibial fracture within the past five years. Postmenopausal women older than 65 who meet the above fracture criteria but have a t-score ≤-2.0 and > -5.0 may be enrolled. Women older than 65 who do not meet the fracture criteria may also be enrolled if their t-score ≤-3.0 and > -5.0. Osteoporosis is defined as when a patient's t-score ≤-2.5, meaning that the patient has a BMD that is two and a half standard deviations below the mean BMD of an ethnically matched thirty year old man or woman, as applicable. All patients are to be in good general health as determined by medical history, physical examination (including vital signs) and clinical laboratory testing.

Table of Contents

Study design.

The planned 2,400 eligible patients will be randomized equally to receive one of the following for 18 months:

BA058 at a dose of 80 µg;

a matching placebo; or

Forteo at a dose of 20 µg.

Study drug will be blinded to patients and medical personnel until the randomization process is completed. Treatment with BA058 at a dose of 80 µg or placebo will remain blinded to all parties throughout the study. Forteo comes as a proprietary prefilled drug and device combination that cannot be repackaged. Therefore, its identity cannot be blinded to treating physicians and patients once use begins. Study medication will be self-administered daily by subcutaneous injection for a maximum of 18 months. All enrolled patients will also receive calcium and vitamin D supplementation from the time of enrollment until the end of the treatment period. It will be recommended to patients that they also continue these supplements through the one month follow-up period.

Primary efficacy endpoints. The primary efficacy endpoint will be the number of BA058-treated patients showing new vertebral fractures at end-of-treatment when compared to placebo as evaluated by a blinded assessor according to a standardized graded scale of severity of the vertebral deformity. The sample size per treatment arm provides 90% power at a two-sided alpha to detect a superiority difference between placebo patients and those who receive BA058 at a dose of 80 µg on vertebral fracture incidence.

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

Table of Contents

Additional secondary endpoints will include change in standing height and changes in serum bone formation markers across treatment, such as P1NP, osteocalcin and bone-specific alkaline phosphatase. The frequency of hypercalcemia across treatment groups will also be assessed.

Each of the BA058 80 µg and placebo groups in our Phase 3 study will be eligible to continue in an extension study and will receive approved alendronate (generic Fosamax®) therapy for osteoporosis management. A key endpoint of the extension study will be the reduction in new vertebral fractures at 24 months in BA058-treated patients who are treated with alendronate at the end of treatment, versus placebo-treated patients who are treated with alendronate at the end of treatment.

Extension study design.

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

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

Overall study safety will be monitored by an independent data safety monitoring board.

BA058-TD Phase 2 study

In the third quarter of 2012, we initiated a Phase 2 randomized, placebo-controlled, parallel group dose-finding clinical study of BA058-TD. The study will evaluate the safety and efficacy of the daily BA058-TD in women with osteoporosis. We intend to enroll about 250 patients and the study will be similar in design to the Phase 2 study for BA058-SC. The study will evaluate the effects of three doses of BA058-TD, compared to placebo and BA058-SC at a dose of 80 µg, on change in BMD and anabolic bone markers over six months of treatment. The study will be powered to detect clinically meaningful changes in BMD and biomarkers as efficacy measures.

Table of Contents

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

Study participation will be preceded by four weeks of pretreatment with calcium and vitamin D supplements and treatment conclusion will be followed by a one month period of safety observation.

We expect top-line data from this study to be available in the third quarter of 2013.

Completed BA058-SC Phase 2 study

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. The purpose of the study was to evaluate the safety and efficacy of daily injections of BA058-SC in women with osteoporosis. Postmenopausal women between the ages of 55 and 85 (inclusive) who had a BMD t-score ≤-2.5 at the lumbar spine or hip (femoral neck) by DXA or a BMD t-score ≤-2 and a prior low trauma fracture or an additional risk factor were candidates for this study. The study evaluated the effects of BA058-SC at multiple doses (placebo, 20 µg, 40 µg and 80 µg) on recovery of BMD, a marker of fracture risk, and on biomarkers of anabolic and resorptive activity in bone. The study also included a Forteo treatment arm for reference. These efficacy measures (BMD and bone biomarkers) were designed for statistical significance. After the initial 24 weeks of treatment, eligible patients were offered a second 24 weeks of their assigned treatment. Safety was assessed throughout the study and reported on at both six months and 12 months. BA058-SC and placebo were self-administered using a prefilled cartridge in a pen-injector device. Forteo was self-administered as the marketed product at the approved dose of 20 µg per day by subcutaneous injection. Four weeks prior to start of treatment, patients began taking calcium and vitamin D supplements that continued throughout the study.

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

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

In the ITT population, the mean percent change in total analyzable spine BMD at week 12 increased with dose as shown in Figure A below. The mean gains in BMD (active treatment placebo) for BA058-SC 40 µg and 80 µg groups were statistically significant ($p = 0.0013$ and $p < 0.001$, respectively). The difference was not statistically significant in the BA058 20 µg group and just missed significance 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 analyzable spine BMD was statistically significant for BA058-SC 40 µg ($p < 0.001$) and 80 µg ($p < 0.001$) groups. The mean BMD gain at week 24 was also statistically significant for the Forteo group ($p < 0.001$). The response of lumbar spine BMD to BA058-SC was dose dependent, and the 80 µg BA058-SC dose produced a larger percentage increase in BMD at the lumbar spine than the approved 20 µg 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 Analyzable 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 analyzable hip BMD were 0.4%, 1.4%, 2.0% and 2.6% for the placebo, BA058 at a dose of 20 µg, BA058 at a dose of 40 µg, and BA058 at a dose of 80 µg groups, respectively. Mean percent change in the Forteo (0.5%) group was similar to placebo, as shown in Figure B below. The change in total analyzable hip BMD showed a dose response to BA058-SC and a more than five-fold benefit of BA058 at a dose of 80 µg over Forteo. A similar relative benefit of BA058 at a dose of 80 µg over Forteo was seen in all regions of the hip.

