PUMA BIOTECHNOLOGY, INC.
Form S-1/A
October 17, 2012
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As filed with the Securities and Exchange Commission on October 17, 2012

Registration No. 333-184187

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 2

to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	2834	77-0683487
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

10880 Wilshire Boulevard, Suite 2150

Los Angeles, California 90024

(424) 248-6500

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

Alan H. Auerbach

President and Chief Executive Officer

Puma Biotechnology, Inc.

10880 Wilshire Boulevard, Suite 2150

Los Angeles, California 90024

(424) 248-6500

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

Copies to:

B. Shayne Kennedy
Latham & Watkins LLP
650 Town Center Drive, 20th Floor
Costa Mesa, CA 92626
(714) 540-1235

William C. Hicks
John T. Rudy
Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
666 Third Avenue
New York, NY 10017
(212) 935-3000

Approximate date of commencement of proposed sale to the public: Promptly after the effective date of this Registration Statement.

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:

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

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee (2)
Common Stock $0.0001 par value	$115,862,500	$13,923.40

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act.
(2) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum offering price. Of this amount, $11,759.75 has been previously paid by the Registrant. An additional $2,163.65 is being paid at the rate currently in effect with respect to the additional $15,862,500 included in the proposed maximum offering price.

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 this 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 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 state where the offer or sale is not permitted.

Subject to Completion Preliminary Prospectus dated October 17, 2012

PROSPECTUS

6,500,000 Shares

Common Stock

We are selling 6,500,000 shares of our common stock.

Our shares currently trade on the OTC Bulletin Board and OTCQB Market under the symbol PBYI. The last reported sale price of our common stock on the OTC Bulletin Board and OTCQB Market on October 16, 2012 was $15.50 per share. Our common stock has been approved for listing on the New York Stock Exchange under the symbol PBYI.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for future filings. See Prospectus Summary Implications of Being an Emerging Growth Company.

Investing in our common stock involves risks that are described in the Risk Factors section beginning on page 11 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to us	$	$

The underwriters may also exercise their option to purchase up to an additional 975,000 shares from us at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

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

BofA Merrill Lynch **Leerink Swann**

Stifel Nicolaus Weisel **Cowen and Company** **UBS Investment Bank**

The date of this prospectus is , 2012.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

This prospectus includes estimates, statistics and other industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and publicly available information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. This prospectus also includes data based on our own internal estimates. We caution you not to give undue weight to such projections, assumptions and estimates.

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PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus. This summary is not complete and does not contain all the information that should be considered before investing in our common stock. Before making an investment decision, investors should carefully read the entire prospectus, paying particular attention to the risks referred to under the headings Risk Factors and Cautionary Statement Regarding Forward-Looking Statements and our financial statements and the notes to those financial statements. As used in this prospectus, unless the context requires otherwise, the terms Company, we, our and us refer to Puma Biotechnology, Inc., a Delaware corporation formed on April 27, 2007 and formerly known as Innovative Acquisitions Corp., and the term Former Puma refers to Puma Biotechnology, Inc., a private Delaware corporation that merged with and into us in October 2011.

Overview

We are a development-stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. We focus on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seek to further develop those drug candidates for commercial use.

We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients and non-small cell lung cancer patients;
- PB272 (neratinib (intravenous)), which we are developing for the treatment of advanced cancer patients; and
- PB357, which we believe can serve as a backup compound to PB272, and which we are currently evaluating for further development in 2013.

We are initially focused on developing neratinib for the treatment of patients with human epidermal growth receptor type 2, or HER2, positive metastatic breast cancer. Studies show that approximately 20% to 25% of breast cancer tumors have an over-expression of the HER2 protein. Women with breast cancer that over-expresses HER2, referred to as HER2 positive breast cancer, are at greater risk for disease progression and death than women whose tumors do not over-express HER2. Therapeutic strategies, such as the use of Herceptin (trastuzumab) and Perjeta (pertuzumab), both produced by Genentech, and Tykerb (lapatinib), produced by GlaxoSmithKline, given in combination with chemotherapy have been developed to improve the treatment of this cancer by blocking HER2.

Currently, the FDA-approved first-line therapy for treatment of HER2 positive metastatic breast cancer is the combination of Perjeta plus Herceptin and taxane chemotherapy. The current FDA-approved second-line therapy is Tykerb, given in combination with the chemotherapy drug capecitabine. In a Phase III clinical trial, patients with HER2 positive metastatic breast cancer who received the combination of Tykerb plus capecitabine demonstrated a median progression free survival of 27.1 weeks and a response rate of 23.7%.

Based on pre-clinical and clinical studies to date, we believe that neratinib may offer an advantage over existing treatments by more potently inhibiting HER2 at a site distinct from those targeted by pertuzumab, trastuzumab, and lapatinib and by acting via a mechanism different from those of other HER2 active drugs. Results from a Phase II clinical study, where patients with second line HER2 positive metastatic breast cancer were administered the combination of neratinib and capecitabine, demonstrated a median progression survival of 40.3 weeks and an overall response rate of 64%. We anticipate commencing our Phase III clinical trial of neratinib (oral) for breast cancer patients who have previously failed HER2 directed therapy in late 2012 or in early 2013.

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We are also exploring the safety and efficacy of neratinib (oral) for the treatment of patients with HER2 positive metastatic breast cancer with brain metastases, for the treatment of HER2 positive neoadjuvant breast cancer, for the treatment of HER2 mutated non-small cell lung cancer and in the treatment of patients with a newly identified breast cancer mutation in HER2 negative breast cancer, as well as neratinib (oral) in combination with temsirolimus in patients with HER2 positive metastatic breast cancer who have failed multiple prior treatments. We have ongoing Phase II clinical trials for each of these applications, except for the newly identified breast cancer mutation in HER2 negative breast cancer patients, a group for which we expect to initiate a study later this year.

We license the exclusive worldwide rights to our current drug candidates from Pfizer Inc., or Pfizer, which had previously been responsible for the clinical trials regarding neratinib. We have modified Pfizer s clinical development strategy and during the next 12 to 18 months plan to:

- commence Phase III clinical trials evaluating the use of neratinib in combination with chemotherapy and other anti-cancer drugs as a second- or third-line treatment for HER2 positive breast cancer;
- initiate Phase II clinical trials to evaluate the use of neratinib for the treatment of HER2 mutated non-small cell lung cancer and in patients with a newly identified breast cancer mutation in HER2 negative breast cancer;
- continue the ongoing Phase II clinical trial of neratinib in the neoadjuvant treatment of HER2 positive breast cancer and the ongoing Phase II trial of neratinib in patients with HER2 positive metastatic breast cancer that has metastasized to the brain; and
- continue to evaluate the application of neratinib in the treatment of other forms of HER2 positive cancers where there may be unmet medical needs.

