

Radius Health, Inc.
Form S-1/A
September 28, 2012

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As filed with the Securities and Exchange Commission on September 28, 2012

Registration No. 333-179397

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

**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
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)
201 Broadway, 6th Floor
Cambridge, Massachusetts 02139
(617) 551-4700

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

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

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)

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Boston, Massachusetts 02116
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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.

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

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

PRELIMINARY PROSPECTUS Subject to Completion September 28, 2012

Prospectus

Shares

Common Stock

Radius Health, Inc. is offering _____ shares of its common stock. See "The offering." Prior to this offering, there has been no public market for our common stock. We currently expect the public offering price of our common stock to be between \$ _____ and \$ _____ per share.

After the pricing of this offering, we expect that our common stock will be listed on the NASDAQ Global Market under the symbol "RDUS."

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 10 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.

	Per share	Total
Public offering price	\$ _____	\$ _____
Underwriting discounts and commissions	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

The underwriters may also purchase up to an additional _____ shares of our common stock at the public offering price, less the underwriting discounts and commissions payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus. If the underwriters exercise this option in full, the total underwriting discounts and commissions will be \$ _____ and our total proceeds, before expenses will be \$ _____.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$ _____ in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these stockholders may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering. In addition, the underwriters could determine to sell fewer shares to these stockholders than the stockholders indicate an interest in purchasing or not to sell any shares to these stockholders.

The underwriters are offering the common stock as set forth under "Underwriting." Delivery of the shares will be made on or about _____, 2012.

UBS Investment Bank

Leerink Swann

Cowen and Company

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with additional information or information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. 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.

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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 June 29, 2012, which was €1.00 = \$1.2668. 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.

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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."

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. 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.

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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 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.

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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 the fracture healing market;
- > 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 have a short operating history. We currently have no commercial products, and we have not received regulatory approval for, nor have we generated commercial revenue from, any of our product candidates. If we do not obtain the necessary United States or worldwide regulatory approvals to commercialize any product candidate, we will not be able to sell our product candidates.
- > Most of our product candidates are in early stages of clinical trials. We cannot predict with any certainty if or when we might submit a New Drug Application, or NDA, for regulatory approval for any of our product candidates or whether any such NDA will be accepted.
- > We have a history of net losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability.
- > We are heavily dependent on the success of 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.

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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 June 30, 2012, we employed thirteen full-time employees and two part-time employees, 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.

CONFLICTS OF INTEREST

Because one of our board members, Jonathan Fleming, is also a member of the board of managers of Leerink Swann LLC, one of the underwriters in this offering, a "conflict of interest" under FINRA Rule 5121 may be deemed to exist. Accordingly, this offer is being made in compliance with FINRA Rule 5121. FINRA Rule 5121 requires that a "qualified independent underwriter" participate in the preparation of this prospectus and the registration statement of which this prospectus is a part and exercise the usual standards of due diligence with respect thereto. UBS Securities LLC has assumed the responsibilities of acting as the qualified independent underwriter in this offering. See "Affiliations/conflicts of interest."

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The offering

Common stock offered by us	shares
Common stock to be outstanding after the offering	shares
Over-allotment option	We have granted the underwriters a 30-day option to purchase up to an additional shares to cover over-allotments.
Use of proceeds	We estimate that our net proceeds from this offering will be approximately \$ million at an assumed public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds of this offering to fund the clinical development of our most advanced product candidates and for other general corporate purposes.
Risk factors	See "Risk factors" beginning on page 10 of this prospectus for a discussion of factors you should carefully consider before you decide to invest in our common stock.

Proposed NASDAQ Global Market symbol RDUS

The number of shares of our common stock outstanding after this offering is based on the number of shares of our common stock outstanding as of June 30, 2012 and excludes:

- > 3,937,386 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$3.10 per share;
- > 803,032 shares of our common stock reserved for future issuance under our 2011 equity incentive plan;
- > 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
- > 2,448,340 shares of our common stock reserved for issuance in satisfaction of dividends accrued as of June 30, 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 the NASDAQ Global Market, 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.