Table of Contents

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

BA058-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 generally somewhat greater for all anabolic markers but also bone resorption markers (C-telopeptides of type I collagen crosslinks, or CTX, and N-telopeptides of type I collagen crosslinks, or NTX), consistent with published data on later gradual loss of Forteo BMD benefit.

BA058-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 significant (serious) adverse events, or SAEs. However, 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. Seven subjects discontinued due to adverse events: one in the BA058 20 µg group, one in the BA058 40 µg group, three in the BA058 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.

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 4%, 12%, 19% and 18% of the placebo, BA058-SC at a dose of 20 µg, 40 µg and 80 µg groups, respectively. Most elevations were noted at the four-hour post-injection time point.

Table of Contents

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, BA058-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 BA058 after six months of treatment. Of these, five were in the BA058 20 µg group, six were in the BA058 40 µg group and five were in the BA058 80 µg group. There were no associated safety events or attenuation of treatment efficacy. One antibody-positive patient in the BA058-SC 40 µg group was found to have evidence of neutralizing activity at 24 weeks without evidence of attenuation of drug efficacy, having a 9.3% gain in total analyzable spine BMD at the week 24 assessment.

Extended 24 weeks of treatment. Patients who completed the initial 24 weeks of treatment and continued to meet eligibility criteria were offered participation in the 24-week extension study in which they would continue their assigned treatment. On completion of the regulatory process to approve the study extension, 69 patients remained eligible and 55 participated, including 13, 10, 7, 11 and 14 patients in BA058-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 analyzable spine BMD, femoral neck BMD and total analyzable hip BMD observed in the BA058-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, BA058 20 µg, BA058 40 µg and BA058 80 µg, groups, respectively, while mean percent change from baseline in the Forteo group was 8.6%. At week 48, the mean femoral neck BMD in the BA058-SC 80 µg group gained 4.1% compared to the mean of the Forteo group at 2.2%. The gain total analyzable hip BMD was 0.7%, 2.0%, 2.1% and 2.7% for the placebo, BA058 20 µg, BA058 40 µg and BA058 80 µg groups, respectively, compared to 1.3% for the Forteo group.

Table of Contents

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

No treatment-related SAEs or deaths were reported during this time period. Two patients discontinued treatment, one for bilateral femoral hernias (BA058-SC 80 µg) and one for moderate syncope (BA058-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 six months of study treatment.

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

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

BA058-SC Phase 1 studies

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

Table of Contents

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

BA058 was rapidly absorbed following injection and reached peak blood levels within one hour. The drug was rapidly cleared from the circulation, resulting in half-life values ranging from 1.05 to 2.59 hours. Following BA058 administration, serum parathyroid hormone decreased, as would be expected, and serum 1,25-dihydroxyvitamin D, an activated form of vitamin D, and serum P1NP rose in a dose-related manner. Both 1,25-dihydroxyvitamin D and P1NP are expected and beneficial effects of the study drug and its class. As expected, serum calcium showed a slight rise following BA058-SC administration, although it remained within the normal range at all times in all patients other than isolated minor and transient elevations in two of seven placebo and three of 32 study subjects.

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

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

BA058-TD

First Phase 1 study. The objectives of the BA058-TD Phase 1 study were to determine the safety, PK and time course of delivery of BA058-TD in healthy postmenopausal women and to compare the PK profiles of BA058-TD delivered transdermally to BA058-SC administered subcutaneously.

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

BA058-TD was characterized by a rapid absorption and elimination. The C_{max}, or maximum plasma concentration of the drug, and half-life times were shorter than for BA058-SC administration.

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

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

Table of Contents

Second and third Phase 1 studies. A second Phase 1 single-day and a third Phase 1 seven-day application study of BA058-TD have been completed in the United States and Canada using an optimized Microneedle Patch system with top-line results announced in December 2011. These studies were designed as safety, dose-ranging and time-course PK and pharmacodynamic studies. The second and third Phase 1 studies also investigated optimal dose, wear time and application site for transdermal delivery of BA058 using an optimized microneedle array. The results obtained using BA058-TD were compared to those of BA058-SC at a dose of 80 µg.

BA058-TD was characterized by a rapid release of BA058 with a faster time to reach peak concentration as well as more rapid elimination in plasma compared to BA058-SC. Peak transdermal drug levels were consistent with BA058-SC. An optimal wear time of five minutes or less was identified as well as effective sites of application.

BA058-TD showed an increase in the bone-formation marker P1NP in serum after seven days of exposure, consistent with bone-building activity.

BA058-TD was shown to be safe and well tolerated in all doses studied.