Strategy

Our strategy is to become a leading oncology-focused biopharmaceutical company. The key elements of our strategy are as follows:

- *Advance PB272 (neratinib), our lead drug candidate, toward regulatory approval and commercialization.* We are primarily focused on developing neratinib for the treatment of patients with HER2 positive metastatic breast cancer. We have modified the previous clinical development strategy that Pfizer employed by focusing our planned Phase II and Phase III clinical trials on the use of neratinib as a second- or third-line metastatic treatment option, which we believe may be underserved by current treatment alternatives and where clinical trials have shown substantial levels of activity. We are also focusing on the development of neratinib in the neoadjuvant treatment of patients with HER2 positive breast cancer and in patients with HER2 positive metastatic breast cancer that has metastasized to the brain.
- *Expand our product pipeline by pursuing additional applications of neratinib.* We believe there are additional applications for neratinib in HER2 mutated non-small cell lung cancer, which we also believe may be underserved by current treatment alternatives, in patients with a newly identified breast cancer mutation in HER2 negative breast cancer patients and in tumor types where HER2 is overexpressed, and we intend to further evaluate the safety and efficacy of neratinib for treating these cancers.
- *Focus on developing innovative cancer therapies.* We focus on oncology drug candidates in order to capture efficiencies and economies of scale. We believe that drug development for cancer markets is particularly attractive because relatively small clinical trials can provide meaningful information regarding patient response and safety. Furthermore, we believe that our capabilities are well suited to the oncology market and represent distinct competitive advantages.

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Build a sustainable pipeline by employing multiple therapeutic approaches and disciplined decision criteria based on clearly defined proof of principal goals. We seek to build a sustainable product pipeline by employing multiple therapeutic approaches and by acquiring drug candidates belonging to known drug classes. In addition, we employ disciplined decision criteria to assess drug candidates, favoring drug candidates that have undergone at least some clinical study. Our decision to license a drug candidate will also depend on the scientific merits of the technology; the costs of the transaction and other economic terms of the proposed license; the estimated amount of capital required to develop the technology; and the economic potential of the drug candidate, should it be commercialized. We believe this strategy minimizes our clinical development risk and allows us to accelerate the development and potential commercialization of current and future drug candidates. We intend to pursue regulatory approval for a majority of our drug candidates in multiple indications.

Evaluate the commercialization strategies on a product-by-product basis in order to maximize the value of each product. As we move our drug candidates through development toward regulatory approval, we will evaluate several options for each drug candidate s commercialization strategy. These options include building our own internal sales force; entering into a joint marketing partnership with another pharmaceutical company or biotechnology company, whereby we jointly sell and market the product; and out-licensing our product, whereby another pharmaceutical company or biotechnology company sells and markets our product and pays us a royalty on sales. Our decision will be made separately for each product and will be based on a number of factors including capital necessary to execute on each option, size of the market that needs to be addressed and terms of potential offers from other pharmaceutical and biotechnology companies. It is too early for us to know which of these options we will pursue for our drug candidates, assuming their successful development.

Product Development Pipeline

The following chart shows each of our current drug candidates and their clinical development stage:

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PB272 (neratinib (oral)) Breast Cancer

Neratinib is a potent irreversible tyrosine kinase inhibitor, or TKI, that blocks signal transduction through the epidermal growth factor receptors, or EGFRs, HER1, HER2 and HER4. We believe neratinib has clinical application in the treatment of several cancers, including breast cancer, non-small cell lung cancer and other tumor types that overexpress HER2. Our initial focus is on the development of neratinib as an oral treatment of patients with HER2 positive metastatic breast cancer.

Advantages of Neratinib

Based on pre-clinical and clinical studies to date, we believe that neratinib may offer an advantage over existing treatments that are used in the treatment of patients with HER2 positive metastatic breast cancer who failed first-line therapy, including treatment with pertuzumab and trastuzumab. Currently, the treatment of metastatic breast cancer patients who have failed first-line therapy with trastuzumab and pertuzumab involves continuing treatment with chemotherapy given in combination with either trastuzumab or lapatinib. We believe that by more potently inhibiting HER2 at a different site and acting via a mechanism different from those of pertuzumab, trastuzumab or lapatinib, neratinib may have potential advantages over these existing treatments, most notably due to its increased selectivity and stronger inhibition of the HER2 target enzyme.

PB272 (neratinib (intravenous))

We also plan to develop neratinib as an intravenously administered agent. In pre-clinical studies, the intravenous version of neratinib resulted in higher exposure levels of neratinib in pre-clinical models. We believe that this may result in higher blood levels of neratinib in patients, and this may translate into enhanced efficacy. We plan to file the Investigational New Drug application, or IND, for the intravenous formulation of neratinib in 2013.

PB357

PB357 is an orally administered agent that is an irreversible TKI that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. PB357 is structurally similar to PB272. Pfizer had completed single dose Phase I trials of PB357. We are currently evaluating PB357 and considering options relative to its development in 2013.

Risks Affecting Us

Our business is subject to numerous risks, as more fully described in the section of this prospectus entitled Risk Factors, including the following:

- We currently have no product revenues and no products approved for marketing, and will need to raise additional capital to operate our business.
- We have a limited operating history and are not profitable and may never become profitable.
- We are heavily dependent on the success of neratinib (oral), our lead drug candidate, which is still under clinical development, and we cannot be certain that neratinib (oral) will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.
- Clinical trials are very expensive, time-consuming and difficult to design and implement.
- The results of our clinical trials may not support our drug candidate claims.

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We depend significantly on intellectual property licensed from Pfizer and the termination of this license would significantly harm our business and future prospects.

Our ability to commercialize our potential products will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Prior to this offering, there has been a limited public market for our common stock, and there can be no assurance that a regular trading market will develop and continue after this offering or that the market price of our common stock will not decline below the public offering price. You may therefore be unable to re-sell shares of our common stock at times and prices that you believe are appropriate.

Corporate History

We were incorporated on April 27, 2007 in Delaware under the name Innovative Acquisitions Corp. Until October 4, 2011, we were a shell company with nominal assets and no operations.

On September 29, 2011, we entered into an Agreement and Plan of Merger with IAC Merger Corporation, a Delaware corporation and our wholly-owned subsidiary, or Merger Sub, and Former Puma.