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

- > the automatic conversion of all outstanding shares of our convertible preferred stock into 20,754,880 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market;
- > the issuance of 1,639,421 shares of our common stock to the holders of our series A-1, A-2 and A-3 convertible preferred stock upon the listing of our common stock on the NASDAQ Global Market in satisfaction of accumulated dividends, as required by the terms of the series A-1, A-2 and A-3 convertible preferred stock, assuming for this purpose that the listing of our common

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stock on the NASDAQ Global Market occurred on June 30, 2012, all of which is described more fully under the section of this prospectus entitled "Capitalization";

- > the amendment and restatement of our certificate of incorporation and the amendment and restatement of our bylaws upon the listing of our common stock on the NASDAQ Global Market;
- > the increase in the number of shares of our common stock reserved for future issuance under our amended 2011 equity incentive plan, which will become effective upon the listing of our common stock on the NASDAQ Global Market;
- > no issuance of the dividends accrued on our series A-5 convertible preferred stock described above;
- > no exercise of the outstanding options or warrants described above; and
- > no exercise of the underwriters' option to purchase up to an additional _____ shares of our common stock to cover over-allotments.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$ _____ in shares of our common stock in this offering at the initial public offering price. Assuming an initial public offering price of \$ _____ per share, which is the midpoint of the price range listed on the cover page of this prospectus, these stockholders would purchase an aggregate of up to approximately _____ of the _____ shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, these stockholders may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering. In addition, the underwriters could determine to sell fewer shares to these stockholders than the stockholders indicate an interest in purchasing or not to sell any shares to these stockholders.

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Summary financial data

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

We derived the statements of operations data for the years ended December 31, 2009, 2010 and 2011 and the balance sheet 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 six months ended June 30, 2011 and 2012 and the balance sheet data as of June 30, 2012 from our unaudited financial statements for period ended June 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.

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Statements of Operations and Comprehensive Loss Data:	Years ended December 31,			Six months ended June 30,	
	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	24,366
General and administrative		5,330	3,630	2,668	4,291
Restructuring			217		
Loss from operations		(41,509)	(15,539)	(15,571)	(28,657)
Other income (expense), net		(236)	824	(7)	(1,184)
Interest income (expense), net		(731)	85	489	(992)
Net loss	\$	(42,476)	\$ (14,630)	\$ (15,089)	\$ (30,833)
Other comprehensive loss, net of tax:					
Unrealized gain (loss) from available-for-sale securities		8	(18)	(232)	5
Comprehensive loss	\$	(42,468)	\$ (14,648)	\$ (15,321)	\$ (30,828)
Earnings (loss) attributable to common stockholders basic and diluted	\$	253	\$ (26,773)	\$ (26,494)	\$ (37,643)
Earnings (loss) per share basic	\$	0.51	\$ (83.42)	\$ (82.68)	\$ (46.18)
Earnings (loss) per share diluted	\$	0.07	\$ (83.42)	\$ (82.68)	\$ (46.18)
Weighted average shares basic		499,944	320,942	320,424	815,053
Weighted average shares diluted		3,454,276	320,942	320,424	815,053
Pro forma earnings (loss) attributable to common stockholders basic and diluted ⁽¹⁾⁽²⁾ (unaudited)	\$	18,461			\$ (30,833)
Pro forma earnings (loss) per share basic ⁽¹⁾ (unaudited)	\$	1.24			\$ (1.38)
Pro forma earnings (loss) per share diluted ⁽¹⁾ (unaudited)	\$	1.17			\$ (1.38)
Weighted-average common shares used in computing pro forma earnings per share basic ⁽¹⁾ (unaudited)		14,848,565			22,373,458
Weighted-average common shares used in computing pro forma earnings per share diluted ⁽¹⁾ (unaudited)		15,753,387			22,373,458

(1) *Unaudited pro forma basic and diluted earnings attributable to common stockholders and pro forma basic and diluted earnings per share are calculated after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into shares of common stock, as if these conversions occurred at the beginning of the respective period, or their original issuance date, if later.*

(2) *Unaudited pro forma basic and diluted earnings attributable to common stockholders for the year ended December 31, 2011, is comprised of net loss and extinguishment of preferred stock, which are both included in basic and diluted earnings attributable to common stockholders. See Note 5, "Net loss per share," to our financial statements for the year ended December 31, 2011. Unaudited pro forma basic and diluted earnings attributable to common stockholders for the six months ended June 30, 2012 comprises net loss. See Note 4, "Net Income (Loss) Per Share," to our financial statements for the period ended June 30, 2012. Unaudited pro forma basic and diluted earnings, calculated using the if-converted method, excludes accretion of preferred stock and earnings attributable to participating preferred stockholders.*