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

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

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

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

BA058-SC was well tolerated over a wide range of doses in two species, rats and primates, for up to six months and nine months, respectively;

safety pharmacology studies demonstrated no respiratory, gastroenterologic, hematologic, renal or central nervous system effects (tachycardia and hypotension were observed in dogs following both intravenous and subcutaneous administration, but such effects were not observed in other species);

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

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

Table of Contents

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

Ongoing preclinical safety studies for BA058

A two-year subcutaneous injection carcinogenicity study of BA058 in Fischer 344 albino rats is currently ongoing and will assess the carcinogenic potential of BA058. The study is being conducted according to the provisions set forth in Guidance ICH-S1A, ICH-S1B, and ICH-S1C(R2), and the design was accepted by the FDA on July 15, 2009. This study will evaluate three BA058 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 includes a cohort of rats being dosed with hPTH(1-34), a daily subcutaneous injection of human parathyroid hormone as a positive control, as it is anticipated that osteosarcomas would be observed with this treatment, as previously published for both rhPTH(1-34) and rhPTH(1-84) in similar 2-year rat carcinogenicity studies. The positive control will also allow confirmation of the sensitivity of the model. At an interim, preliminary analysis of histopathology on pre-terminal rats only, we have observed osteosarcomas in our carcinogenicity study in both the BA058 and hPTH(1-34) treated groups, which has been reported to regulatory agencies. Our carcinogenicty study is continuing as originally planned. The final results from the rat carcinogenicity study may show that BA058 dosing results in more osteosarcomas than PTH, at similar exposure multiples to the human therapeutic dose, which may have a material adverse bearing on approval of BA058. This study is being conducted in parallel with the Phase 3 clinical study.

We also expect to conduct one preclinical bone quality study in OVX rats for 12 months of daily BA058 subcutaneous injection and a second preclinical bone quality study in adult OVX monkeys for 16 months. The primary objective of these studies is to demonstrate that long-term treatment with BA058-SC will not lead to deleterious effects on bone quality by determining BA058's effect on the mass, architecture and strength of bones. These studies will be conducted in parallel with the Phase 3 clinical study and, in both studies, BA058 will be compared to placebo. The 12-month rat study is being performed in OVX skeletally mature Sprague-Dawley rats, an appropriate species for osteoporosis studies as a result of the cancellous bone changes and bone strength changes similarly noted in humans. In this study, a 13-week bone depletion period will occur after ovariectomy/sham surgery and prior to initiation of daily subcutaneous injection dosing with vehicle or three different dose levels of BA058.

The 16-month nonhuman primate study is being performed in OVX monkeys, a larger remodeling species whose bone depletion can be induced by estrogen deficiency, as in human menopause. In this study, an approximate nine-month bone depletion period will occur after OVX/sham surgery and prior to initiation of daily subcutaneous injection dosing with vehicle or three dose levels of BA058. The specific objectives and measured outcomes of both studies are to investigate the potential safety and restoring efficacy of BA058 on bone. Effects on bone mass, both cortical bone and cancellous bone, will be assessed by BMD and peripheral quantitative computed tomography. Effects on cortical and cancellous bone strength will be determined by biomechanical testing. The mechanisms by which BA058 affects bone will be assessed by evaluation of biomarkers of bone turnover and histomorphometric indices of bone turnover. PK of BA058 and development of antidrug antibodies will also be evaluated.

Table of Contents

Manufacturing of BA058

The active pharmaceutical ingredient, or API, of BA058 is manufactured on a contract basis by Lonza under GMP conditions using a solid phase peptide synthesis assembly process, and purification by high pressure liquid chromatography. BA058-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. BA058-TD is manufactured by 3M based on their patented microneedle technology to administer drugs through the skin, as an alternative to subcutaneous injection.

Patents relating to BA058

Composition of matter of BA058 is claimed in the United States (U.S. Patent No. 5,969,095), Europe, Australia, Canada, China, Hong Kong, South Korea, New Zealand, Poland, Russia, Singapore, Mexico, Hungary, and Taiwan. These cases have a normal patent expiration date of 2016 absent the possibility of patent term extension. The Phase 3 clinical dosage of BA058 by the subcutaneous route for use in treating osteoporosis is covered by Patent No. 7,803,770 until 2028 (statutory term extended with 175 days of patent term adjustment due to delays in patent prosecution by the USPTO) in the United States (absent any patent term extension under the Hatch-Waxman Act). The intended therapeutic formulation for BA058-SC is covered by Patent No. 8,148,333 until 2027 (statutory term extended with 36 days of patent term adjustment due to delays in patent prosecution by the USPTO) in the United States (absent any patent term extension under the Hatch-Waxman Act). Related cases granted in China, Australia, Singapore, and Ukraine, and currently pending in Europe, China, Australia, Canada, Japan, Brazil, Mexico, Singapore, South Korea, India, Israel, New Zealand, Norway, Russia, and Hong Kong will have a normal un-extended patent expiration date of 2027. An international patent application and a corresponding U.S. patent application were filed in 2012 (claiming priority to 2011) which cover various aspects of BA058 for microneedle application. Any claims that might issue from these applications will have a normal expiration date no earlier than 2032.

Competition for BA058

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

Potential competitors with BA058 include, but are not limited to, Amgen, UCB, Merck & Co., Novartis, Lilly, Asahi Kasei and Zosano. Lilly launched Forteo in December 2002 as the first-to-market anabolic or bone-building agent for the treatment of osteoporosis. In April 2012, UCB and Amgen started a Phase 3 clinical trial program for their sclerostin antibody for the treatment of osteoporosis. Zosano and Asahi Kasei are also developing a transdermal form of rhPTH(1-34) that would compete with BA058-TD. We have no products approved for sale and therefore have no share of any therapeutic markets in which we hope to introduce BA058.