On October 4, 2011, Merger Sub merged with and into Former Puma, and Former Puma, as the surviving entity, became our wholly-owned subsidiary. In this prospectus, we refer to the merger between Merger Sub and Former Puma as the Merger.

Immediately prior to the consummation of the Merger, Former Puma completed a private placement pursuant to a Securities Purchase Agreement dated October 4, 2011, or the Securities Purchase Agreement, with certain institutional and accredited investors. In this prospectus, we refer to this private placement as the Initial Financing. Pursuant to the Securities Purchase Agreement, Former Puma sold 14,666,733 shares of its common stock at a price per share of $3.75 for aggregate gross proceeds of approximately $55 million. Former Puma also issued a warrant to each investor that provided such investor with anti-dilution protection in regard to certain issuances of securities. These warrants expired unexercised, in accordance with their terms, following the quotation of our common stock on the OTC Bulletin Board. Former Puma also issued a warrant to Alan H. Auerbach, our President and Chief Executive Officer, that will entitle Mr. Auerbach to purchase a number of shares sufficient to maintain ownership of 20% of our outstanding shares of common stock as of the closing of this offering, at a price per share equal to the price per share paid by investors in this offering.

Following the Initial Financing, Former Puma had 18,666,733 shares of its common stock issued and outstanding. At the effective time of the Merger, each share of Former Puma s common stock outstanding prior to the effective time was cancelled and automatically converted into the right to receive one share of our common stock as consideration for the Merger. Simultaneously, we issued to Former Puma s former stockholders an aggregate of 18,666,733 shares of our common stock. In connection with the Merger, we also assumed all of Former Puma s outstanding warrants as well as an unsecured convertible promissory note for $150,000 held by Mr. Auerbach, which he subsequently converted, in accordance with its terms, to 40,000 shares of our common stock.

The Merger was accounted for as a reverse acquisition with Former Puma as the accounting acquirer and us as the legal acquirer. Upon completion of the Merger, all of our directors and officers prior to the Merger resigned and the directors and officers of Former Puma became our directors and officers. The business plan of Former Puma also became our business plan.

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Following the closing of the Merger, pursuant to the terms of a Redemption Agreement dated October 4, 2011, or the Redemption Agreement, between us and our stockholders immediately prior to the Merger, we completed the repurchase of all of our common stock issued and outstanding immediately prior to the Merger. Upon completion of the Merger and the redemption, the former stockholders of Former Puma held 100% of the outstanding shares of our common stock.

As a final step in the reverse merger process, our board of directors approved a short-form merger pursuant to which Former Puma merged with and into us, leaving us as the surviving corporation. In connection with the short-form merger, we changed our corporate name from Innovative Acquisitions Corp. to Puma Biotechnology, Inc. The short-form merger became effective on October 4, 2011.

In November 2011, we entered into subscription agreements with 139 accredited investors, including Thomas R. Malley, one of our directors, pursuant to which we sold in a private placement an aggregate of 1,333,267 shares of our common stock at a price per share of $3.75. In this prospectus, we refer to this private placement as the Subsequent Financing. We received aggregate gross proceeds of approximately $5.0 million from the Subsequent Financing. The issuance of the shares in the Subsequent Financing was exempt from registration under Section 4(2) of the Securities Act, and Rule 506 of Regulation D promulgated thereunder, inasmuch as the shares were issued to accredited investors without any form of general solicitation or general advertising.

Corporate Information

Our principal executive offices are located at 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024. Our telephone number is (424) 248-6500. Our website is www.pumabiotechnology.com. Information contained on our website is not incorporated by reference into, and should not be considered a part of, this prospectus.

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, which such fifth anniversary will occur in 2017. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenues exceed $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

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We have elected to take advantage of certain of the reduced disclosure obligations regarding executive compensation in this registration statement and may elect to take advantage of other reduced burdens in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

We are also a smaller reporting company as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosure available to smaller reporting companies.

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THE OFFERING

Common stock offered by us	6,500,000 shares
Common stock outstanding after this offering:	26,540,000 shares
Option to purchase additional shares	The underwriters have a 30-day option to purchase up to an additional 975,000 shares of our common stock at the public offering price less the underwriting discounts and commissions.
Use of Proceeds	We intend to use the net proceeds of this offering for the overall development of our drug candidates, including, but not limited to, research and development and clinical trial expenditures, and for general corporate and working capital purposes.
Offering Price	$15.50
Current market for our shares	Our shares currently trade on the OTC Bulletin Board and the OTCQB Market under the symbol PBYI.
Anticipated New York Stock Exchange symbol	PBYI

Unless otherwise noted, the number of shares of our common stock to be outstanding after this offering is based on 20,040,000 shares outstanding as of June 30, 2012, and excludes:

- 1,392,500 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2012 at a weighted average exercise price of $4.97 per share;
- 2,136,912 shares of common stock reserved for future issuance under our incentive award plan; and
- an indeterminate number of shares issuable to Alan Auerbach, our Chief Executive Officer, upon exercise of a warrant that entitles Mr. Auerbach to purchase a number of shares sufficient to maintain his ownership of 20% of our outstanding shares of common stock as of the closing of this offering. This warrant becomes exercisable upon the completion of this offering and, assuming we sell 6,500,000 shares in this offering at a public offering price of $15.50 per share, the last reported sale price of our common stock set forth on the cover page of this prospectus, Mr. Auerbach would be entitled to purchase 1,585,000 shares at $15.50 per share.

Unless we specifically state otherwise, all information in this prospectus assumes no exercise of the underwriters option to purchase additional shares of common stock.

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SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. The statement of operations data for the year ended December 31, 2011 and the period from September 15, 2010 (inception) to December 31, 2010 and the balance sheet data as of December 31, 2011 are derived from our audited financial statements included elsewhere in this prospectus. The statement of operations data for the six months ended June 30, 2011 and 2012 and for the period from September 15, 2010 (inception) to June 30, 2012 and the balance sheet data as of June 30, 2012 have been derived from our unaudited financial statements appearing elsewhere in this prospectus. You should read this data together with our audited financial statements and related notes appearing elsewhere in this prospectus and the information under the captions Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations. Our historical results are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results to be expected for a full fiscal year.