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(3) *Unaudited basic and diluted weighted-average common shares used in computing pro forma earnings per share for the year ended December 31, 2011 are calculated assuming that the Former Operating Company's Series A, B and C convertible preferred stock was exchanged for our series A-2, A-3 and A-4 convertible preferred stock at the beginning of the respective period, that our series A-2, A-3 and A-4 convertible preferred stock was outstanding for the entire respective period and that the Former Operating Company's series A, B and C convertible preferred stock was not outstanding for any portion of the respective period. See Note 4, "Recapitalization," to our financial statements for the year ended December 31, 2011.*

Balance Sheet Data:	As of June 30, 2012		
	Actual	Pro forma(1)	Pro forma as adjusted(1)(2)
(unaudited, in thousands)			
Cash, cash equivalents and marketable securities	\$ 45,874	\$ 45,874	
Working capital	42,609	42,609	
Total assets	51,969	51,969	
Convertible preferred stock ⁽³⁾	163,468		
Note payable, net of current portion and discount	17,083	17,083	
Total stockholders' (deficit) equity	(156,117)	7,351	

(1) *Gives effect to:*

- > *the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2012 into 20,754,880 shares of our common stock upon the listing of our common stock on the NASDAQ Global Market; and*
- > *the issuance of 1,639,421 shares of our common stock to the holders of our series A-1, A-2 and A-3 convertible preferred stock upon the listing of our common stock on the NASDAQ Global Market in satisfaction of accumulated dividends, as required by the terms of the series A-1, A-2 and A-3 convertible preferred stock, assuming for this purpose that the listing of our common stock on the NASDAQ Global Market occurred on June 30, 2012, all of which is described more fully under the section of this prospectus entitled "Capitalization."*

The pro forma information above excludes 2,448,340 shares of our common stock reserved for issuance in satisfaction of dividends accrued as of June 30, 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 the NASDAQ Global Market, and additional shares that will accrue quarterly based on the progress of certain preclinical and clinical trials conducted for us by 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.

(2) *Gives further effect to our issuance and sale of _____ shares of our common stock in this offering at an assumed public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase or decrease in the assumed public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of the pro forma as adjusted cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity (deficit) by approximately \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of one million shares in the number of shares to be offered by us would increase or decrease each of the pro forma as adjusted cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity (deficit) by approximately \$ _____ million, assuming that the public offering price is \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering.*

(3) *Consists of series A-1, A-2, A-3, A-4 and A-5 convertible preferred stock. See "Capitalization."*

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Risk factors

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

RISKS RELATED TO OUR BUSINESS

Risks related to our financial position and need for capital

We 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 \$30.8 million for the six months ended June 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 June 30, 2012, we had an accumulated deficit of \$156.1 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, including after the consummation of this offering. Our failure to achieve or maintain profitability or to raise additional capital could negatively impact the value of our securities.

We currently have no product revenues and will need to raise additional capital to operate 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 the proceeds from this offering, together with our existing resources, will be sufficient to fund our planned operations until the end of the first

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quarter of 2014. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies.

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

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

- > dispose of our business or certain assets;
- > change our business, management, ownership or business locations;
- > incur additional debt or liens;
- > make certain investments or declare dividends;
- > acquire or merge with another entity for consideration in excess of an allowable amount;
- > engage in transactions with affiliates; or
- > encumber our intellectual property.

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

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

We will need to seek additional sources of financing, which may not be available on favorable terms, if at all.

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

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,

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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 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.

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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, 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.

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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 daily oral doses of alendronate (generic Fosamax®) or other standard of care 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.

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 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.

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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.

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

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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 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

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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
- > 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:

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

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cost-effectiveness of our product relative to competing products;

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

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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.

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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 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.

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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 (\$52.1 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 the NASDAQ Global Market. 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 (\$46.6 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.

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

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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 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.

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

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

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

Risks related to marketing and sale of our products

We have no experience selling, marketing or distributing products and 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

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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 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.

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

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

Risks related to our intellectual property

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

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

If our efforts to protect our intellectual property related to 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,

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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."

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."

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

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

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

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> 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 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.

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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;
- > 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

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- > 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.

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

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price, or we could issue additional securities as consideration for these acquisitions, which could cause our stockholders to suffer significant dilution.

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

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

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

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

RISKS RELATING TO OUR COMMON STOCK AND THIS OFFERING

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

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

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

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

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

>