Non-head-to-head comparison of BA058-SC and Amgen anti-sclerostin antibody Phase 2 study results

Our BA058-SC Phase 2 clinical study used substantially similar patient inclusion and exclusion criteria as a study completed by Amgen of the use of a human anti-sclerostin antibody, romosozumab or AMG 785, for the treatment of osteoporosis. A comparison of the 6-month and 12-month spine BMD results of the AMG 785 study at the 210 mg once-monthly subcutaneous dosing regimen,

Table of Contents

including both patients treated with AMG 785 and a control group of patients treated with Forteo, and our BA058-SC study at the 80 mcg single daily subcutaneous dose are set forth in the following table. While we believe the comparison is useful in evaluating the results of our Phase 2 clinical study of BA058-SC, the BA058-SC and AMG 785 studies were separate trials conducted at different sites, and we have not conducted a head-to-head comparison of the drugs in a single clinical trial. Results of an actual head-to-head comparison study may differ significantly from those set forth in the following table. In addition, because the BA058-SC and AMG 785 studies were separate studies and because the BA058-SC Phase 2 clinical study involved a lesser number of patients, differences between the results of the two studies may not be statistically or clinically meaningful.

	BA058-SC Phase 2(1)		**AMG 785 Phase 2(2)**	
Product	BA058	Forteo	AMG 785	Forteo
Dose	80 mcg	20 mcg	210 mg	20 mcg
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 6 months	+6.7%	+5.5%	+8.0%	+4.7%
Spine Mean Percent BMD Change from Baseline 12 months	+12.9%	+8.6%	+11.3%	+7.0%

(1) BA058-SC Study n=221 (6 months) and n=55 (12 months), 5 arms

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

RAD1901

Clinical development program

In June 2006, we exclusively licensed the worldwide rights (except Japan) to RAD1901 from Eisai. In particular, we have licensed US Patent No. 7,612,114 (effective filing date December 25, 2003, statutory term extended to August 18, 2026 with 967 days of patent term adjustment due to delays by the USPTO). We are developing RAD1901, a SERM, in an oral formulation as a treatment for vasomotor symptoms, commonly known as hot flashes.

Background on vasomotor symptoms

Hot flashes and night sweats are common symptoms during menopause, with up to 85% of women experiencing them during the menopause transition, for a median duration of four years. In 2008, more than 11.5 million women in the United States were in the 45- to 49-year age range to enter menopause. In addition, most women receiving systemic therapy for breast cancer suffer hot flashes, often with more severe or prolonged symptoms than women experiencing menopause. These symptoms can disrupt sleep and interfere with quality of life. An estimated two million women undergo menopause every year in the United States, with a total population of 50 million postmenopausal women.

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

Table of Contents

Pharmacologic characteristics

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

Phase 1 study

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

RAD1901 was generally well tolerated. All 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.

Phase 2 study

A Phase 2 proof of concept study was conducted in 100 healthy postmenopausal 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.

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

Our current strategy is to collaborate with third parties for the further development and commercialization of RAD1901. Therefore, the date of any FDA approval of RAD1901, if ever, cannot be predicted at this time. As a result of the uncertainties around the completion of a collaboration arrangement for RAD1901 with third parties, we are unable to determine the duration and costs to complete current or future clinical stages of our RAD1901 product candidate or when, or to what extent, we will generate revenues from the commercialization and sale of RAD 1901. From January 1, 2009 through December 31, 2011, we incurred $3.9 million in research and development costs related to RAD1901. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for RAD1901 could significantly increase our need to raise additional working capital funds and materially adversely affect our product development efforts and our business overall. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our cash flow needs. If we do not succeed in the timely raising of additional funds on acceptable terms, we may be unable to complete

Table of Contents

planned preclinical and clinical studies or obtain approval of any product candidates, including RAD1901 from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders.

Manufacturing of RAD1901

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

Patents relating to RAD1901

RAD1901 as a composition of matter is covered by US Patent No. 7,612,114 (statutory term extended to 2026 with 967 days of patent term adjustment absent any Hatch-Waxman extension). Corresponding cases issued in Australia and Canada and pending in India and Europe will have a normal expiration in 2023. A patent application covering methods of using RAD1901 for the treatment of vasomotor symptoms has been filed in the United States (published as US 2010/0105733A1), Europe and Canada and any claims issuing will have a normal expiration in 2027. A patent application covering combination therapy using RAD1901 has been filed in the United States (published as US 2011/0124617) and any claims issuing will have a normal expiration in 2029. In addition, a Patent Cooperation Treaty, or PCT, application covering a dosage form has been filed, and any claims that might issue from applications claiming priority to the PCT or the underlying US Provisional Application No. 61/334,095 will have a normal expiration date no earlier than 2031.

Competition for RAD1901

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

Our potential competitors in relation to RAD1901 include, but are not limited to, Pfizer (NDA under review) and Depomed (Phase 3) who both have agents in more advanced stages of development than RAD1901. We believe that RAD1901 will be able to compete with other agents for the treatment of hot flashes because we expect it to have a similar efficacy and better safety profile than estrogen products, as well as a better efficacy and safety profile than non-estrogen products. We have no products approved for sale and therefore have no share of any therapeutic markets in which we hope to introduce RAD1901.

RAD140

Pharmacologic characteristics

RAD140 is a nonsteroidal SARM that resulted from an internal drug discovery program that began in 2005. RAD140 has demonstrated potent anabolic activity on muscle and bone in preclinical studies and has completed 28-day preclinical toxicology studies in both rats and monkeys. Because of its high anabolic efficacy, receptor selectivity, potent oral activity and long duration half life, we believe

Table of Contents

that RAD140 has clinical potential in a number of indications where the increase in lean muscle mass and/or bone density is beneficial; such as treating the weight loss due to cancer cachexia, muscle frailty and osteoporosis.