	Period from September 15, 2010 (inception) to December 31, 2010	Year Ended December 31, 2011	Six Months Ended June 30, 2012 (unaudited)	Six Months Ended June 30, 2011 (unaudited)	Period from September 15, 2010 (inception) to June 30, 2012 (unaudited)
Statement of Operations Data:					
Operating expenses:					
General and administrative	$ 6,931	$ 9,319,587	$ 2,936,503	$ 38,038	$ 12,263,021
Research and development		826,372	23,574,289		24,400,661
Depreciation and amortization		10,702	118,236	168	128,938
Totals	6,931	10,156,661	26,629,028	38,206	36,792,260
Loss from operations	(6,931)	(10,156,661)	(26,629,028)	(38,206)	(36,792,260)
Other income (expense):					
Interest income		3,783	48,152		51,935
Other income (expense)		(80,000)			(80,000)
Totals		(76,217)	48,152		(28,065)
Net loss	$ (6,931)	$ (10,232,878)	$ (26,580,876)	$ (38,206)	$ (36,820,685)
Net loss applicable to common stock (1)	$ (6,931)	$ (10,232,878)	$ (26,580,876)	$ (38,206)	$ (36,820,685)
Net loss per share of common stock, basic and diluted (1)	$ (0.002)	$ (1.32)	$ (1.326)	$ (0.01)	
Weighted-average shares of common stock outstanding, basic and diluted (1)	4,000,000	7,746,529	20,040,000	4,000,000	

(1) Please see Note 3 to our audited financial statements for the year ended December 31, 2011 and Note 2 to our unaudited financial statements for the six months ended June 30, 2012 included elsewhere in this prospectus for an explanation of the method used to calculate basic and diluted net loss per share of common stock.

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	As of December 31, 2011	As of June 30, 2012	
		Actual	Pro Forma (1)
Balance Sheet Data:			
Cash and cash equivalents	$ 53,381,734	$ 41,001,998	$ 135,079,195
Total assets	55,398,167	44,436,429	138,513,626
Total liabilities	1,025,632	16,397,586	16,397,586
Deficit accumulated during the development stage	(10,239,809)	(36,820,685)	(48,144,451)
Total stockholders equity	54,372,535	28,038,843	122,116,040

(1) Reflects the sale by us of an assumed 6,500,000 shares of our common stock in this offering at an assumed offering price of $15.50 per share, the last reported sale price of our common stock on October 16, 2012, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and the application of the net proceeds from such sale. Each $1.00 increase (decrease) in the assumed offering price, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders equity by approximately $6.1 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming that the number of shares offered by us, as set forth above, remains the same. Each increase of 1.0 million shares in the number of shares offered by us at the assumed public offering price would increase each of cash and cash equivalents, working capital, total assets and total stockholders equity by approximately $14.6 million. Similarly, each decrease of 1.0 million shares in the number of shares offered by us at the assumed public offering price would decrease each of cash and cash equivalents, working capital, total assets and total stockholders equity by approximately $14.6 million. The pro forma information discussed above is illustrative only and will be adjusted based on the actual public offering price.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this prospectus, you should carefully consider the factors discussed below when considering an investment in our common stock. If any of the events contemplated by the following discussion of risks should occur, our business, results of operations and financial condition could suffer significantly. As a result, you could lose some or all of your investment in our common stock. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Risks Related to our Business

We currently have no product revenues and no products approved for marketing, 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 FDA, and other regulatory authorities overseas for one or more of our drug candidates, we cannot market or sell our products and will not have product revenues. Currently, our only drug candidates are neratinib (oral), neratinib (intravenous) and PB357, and none of these products has been approved by the FDA for sale in the United States or by other regulatory authorities for sale outside the United States. Moreover, each of these drug candidates is in the early stages of development and will require significant time and capital before we can even apply for approval from the FDA. Therefore, for the foreseeable future, we do not expect to achieve any product revenues and will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants, and potentially, future offerings of our securities. Following this financing, we believe that our cash on hand is sufficient to fund our operations for the next two years. However, changes may occur that would consume our available capital faster than anticipated, including changes in and progress of our development activities, acquisitions of additional drug candidates and changes in regulation. In such situations, we may need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in timely raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of any drug candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development 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 our stockholders.

We have a limited operating history and are not profitable and may never become profitable.

We were formed in April 2007 and were a shell company with no specific business plan or purpose until we acquired Former Puma on October 4, 2011. Former Puma was a development-stage company formed in September 2010 and, prior to entering into the license agreement with Pfizer in August 2011, its operations were limited to identifying compounds for in-licensing. As a result, we have a history of operating losses and no meaningful operations upon which to evaluate our business. We expect to incur substantial losses and negative operating cash flow for the foreseeable future as we continue development of our drug candidates, which we do not expect will be commercially available for a number of years, if at all. Even if we succeed in developing and commercializing one or more drug candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. The successful development and commercialization of any drug candidates will require us to perform a variety of functions, including:

- undertaking pre-clinical development and clinical trials;
- hiring additional personnel;
- participating in regulatory approval processes;
- formulating and manufacturing products;

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initiating and conducting sales and marketing activities; and

implementing additional internal systems and infrastructure.

We will likely need to raise additional capital in order to fund our business and generate significant revenue in order to achieve and maintain profitability. We may not be able to generate this revenue, raise additional capital or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

We are heavily dependent on the success of neratinib (oral), our lead drug candidate, which is still under clinical development, and we cannot be certain that neratinib (oral) will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

We currently have no products that are approved for commercial sale and may never be able to develop marketable drug products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead drug candidate, neratinib (oral). Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of neratinib (oral). We cannot be certain that neratinib (oral) will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market neratinib (oral) in the United States until it receives approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until it receives the requisite approval from such countries. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of an NDA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of neratinib (oral) for many reasons, including:

we may not be able to demonstrate that neratinib (oral) is safe and effective as a treatment for our targeted indications to the satisfaction of the FDA;

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

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

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

the FDA may not find the data from pre-clinical studies and clinical studies sufficient to demonstrate that the clinical and other benefits of neratinib (oral) outweigh its safety risks;

the FDA may disagree with our interpretation of data from our pre-clinical 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 pre-clinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions;

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the advisory committee may recommend that the FDA require, as a condition of approval, additional pre-clinical 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;

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

the FDA may change its approval policies or adopt new regulations.

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

Each of our drug candidates is still in development and will require extensive clinical testing before we are prepared to submit an NDA for regulatory approval. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for any of our drug candidates or whether any such NDA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials of our drug candidates will take at least several 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:

failure to obtain regulatory approval to commence a trial;

unforeseen safety issues;

determination of dosing issues;

lack of effectiveness during clinical trials;

inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites;

slower than expected rates of patient recruitment;

failure to manufacture sufficient quantities of a drug candidate for use in clinical trials;

inability to monitor patients adequately during or after treatment; and

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

Further, we, the FDA or an Institutional Review Board, or IRB, may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our drug candidates could be harmed, and our ability to

generate revenues from the drug candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations.

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Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the study. Furthermore, any negative results we may report in clinical trials of any of our drug candidates may make it difficult or impossible to recruit and retain patients in other clinical studies of that same drug candidate. Delays or failures in planned patient enrollment and/or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our drug candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our drug candidates for our targeted indications. Success in pre-clinical 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 pre-clinical testing. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a drug candidate and may delay development of other drug 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 drug candidates and generate product revenues.

Physicians and patients may not accept and use our drugs.

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

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug;
- cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or other healthcare payors; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for our drug candidates.

We depend upon independent investigators and collaborators, such as CROs, universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not

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our employees and we cannot control the amount or timing of resources that they devote to our programs. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with regulatory requirements and the applicable protocol. These investigators 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 or otherwise fails to satisfy applicable regulatory requirements, 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 our competitors to our detriment, our competitive position would be harmed. If any of our relationships with these third-party collaborators terminate, we may not be able to enter into arrangements with alternative third-parties on commercially reasonable terms, or at all. Switching or adding additional third parties to our clinical trial programs can involve substantial costs and require extensive management time and focus.

We will rely exclusively on third parties to formulate and manufacture our drug candidates. The commercialization of any of our drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

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 drug candidates. While our drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. We are using the same third-party contractors to manufacture, supply, store and distribute drug supplies for our clinical trials. If we are unable to continue our relationships with one or more of these third-party contractors, we could experience delays in our development efforts as we locate and qualify new manufacturers. If any of our current drug candidates or any drug candidates we may develop or acquire in the future receive FDA approval, we intend to rely on one or more third-party contractors to manufacture the commercial supply of our drugs. 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 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 regulations on current good manufacturing practices, or cGMPs 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 (i) our clinical trials, (ii) the approval, if any, of our drug candidates by the FDA or (iii) the commercialization of our drug candidates or result in higher costs or deprive us of potential product revenues.

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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 will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator s strategic interest in the products under development and such collaborator s ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sale and marketing of our products if and when they are approved; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they 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. We also cannot assure you 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.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures despite the implementation of security measures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs and the development of our product candidates could be delayed.

Health care reform measures may hinder or prevent our drug candidates commercial success.

The United States and some foreign jurisdictions have enacted or are considering enacting a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changed and will continue to change the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

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an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers outpatient drugs to be covered under Medicare Part D, beginning in 2011;

extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers Medicaid rebate liability;

increase in the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;

new requirements to report certain financial arrangements with physicians, including reporting any transfer of value made or distributed to prescribers and other healthcare providers, effective March 30, 2013, and reporting any investment interests held by physicians and their immediate family members during the preceding calendar year;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

a licensure framework for follow-on biologic products; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The PPACA also requires adults not covered by employer or government-sponsored insurance plans to maintain health insurance coverage or pay a penalty, a provision commonly referred to as the individual mandate. Following court challenges to the constitutionality of the individual mandate and aspects of Medicaid expansion, on June 28, 2012, the U.S. Supreme Court upheld the constitutionality of the individual mandate, and invalidated requirements that states forfeit certain federal funding if they do not expand Medicaid coverage as prescribed by PPACA. Although the Court left the remainder of PPACA intact, Congress has proposed a number of legislative initiatives, including the possible repeal of PPACA in its entirety. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict all of the ways in which future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Nevertheless, we anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Thus, we expect to experience pricing pressures in connection with the sale of neratinib (oral), neratinib (intravenous), PB357 and any other products that we may develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payors and healthcare providers to use generic drugs that contain the active

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ingredients found in neratinib (oral), neratinib (intravenous), PB357 or any other drug candidates that we may develop. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, results of operations and financial condition.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act and the state law equivalents of such laws. These laws may impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, including private insurance programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim, or the knowing use of false statements, to obtain payment from the federal government. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government, and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of pharmaceutical, medical device and other healthcare companies to have to defend False Claims Act actions. When it is determined that an entity has violated the False Claims Act, the entity may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

The recently enacted PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

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

The market for our drug candidates is characterized by intense competition and rapid technological advances. If any of our drug candidates receives FDA approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. If our products fail to capture and maintain market share, we may not achieve sufficient product revenue 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 oncology compounds that have already been approved or are 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 the following:

- developing drugs;
- undertaking pre-clinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

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 reimbursement will be available from the following:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payors.

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

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

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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.

The loss of one or more key members of our management team could adversely affect our business.

Our success and future growth depends to a significant degree on the skills and continued services of our management team, in particular Alan H. Auerbach, our President and Chief Executive Officer. If Mr. Auerbach resigns or becomes unable to continue in his present role and is not adequately replaced, our business operations could be materially adversely affected. We do not maintain key man life insurance for Mr. Auerbach.

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

As of June 30, 2012, we had 41 employees, including our President and Chief Executive Officer. Our future success depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled scientific, technical, marketing, managerial and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite their collective efforts. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial and financial personnel would have a material adverse effect on our business, prospects, financial condition and results of operations.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations and our ability to successfully manage our growth. Our future growth, if any, may place a significant strain on our management and on our administrative, operational and financial resources. Our ability to manage our growth effectively will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems could have a material adverse effect on our business, financial condition and results of operations.

We may be adversely affected by the current economic environment.

Our ability to attract and retain collaborators or customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States and inflationary pressures. We cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaborators or customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our collaboration partners or customers may experience reductions in revenues, profitability and/or cash flow that could lead them to modify, delay or cancel orders for our products once

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commercialized. If collaboration partners or customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. This, in turn, could adversely affect our financial condition and liquidity. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, prior to the effectiveness of certain provisions of the PPACA, a substantial number of people may become uninsured or underinsured. To the extent economic challenges result in fewer individuals pursuing or being able to afford our products once commercialized, our business, results of operations, financial condition and cash flows could be adversely affected.

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. If we are unable to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, the commercialization of pharmaceutical products we develop, alone or with collaborators, could be prevented or inhibited.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third party financial institutions in excess of the Federal Deposit Insurance Corporation (FDIC) insurance limit. While we monitor daily the cash balances in the operating accounts and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit fails or is subject to other adverse conditions in the financial or credit markets. To date we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

Risks Related to Our Intellectual Property

We depend significantly on intellectual property licensed from Pfizer and the termination of this license would significantly harm our business and future prospects.