Our current strategy is to collaborate with third parties for the further development and commercialization of RAD140 so the date of any FDA approval of RAD140, if ever, cannot be predicted at this time. As a result of the uncertainties around the completion of a collaboration arrangement for RAD140 with third parties, we are unable to determine the duration and costs to complete current or future clinical stages of our RAD140 product candidate or when, or to what extent, we will generate revenues from the commercialization and sale of RAD140. From January 1, 2009 through December 31, 2011, we incurred $2.4 million in research and development costs related to RAD140. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for RAD140 could significantly increase our need to raise additional working capital funds and materially adversely affect our product development efforts and our business overall. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our cash flow needs. If we do not succeed in the timely raising of additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical studies or obtain approval of any product candidates, including RAD140 from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders.

Patents relating to RAD140

RAD140 as a composition of matter and methods of using RAD140 is covered by US Patent No. 8,067,448 (effective filing date February 19, 2009, and a statutory term extended to September 25, 2029 with 281 days of patent term adjustment due to delays by the USPTO) and U.S. Patent No. 8,268,872 (effective filing date February 19, 2009 with term understood to be extended with 232 days of Patent Term Adjustment). Related patents have been granted in Australia and Mexico and additional patent applications are pending in the United States and numerous additional countries worldwide. Any patents issued from these filings will have a normal expiration in 2029 absent any extensions.

Competition for RAD140

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

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

Table of Contents

COLLABORATIONS AND LICENSE AGREEMENTS

Nordic Bioscience

We entered into a letter of intent with Nordic on September 3, 2010, pursuant to which we funded preparatory work by Nordic in respect of a Phase 3 clinical study of BA058-SC. The letter of intent was extended on December 15, 2010 and on January 31, 2011. Pursuant to the letter of intent and the two extensions, we funded an aggregate $1.5 million of preparatory work by Nordic during 2010 and funded an additional $750,000 of preparatory work by Nordic during 2011. On March 29, 2011, we entered into a Clinical Trial Services Agreement (which superseded and subsumed the letter of intent and its two extensions), a Work Statement NB-1 under such Clinical Trial Services Agreement and a related Stock Issuance Agreement with Nordic. Pursuant to Work Statement NB-1, as amended on December 9, 2011 and June 18, 2012, Nordic is managing the Phase 3 clinical study of BA058-SC and we are required to make various payments denominated in both euros and U.S dollars over the course of the Phase 3 study of a total of both €41.2 million ($52.9 million) and $3.2 million.

Pursuant to the Stock Issuance Agreement, Nordic agreed to purchase the equivalent of €371,864 of the Former Operating Company's series A-5 convertible preferred stock at a price per share equal to $8.142. Nordic purchased 64,430 shares of the Former Operating Company's series A-5 convertible preferred stock on May 17, 2011 for proceeds of $525,154 to the Former Operating Company. These shares were exchanged in the Merger for 6,443 shares of our series A-5 preferred stock, which will convert automatically into 64,430 shares of common stock upon the listing of the common stock on a national securities exchange. The Stock Issuance Agreement provides that Nordic will receive additional shares of capital stock, having an aggregate value of up to €36.8 million ($47.3 million), which, following the automatic conversion of all of our preferred stock as a result of the listing of our common stock on a national securities exchange, will be in the form of shares of common stock, at certain times during the performance of the Phase 3 clinical study that is the subject of Work Statement NB-1.

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

The Clinical Trial Services Agreement contains customary risk allocation clauses with each party indemnifying the other in respect of third-party claims arising out of or resulting from: (i) the negligence or intentional misconduct of such party, its employees, agents or representatives in performing its obligations under the Clinical Services Agreement or any Work Statement; and (ii) any breach by such party of its representations and warranties under the Clinical Trial Services Agreement. We have agreed to indemnify Nordic in respect of third-party claims for product liability or personal injury arising from or relating to our products or our use of any deliverables. In addition, we separately provide indemnification to the investigative sites performing services pursuant to Work Statement NB-1

Table of Contents

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

In December 2011, we entered into an amendment to the Work Statement, or the First Amendment. Pursuant to the original terms of the Work Statement, the study was to be conducted in 10 countries at a specified number of sites within each country. The terms of the First Amendment provide for two additional countries (the United States and India) in which the study will be conducted, specify a certain number of sites within each such additional country for the conduct of the study, and amend various terms and provisions of the Work Statement to reflect the addition of such countries and sites within the study's parameters. Payments to be made by us to Nordic under the First Amendment in connection with the conduct of the study in such additional countries are denominated in both euros and U.S. dollars and total up to both €717,700 ($922,675) and $289,663 for the 15 additional study sites in India contemplated by the First Amendment and up to both €1.2 million ($1.6 million) and $143,369 for the five additional study sites in the United States contemplated by the First Amendment.

In June 2012, we entered into a second amendment to the Work Statement, or the Second Amendment. Pursuant to the original terms of the Work Statement, as amended by the First Amendment, the study was to be conducted in 12 countries at a specified number of sites within each country. The terms of the Second Amendment (i) increase the overall number of sites by adding sites in Europe, Brazil and Argentina and removing other sites, (ii) specify a certain number of sites within each country for the conduct of the study, and (iii) amend various terms and provisions of the Work Statement to reflect additional services provided at existing sites and the addition of the new study sites within the study's parameters. The Second Amendment also provided that cash payments to Nordic under the Clinical Trial Services Agreement as well as the payment of shares of series A-6 preferred stock under the related Stock Issuance Agreement shall each be reduced by an amount of €11,941 ($15,351) per subject for any subjects enrolled in India or the United States. Such reductions shall be applied in pro rata monthly installments. Payments to be made by us to Nordic under the Second Amendment in connection with the extra services provided at existing sites and the conduct of the study at the new study sites are denominated in both euros and U.S. dollars and total €3.7 million ($4.8 million) and $205,540, respectively.