We depend significantly on our license agreement with Pfizer. Our license agreement with Pfizer may be terminated by Pfizer if we materially breach the agreement and fail to cure our breach during an applicable cure period. Our failure to use commercially reasonable efforts to develop and commercialize licensed products in certain specified major market countries would constitute a material breach of the license agreement. Pfizer may also terminate the license agreement if we become involved in bankruptcy, receivership, insolvency or similar proceedings. In the event our license agreement with Pfizer is terminated, we will lose all of our rights to develop and commercialize the drug candidates covered by such license, which would significantly harm our business and future prospects.

Our proprietary rights may not adequately protect our intellectual property and potential products, and if we cannot obtain adequate protection of our intellectual property and potential products, we may not be able to successfully market our potential products.

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our products, formulations, processes, methods and other technologies. We will only be able to protect these technologies and products from unauthorized use by third parties to the extent that valid and enforceable intellectual property rights, including patents, cover them, or other market exclusionary rights apply.

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The patent positions of pharmaceutical companies, like ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies patents has emerged to date in the United States. The general environment for pharmaceutical patents outside the United States also involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced, or that the scope of these patent rights could provide a sufficient degree of future protection that could permit us to gain or keep our competitive advantage with respect to these products and technology. For example, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to make, use, sell, offer to sell or import competitive products without infringing our patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming inventions similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings in connection with patent rights, which may be costly whether we win or lose.

The patents we have licensed may be subject to challenge and possibly invalidated or rendered unenforceable by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property.

In addition, others may independently develop similar or alternative products and technologies that may be outside the scope of our intellectual property. Furthermore, others may have invented technology claimed by our patents before we or our licensors did so, and they may have filed patents claiming such technology before we did so, weakening our ability to obtain and maintain patent protection for such technology. Should third parties obtain patent rights to similar products or technology, this may have an adverse effect on our business.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets, however, are difficult to protect. While we believe that we will use reasonable efforts to protect our trade secrets, our own or our strategic partners employees, consultants, contractors or advisors may unintentionally or willfully disclose our information to competitors. We seek to protect this information, in part, through the use of non-disclosure and confidentiality agreements with employees, consultants, advisors and others. These agreements may be breached, and we may not have adequate remedies for a breach. In addition, we cannot ensure that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information or prevent their unauthorized use or disclosure.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our potential products, disputes may arise as to the proprietary rights in such information, which may not be resolved in our favor. Consultants and key employees that work with our confidential and proprietary technologies are required to assign all intellectual property rights in their discoveries to us. However, these consultants or key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. If we were to prosecute a claim that a third party had illegally obtained and was using our trade secrets, it could be expensive and time consuming and the outcome could be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any legal or contractual claim to prevent them from using such information, and our business could be harmed.

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Our ability to commercialize our potential products will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our ability to commercialize our potential products will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third-party intellectual property rights in our field are complicated and continuously evolving. The coverage of patents is subject to interpretation by the courts, and this interpretation is not always consistent.

Other companies may have or may acquire intellectual property rights that could be enforced against us. If they do so, we may be required to alter our products, formulations, processes, methods or other technologies, obtain a license, assuming one can be obtained, or cease our product-related activities. If our products or technologies infringe the intellectual property rights of others, they could bring legal action against us or our licensors or collaborators claiming damages and seeking to enjoin any activities that they believe infringe their intellectual property rights. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving the invalidity of a patent is particularly difficult in the United States, since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third-party patent, we may need to cease the commercial sale of our products.

Because patent applications can take many years to issue, there may be currently pending applications unknown to us or reissue applications that may later result in issued patents upon which our products or technologies may infringe. There could also be existing patents of which we are unaware that our products or technologies may infringe. In addition, if third parties file patent applications or obtain patents claiming products or technologies also claimed by us in pending applications or issued patents, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our filed foreign patent applications. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Additionally, any uncertainties resulting from the initiation and continuation of any litigation may have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If a third party claims that we infringe its intellectual property rights, it could cause our business to suffer in a number of ways, including:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit, the third party s patent is ultimately invalid or unenforceable, or we are ultimately found to have not infringed;
- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a third party s patent;
- we may be ordered by a court to stop making, selling or licensing our products or technologies without a license from a patent holder, and such license may not be available on commercially acceptable terms, if at all, or may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our products so that they do not infringe upon others patent rights, which may not be possible or could require substantial investment and/or time.

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If any of these events occur, our business could suffer and the market price of our common stock may decline.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other companies in these industries, including our competitors or potential competitors. We may become subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, although no such claims are pending. Litigation may be necessary to defend against these claims. Even if we successfully defend any such claims, we may incur substantial costs in such defense, and our management may be distracted by these claims.

Risks Related to This Offering and Owning Our Common Stock

Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock. In addition, numerous other factors could result in substantial volatility in the trading price of our stock.

In connection with this offering, our common stock has been approved for listing on the New York Stock Exchange. Prior to this offering, shares of our common stock have been quoted for trading on the OTC Bulletin Board and OTCQB Market in limited volumes. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on that stock exchange or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. As of June 30, 2012, we had 20,040,000 shares of common stock outstanding, and stockholders holding at least 5% of our stock, individually or with affiliated entities, collectively beneficially owned or controlled approximately 77.5% of such shares. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our relatively small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. Moreover, if there is no active trading market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements of medical innovations or new products by our competitors;
- issuance of new or changed securities analysts reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the biopharmaceutical industry;
- timing and announcement of regulatory approvals;
- any future sales of our common stock or other securities in connection with raising additional capital or otherwise;

any major change to the composition of our board of directors or management; and

general economic conditions and slow or negative growth of our markets.

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The stock market in general, and market prices for the securities of technology-based companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

Investors in this offering will suffer immediate and substantial dilution of their investment.

If you purchase common stock in this offering, you will pay more for your shares than our pro forma net tangible book value per share. Based upon an assumed public offering price of $15.50 per share, the last reported sale price of our common stock set forth on the cover page of this prospectus, you will incur immediate and substantial dilution of $10.90 per share, representing the difference between our assumed public offering price and our pro forma net tangible book value per share. The dilution is due in large part to the fact that our earlier investors paid substantially less than the public offering price when they purchased their shares of our capital stock. You will experience additional dilution upon exercise of any warrant, upon exercise of options to purchase common stock under our incentive award plan, or if we otherwise issue additional shares of our common stock. For a further description of the dilution that you will experience immediately after this offering, see Dilution.

Our management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.

Our management will have broad discretion to use the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply the net proceeds of this offering in ways that increase the value of your investment.

The price of our common stock could be subject to volatility related or unrelated to our operations.