On July 26, 2012, we entered into a Letter of Intent, or the Letter of Intent, with Nordic, which provides that we and Nordic will, subject to our compliance with certain requirements of our certificate of incorporation and applicable securities laws, negotiate in good faith to enter into (1) a Work Statement NB-2, or the Work Statement NB-2, and (2) an amendment to the Stock Issuance Agreement. The Work Statement NB-2 is contemplated by the terms of the Work Statement under the Clinical Trial Services Agreement.

The Letter of Intent further provides that Nordic will begin providing clinical trial services relating to the Phase 2 clinical study of our BA058 Transdermal product, as contemplated by the Work Statement and the draft Work Statement NB-2. Payments in cash to be made by us to Nordic under the Letter of Intent in connection with the services to be provided are denominated in both euros and U.S. dollars and total up to €3.5 million ($4.5 million) and $257,856, respectively. In addition, we will issue to Nordic, subject to the execution of the Work Statement NB-2 and the Stock Issuance Agreement Amendment, shares of our series A-6 preferred stock having a value of at least $2.9 million, as additional payment for services to be provided under the Work Statement NB-2 and the Work Statement.

Table of Contents

The Letter of Intent will terminate on the earlier of (1) the date on which we and Nordic enter into the Work Statement NB-2 and the Stock Issuance Agreement Amendment and (2) November 15, 2012 (pursuant to an extension mutually agreed to by us and Nordic).

3M

In December 2008, we entered into a Feasibility Agreement with 3M whereby 3M assessed the feasibility of developing a BA058-TD patch product and supplying the product for preclinical studies in an animal model. Upon successful completion of the feasibility study, during June 2009, we entered into a Development and Clinical Supplies Agreement with 3M under which 3M is responsible to develop a BA058-TD patch product and manufacture clinical and toxicology supplies of such patch product for preclinical, Phase 1 and Phase 2 studies on an exclusive basis during the term of the agreement. In December 2012, we executed 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 BA05-TD clinical study. In addition, 3M agreed that it will not use jointly owned intellectual property developed during and resulting from its work with Radius on BA058-TD in relation to any other PTH and PTHrP analogue or derivative.

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 $10.1 million, in the aggregate, through September 30, 2012 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 BA058-TD meeting applicable specifications; and us indemnifying 3M in respect of third-party claims arising with from our or our agent's use, testing or clinical studies of BA058-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 BA058 to research, develop, manufacture and commercialize certain compounds and related products in all countries, except Japan (where we do not hold commercialization rights) and France (where our commercialization rights are subject to certain co-marketing and co-promotion rights retained by Ipsen). Ipsen also granted us an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen also granted us an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling us to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan (where we do not hold commercialization rights) and France (where our commercialization rights are subject to certain co-marketing and co-promotion rights retained by Ipsen). With respect to France, if Ipsen exercises its co-marketing and co-promotion rights then Ipsen may elect to receive a percentage of the aggregate revenue from the sale of products by both parties in

Table of Contents

France (subject to a mid-double digit percentage cap) and Ipsen shall bear a corresponding percentage of the costs and expenses incurred by both parties with respect to such marketing and promotion efforts in France; Ipsen shall also pay us a mid-single digit royalty on Ipsen's allocable portion of aggregate revenue from the sale of products by both parties in France. Specifically, we licensed US Patent No. 5,969,095 (effective filing date March 29, 1996, statutory term expires March 29, 2016) entitled "Analogs of Parathyroid Hormone," US Patent No. 6,544,949, (effective filing date March 29, 1996, statutory term ends March 29, 2016) entitled "Analogs of Parathyroid Hormone" and the corresponding foreign patents and continuing patent applications.

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

As consideration for the rights to BA058 licensed to us by Ipsen, we paid Ipsen a non-refundable, non-creditable initial license fee of $250,000. The License Agreement requires us to make payments to Ipsen upon the achievement of certain development milestones in the range of $750,000 and upon the achievement of certain development, regulatory and commercial milestones in the range of €10.0 million to €36.0 million ($12.9 million to $46.3 million), and we have, as of September 30, 2012, paid $750,000 in milestone payments and issued 17,326 shares of series A-1 convertible preferred stock to Ipsen on May 17, 2011 in lieu of a €1.0 million cash payment due to Ipsen upon initiation of the first BA058 Phase 3 clinical study. If we or our sublicensees commercialize a product that includes the compound licensed from Ipsen or any analog thereof, we will be obligated to pay to Ipsen a fixed five percent royalty based on net sales of the product on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country.

The date of the last to expire of the BA058 patents, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense the rights licensed from Ipsen to a third party, we are obligated to pay Ipsen a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, we will be obligated to pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of our patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country. The License Agreement expires on a country by country basis on the later of (i) the date the last remaining valid claim in the licensed patents expires, in that country; or (ii) 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 commitee, 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

Table of Contents

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: (i) the gross negligence or willful misconduct of such party, its affiliates, licensees, distributors or contractors; (ii) any breach by such party of its representations and warranties or any other provision of the License Agreement or any related agreement; (iii) the manufacture on behalf of such party of any licensed product or compound; (iv) (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 (v) (in our case) the making, use, development, handling or commercialization of any licensed compound or any licensed product by or on our behalf or any of our affiliates, licensees or contractors. The License Agreement contains other customary clauses and terms as are common in similar agreements in the industry. The License Agreement was amended on September 12, 2007 and May 11, 2011.

In January 2006, we entered into a Pharmaceutical Development Agreement as contemplated by the License Agreement with Ipsen. The Pharmaceutical Development Agreement, as amended in July 2007, February 2009, June 2010 and December 2011, provides for the supply of quantities of licensed product for use in certain clinical trials. Beaufour Ipsen Industrie SAS, a subsidiary of Ipsen, is responsible for the supply of BA058-SC in liquid form in a multi-dose cartridge for use in a pen delivery device. The multi-dose cartridges are manufactured for Beaufour Ipsen Industrie SAS by Vetter under a separate agreement between those parties, and BA058 API is manufactured by Lonza for us and is delivered to Vetter for vialing in the multi-dose cartridges. The Pharmaceutical Development Agreement expires upon the completion of the work plan entered into under the Pharmaceutical Development Agreement unless it is sooner terminated. The Pharmaceutical Development Agreement shall automatically terminate upon termination of the Ipsen license Agreement. We may terminate the Pharmaceutical Development Agreement at any time and for any reason with a specified prior notice period to Ipsen. Either party may terminate the Pharmaceutical Development Agreement upon a material breach by the other party with respect to the Pharmaceutical Development Agreement or the Ipsen License Agreement unless such other party cures the alleged breach within the notice period specified in the Development and Manufacturing Services Agreement. The Pharmaceutical Development Agreement contains other customary clauses and terms as are common in similar agreements in the industry.

Eisai

In June 2006, we exclusively licensed the worldwide (except Japan) rights to research, develop, manufacture and commercialize RAD1901 and related products from Eisai. Specifically, we licensed the patent application that subsequently issued as US Patent No. 7,612,114 (effective filing date December 25, 2003, statutory term extended to August 18, 2026 with 967 days of patent term adjustment due to delays by the USPTO) entitled "Selective Estrogen Receptor Modulator," the corresponding foreign patent applications and continuing patent applications. As consideration for the rights to RAD1901, we paid Eisai an initial license fee of $500,000. 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

Table of Contents

(inclusive of the $500,000 initial license fee), payable upon the achievement of certain clinical and regulatory milestones. As of September 30, 2012, we do not believe there were any milestones probable of being achieved in the foreseeable future.

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

We were also granted the right to sublicense with prior written approval from Eisai, and subject to a right of first negotiation held by Eisai if we seek to grant sublicenses limited to particular Asian countries. If we sublicense the licensed technology to a third party, we will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees we receive from such sublicensee and royalties in low single digit range based on net sales of the sublicensee. The license agreement expires on a country by country basis on the later of (i) 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 (ii) 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 filed 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; (b) is a certain type of pharmaceutical company; or (c) is a hostile takeover bidder against us which has not been approved by our board of directors as constituted immediately prior to such change of control.

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

Lonza

In October 2007, we entered into a Development and Manufacturing Services Agreement with Lonza. We and Lonza have entered into a series of Work Orders pursuant to the Development and Manufacturing Services Agreement pursuant to which Lonza has performed pharmaceutical development and manufacturing services for our BA058 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 April 4, 2013 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 filing of an NDA in the United States with

Table of Contents

the FDA and similar applications required by the EMA and other authorities, excluding authorities in Japan, for BA058, 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 ($467,316, plus up to $1.4 million), for the regulatory qualification and validation campaigns (based on a rate of 180 grams of product being used in connection with the activities to be conducted as part of such campaigns).

Charles River Laboratories

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

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

GOVERNMENT REGULATION

United States FDA process

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA 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 BA058, RAD1901 and RAD140 will each be subject to review by the FDA as a drug under NDA standards though we currently only have an IND application in relation to BA058 in the United States.

Table of Contents

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

- preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin and must be updated annually;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication to FDA's satisfaction;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP regulations; and
- FDA review and approval of the NDA.

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

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

Clinical trials necessary for product approval are typically conducted in three sequential Phases, but the Phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board, or IRB, for each institution where the trials will be conducted, and each IRB must monitor the study until completion. Study subjects must sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy extensive good clinical practice, or GCP, regulations and regulations for informed consent and privacy of individually identifiable information. Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 1 studies are usually conducted in healthy individuals and are not intended to treat disease or illness. However, Phase 1b studies are conducted in healthy volunteers or in patients diagnosed with the disease, or condition for which the study drug is intended, who demonstrate some biomarker, surrogate, or possibly clinical outcome that could be considered for "proof of concept." Proof of concept in a Phase 1b 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: (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Several different doses of the drug may be looked at in Phase 2 to see which dose has the desired effects. Patients are monitored for side effects and for any improvement in

Table of Contents

their illness, symptoms, or both. Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. A Phase 3 trial usually compares how well the study drug works compared with an inactive placebo and/or another approved medication. One group of patients may receive the new drug being tested, while another group of patients may receive the comparator drug (already-approved drug for the disease being studied), or placebo. There can be no assurance that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

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

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

The FDA has various programs, including fast track, priority review and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those intended to treat serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. A company cannot be sure that any of its drugs will qualify for any of these programs, or if a drug does qualify, that the review time will be reduced.

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

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain

Table of Contents

additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

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

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

The Hatch-Waxman Act provides five years of data exclusivity for new chemical entities which prevents the FDA from accepting ANDAs and 505(b)(2) applications containing the protected active ingredient. We expect to be eligible for five years of data exclusivity following any FDA approval of BA058-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 BA058-SC is approved for commercialization and we are successful in performing a clinical trial of BA058-TD that provides a new basis for approval (a different delivery mechanism) it is possible that we may become eligible for an additional three-year period of data exclusivity which protects against the approval of ANDAs and 505(b)(2) applications for the protected use but will not prohibit the FDA from accepting or approving ANDAs or 505(b)(2) applications for other products containing the same active ingredient.