If a market for our common stock develops, its market price could fluctuate substantially due to a variety of factors, including market perception of our ability to meet our growth projections and expectations, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our business and the business of others in our industry. In addition, the stock market itself is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons related and unrelated to their operating performance and could have the same effect on our common stock.

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We also have incurred substantial expenses in connection with the preparation and filing of this registration statement. We will also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or the SEC, or any stock exchange or inter-dealer quotations system on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities

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more time-consuming and costly. We are unable to currently estimate these costs with any degree of certainty. We also expect that these new rules and regulations may make it difficult and expensive for us to obtain director and officer liability insurance, and if we are able to obtain such insurance, we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage available to privately-held companies. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

We are an emerging growth company, and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined by the JOBS Act. For as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various public company reporting requirements. These exemptions include, but are not limited to, (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements, and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years after the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act, which such fifth anniversary will occur in 2017. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenues exceed $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period. We have taken advantage of certain of the reduced disclosure obligations regarding executive compensation in this registration statement and may elect to take advantage of other reduced burdens in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, we have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors views of us.

We are subject to the rules and regulations of the SEC, including those rules and regulations mandated by the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to include in their annual report a statement of management s responsibilities for establishing and maintaining adequate internal control over financial reporting, together with an assessment of the effectiveness of those internal controls. Section 404 also requires the independent auditors of certain public companies to attest to, and report on, this management assessment; however, as a smaller reporting company and an emerging growth company, we are not yet subject to this attestation requirement. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our

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financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

If securities or industry analysts do not publish, or cease publishing, research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

If a trading market for our common stock develops, the trading market for our common stock will be influenced by whether industry or securities analysts publish research and reports about us, our business, our market or our competitors and, if any analysts do publish such reports, what they publish in those reports. We may not obtain analyst coverage in the future. Any analysts who do cover us may make adverse recommendations regarding our stock, adversely change their recommendations from time to time, and/or provide more favorable relative recommendations about our competitors. If any analyst who may cover us in the future were to cease coverage of our company or fail to regularly publish reports on us, or if analysts fail to cover us or publish reports about us at all, we could lose, or never gain, visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We do not foresee paying cash dividends in the foreseeable future.

We currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. As a result, you should not rely on an investment in our securities if you require dividend income. Capital appreciation, if any, of our shares may be your sole source of gain for the foreseeable future. Moreover, you may not be able to re-sell your shares in us at or above the price you paid for them.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. Furthermore, our ability to utilize NOLs of any companies we may acquire in the future may be subject to limitations. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These forward-looking statements include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the regulatory approval of our drug candidates;
- our use of clinical research centers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to market any of our products;
- our history of operating losses;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing.

These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, ongoing, expect, believe, intend and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this prospectus, including the sections entitled Business, Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as other sections. These forward-looking statements involve risks and uncertainties, including the risks discussed in the section entitled Risk Factors, that could cause our actual results to differ materially from those in the forward-looking statements. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document. The risks discussed in this prospectus should be considered in evaluating our prospects and future financial performance.

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USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $94.1 million (or $108.3 million if the underwriters exercise their option to purchase additional shares in full), after deducting the underwriters discount and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed offering price of $15.50 would increase (decrease) the net proceeds to us from this offering by approximately $6.1 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming that the number of shares offered by us, as set forth above, remains the same. Each increase of 1.0 million shares in the number of shares offered by us at the assumed public offering price would increase the net proceeds to us in this offering by approximately $14.6 million. Similarly, each decrease of 1.0 million shares in the number of shares offered by us at the assumed public offering price would decrease the net proceeds to us from this offering by approximately $14.6 million. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may impact the amount of time prior to which we will need to seek additional capital.

We intend to use the net proceeds to us from this offering for the overall development of our drug candidates, including, but not limited to, research and development and clinical trial expenditures, and for general corporate and working capital purposes. Pending the application of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term, investment-grade, interest-bearing securities.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds to us from this offering and investors will be relying on the judgment of our management regarding the application of the proceeds from this offering. We reserve the right to change the use of these proceeds as a result of certain contingencies such as competitive developments, the results of our commercialization efforts, acquisition and investment opportunities and other factors.

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PRICE RANGE OF COMMON STOCK

Since April 20, 2012, shares of our common stock have been quoted for trading on the OTC Bulletin Board and OTCQB Market under the symbol PBYI. The following table shows the reported high and low closing bid quotations per share for our common stock based on information provided by the OTC Bulletin Board and OTCQB Market. Such over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and, may not necessarily represent actual transactions.

Fiscal Year 2012	High	Low
Second Quarter (April 20 June 30)	$ 14.03	$ 10.00
Third Quarter (July 1 September 30)	$ 15.00	$ 11.00

The last reported sale price for our common stock on October 16, 2012 was $15.50 per share. As of September 30, 2012, there were approximately 98 registered holders of record of our common stock. Since many holders hold shares in street name, we believe that there are a significantly larger number of beneficial owners of our common stock than the number of record holders. In connection with this offering, our common stock has been approved for listing on the New York Stock Exchange under the symbol PBYI.

DIVIDEND POLICY

We never have declared or paid any cash dividends on our capital stock. Currently, we anticipate that we will retain all available funds for use in the operation and expansion of our business and do not anticipate paying any cash dividends after the offering and for the foreseeable future. Any future determination relating to dividend policy will be made at the discretion of our board of directors and will depend on our future earnings, capital requirements, financial condition, prospects, applicable Delaware law, which provides that dividends are only payable out of surplus or current net profits, and other factors that our board of directors deems relevant.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2012 on:

an actual basis; and

a pro forma basis giving additional effect to the sale of 6,500,000 shares of our common stock offered in this offering, assuming a public offering price of $15.50 per share, the last reported sale price of our common stock set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The information in this table is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual public offering price. You should read this table in conjunction with the information contained in Use of Proceeds, Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as our financial statements and the notes thereto included elsewhere in this prospectus.