The Hatch-Waxman Act requires NDA applicants and NDA holders to provide certain information about patents related to the drug for listing in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). ANDA and 505(b)(2) applicants must then certify regarding each of the patents listed with the FDA for the reference product. A certification that a listed patent is invalid or will not be infringed by the marketing of the applicant's product is called a "Paragraph IV certification." If the ANDA or 505(b)(2) applicant provides such a notification of patent invalidity or noninfringement, 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

Table of Contents

a reviewable filing by the agency, the ANDA or 505(b)(2) applicant then must provide, within 20 days, notice to the NDA holder and patent owner stating that the application has been submitted and providing the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. The NDA holder or patent owner then may file suit against the ANDA or 505(b)(2) applicant for patent infringement. If this is done within 45 days of receiving notice of the Paragraph IV certification, a one-time 30-month stay of the FDA's ability to approve the ANDA or 505(b)(2) application is triggered. The 30-month stay begins at the end of the NDA holder's data exclusivity period, or, if data exclusivity has expired, on the date that the patent holder is notified of the submission of the ANDA. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

European Union EMA process

In the EU, medicinal products are authorized following a similar demanding process as that required in the United States. Applications are based on the ICH Common Technical Document and must include a detailed plan for pediatric approval, if such approval is sought. Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

Centralized procedure. Under the centralized procedure, after the EMA issues an opinion, the European Commission issues a single marketing authorization valid across the European Union, 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 European Union country of a medicinal product that has not yet been authorized in any European Union 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 European Union Member State, in accordance with the national procedures of that country. Thereafter, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In light of the fact that there is no policy at the EU level governing pricing and reimbursement, the 27 European Union 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 to support future regulatory approval of BA058-SC with EMA but have not

Table of Contents

initiated any discussions with EMA with respect to seeking regulatory approval of our other products in Europe.

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 generic versions of innovator drug products in the EU. Abridged applications for the authorization of generic versions of drugs authorized by EMA can be submitted to the EMA through a centralized procedure referencing the innovator's data and demonstrating bioequivalence to the reference product, among other things.

New medicinal products in the EU can receive eight years of data exclusivity coupled with two years of market exclusivity, and a potential one year extension, if the marketing authorizations holder obtains an authorization for one or more new therapeutic indications that demonstrates "significant clinical benefit" in comparison with existing therapies; this system is usually referred to as "8+2+1". We expect to be eligible for at least ten years of market exclusivity following any approval of BA058-SC.

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

Other international markets drug approval process

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

Pricing and reimbursement

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability and level of reimbursement from third-party payors 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 are required to provide discounts and pay rebates to state and federal governments and agencies in

Table of Contents

connection with purchases of our products that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted which could potentially impact the reimbursement rates for the products we are developing and may develop in the future and also could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of products that, if successfully developed, we bring to market.

There is no legislation at the EU level governing the pricing and reimbursement of medicinal products in the EU. As a result, the competent authorities of each of the 27 EU Member States have adopted individual strategies regulating the pricing and reimbursement of medicinal products in their territory. These strategies often vary widely in nature, scope and application. However, a major element that they have in common is an increased move towards reduction in the reimbursement price of medicinal products, a reduction in the number and type of products selected for reimbursement and an increased preference for generic products over innovative products. These efforts have mostly been executed through these countries' existing price-control methodologies. The government of the UK, while continuing for now to utilize its established Pharmaceutical Pricing Reimbursement Scheme approach, has announced its intentions to phasing in, by 2014, 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 uncertainty exists as to the reimbursement status of newly approved healthcare products by third-party payors.

Sales and marketing

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

We may also be subject to various federal and state laws pertaining to healthcare "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to

Table of Contents

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

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

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

Other laws and regulatory processes

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the United States, including laws relating to the oversight activities of the SEC and, following the listing of our capital stock on the NASDAQ Global Market, we will be subject to the regulations of the NASDAQ Global Market. In addition, 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.

Table of Contents

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.

INTELLECTUAL PROPERTY

As of December 31, 2012, we owned four issued United States patents, as well as ten pending United States patent applications and 33 pending foreign patent applications in Europe and 14 other jurisdictions, seven granted foreign patents and two pending international applications. As of December 31, 2012, we had licenses to nine United States patents, one United States patent application as well as numerous foreign counterparts to many of these patents and patent applications. We licensed these patents and patent applications on an exclusive basis for all countries except Japan, though our rights in France with respect to BA058 are subject to certain co-promotion and co-marketing rights held by Ipsen and our rights to sublicense in certain Asia Pacific countries in respect of RAD1901 are subject to a right of first refusal held by Eisai, all as described herein in our discussion of our license agreements with Ipsen and Eisai.

EMPLOYEES

As of September 30, 2012, we employed fourteen full-time employees and one part-time employee, three of whom held Ph.D. or M.D. degrees. Nine of our employees were engaged in research and development activities and six were engaged in support administration, including business development and finance. We intend to use CROs and other third parties to perform our clinical studies and manufacturing.

PROPERTIES

On July 15, 2011, we entered into a lease, or the Lease, for our executive offices with Broadway Hampshire Associates Limited Partnership, or the Landlord, for approximately 5,672 rentable square feet of space in the building located at 201 Broadway, Cambridge, Massachusetts 02139.

The Lease has an initial term of three years, commenci