	As of June 30, 2012	
	Actual	Pro Forma (1)
Cash and cash equivalents	$ 41,001,998	$ 135,079,195
Common stock: $0.0001 par value, 100,000,000 shares authorized, 20,040,000 shares issued and outstanding (actual); $0.0001 par value, 100,000,000 shares authorized, 26,540,000 shares issued and outstanding (pro forma)	2,004	2,654
Additional paid-in capital	64,857,524	170,257,837
Accumulated deficit	(36,820,685)	(48,144,451)
Total stockholders equity	28,038,843	122,116,040
Total capitalization	44,436,429	138,513,626

(1) Each $1.00 increase (decrease) in the assumed offering price would increase (decrease) cash and cash equivalents, additional paid-in capital, total stockholders equity and total capitalization by approximately $6.1 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Each increase of 1.0 million shares in the number of shares offered by us at the assumed public offering price would increase cash and cash equivalents, additional paid-in capital, total stockholders equity and total capitalization by approximately $14.6 million. Similarly, each decrease of 1.0 million shares in the number of shares offered by us at the assumed public offering price would decrease cash and cash equivalents, additional paid-in capital, total stockholders equity and total capitalization by approximately $14.6 million. The pro forma information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The information in the above table excludes, as of June 30, 2012:

1,392,500 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2012 at a weighted average exercise price of $4.97 per share;

2,136,912 shares of common stock reserved for future issuance under our incentive award plan; and

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an indeterminate number of shares issuable to Alan Auerbach, our Chief Executive Officer, upon exercise of a warrant that entitles Mr. Auerbach to purchase a number of shares sufficient to maintain his ownership of 20% of our outstanding shares of common stock as of the closing of this offering. This warrant becomes exercisable upon the completion of this offering and, assuming we sell 6,500,000 shares in this offering at a price of $15.50 per share, the last reported sale price of our common stock set forth on the cover page of this prospectus, Mr. Auerbach would be entitled to purchase 1,585,000 shares at $15.50 per share.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock upon closing of this offering. Net tangible book value per share of our common stock is determined at any date by subtracting our total liabilities from the amount of our total tangible assets (total assets less intangible assets) and dividing the difference by the number of shares of our common stock deemed to be outstanding at that date.

Our historical net tangible book value as of June 30, 2012 was approximately $28.0 million, or $1.40 per share, based on 20,040,000 shares of common stock outstanding as of June 30, 2012. After giving effect to our receipt of approximately $94.1 million of estimated net proceeds (after deducting underwriting discounts and commissions and estimated offering expenses payable by us) from our sale of 6,500,000 shares of common stock in this offering at an assumed public offering price of $15.50 per share, the last reported sale price of our common stock set forth on the cover page of this prospectus, our pro forma net tangible book value as of June 30, 2012 would have been approximately $122.1 million, or $4.60 per share. This amount represents an immediate increase in net tangible book value of $3.20 per share of our common stock to existing stockholders and an immediate dilution in net tangible book value of $10.90 per share of our common stock to new investors purchasing shares of common stock in this offering.

The following tables illustrate this dilution on a per share basis:

Assumed public offering price per share	$ 15.50
Net tangible book value per share as of June 30, 2012 before giving effect to the offering of shares by us	$ 1.40
Increase in net tangible book value per share attributable to new investors	3.20
Pro forma net tangible book value per share after this offering	$ 4.60
Dilution per share to new investors in this offering	$ 10.90

Each $1.00 increase (decrease) in the assumed offering price would increase (decrease) our pro forma net tangible book value by approximately $6.1 million, our pro forma net tangible book value per share after this offering by $0.23 per share and the dilution in pro forma net tangible book value to new investors in this offering by $10.67 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Each increase of 1.0 million shares in the number of shares offered by us at the assumed public offering price would increase our pro forma net tangible book value by approximately $14.6 million, our pro forma net tangible book value per share after this offering by $0.53 per share and the dilution in pro forma net tangible book value to new investors in this offering by $10.37 per share. Similarly, each decrease of 1.0 million shares in the number of shares offered by us at the assumed public offering price would decrease our pro forma net tangible book value by approximately $14.6 million, our pro forma net tangible book value per share after this offering by $0.57 per share and the dilution in pro forma net tangible book value to new investors in this offering by $11.47 per share.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma net tangible book value per share after giving effect to this offering would be $4.95 per share, which amount represents an immediate increase in pro forma net tangible book value of $3.55 per share of our common stock to existing stockholders and an immediate dilution in net tangible book value of $10.55 per share of our common stock to new investors purchasing shares of common stock in this offering.

The discussion and table above exclude, as of June 30, 2012:

- 1,392,500 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2012 at a weighted average exercise price of $4.97 per share;

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2,136,912 shares of common stock reserved for future issuance under our incentive award plan; and

an indeterminate number of shares issuable to Alan Auerbach, our Chief Executive Officer, upon exercise of a warrant that entitles Mr. Auerbach to purchase a number of shares sufficient to maintain his ownership of 20% of our outstanding shares of common stock as of the closing of this offering. This warrant becomes exercisable upon the completion of this offering and, assuming we sell 6,500,000 shares in this offering at $15.50 per share, the last reported sale price of our common stock set forth on the cover page of this prospectus, Mr. Auerbach would be entitled to purchase 1,585,000 shares at $15.50 per share.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

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SELECTED FINANCIAL DATA

You should read the following selected financial data together with our audited and unaudited financial statements and related notes appearing elsewhere in this prospectus and the information under the captions Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations. Our historical results are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results to be expected for a full fiscal year.

The following tables set forth a summary of our historical financial data as of, and for the period ended on, the dates indicated. The statement of operations data for the year ended December 31, 2011 and the period from September 15, 2010 (inception) to December 31, 2010 and the balance sheet data as of December 31, 2010 and 2011 are derived from our audited financial statements included elsewhere in this prospectus. The statement of operations data for the six months ended June 30, 2011 and 2012 and for the period from September 15, 2010 (inception) to June 30, 2012 and the balance sheet data as of June 30, 2012 have been derived from our unaudited financial statements appearing elsewhere in this prospectus.

	Period from September 15, 2010 (inception) to December 31, 2010	Year Ended December 31, 2011	Six Months Ended June 30, 2012 (unaudited)	Six Months Ended June 30, 2011 (unaudited)	Period from September 15, 2010 (inception) to June 30, 2012 (unaudited)
Statement of Operations Data:					
Operating expenses:					
General and administrative	$ 6,931	$ 9,319,587	$ 2,936,503	$ 38,038	$ 12,263,021
Research and development		826,372	23,574,289		24,400,661
Depreciation and amortization		10,702	118,236	168	128,938
Totals	6,931	10,156,661	26,629,028	38,206	36,792,260
Loss from operations	(6,931)	(10,156,661)	(26,629,028)	(38,206)	(36,792,260)
Other income (expenses):					
Interest income		3,783	48,152		51,935
Other income (expense)		(80,000)			(80,000)
Totals		(76,217)	48,152		(28,065)
Net loss	$ (6,931)	$ (10,232,878)	$ (26,580,876)	$ (38,206)	$ (36,820,685)
Net loss applicable to common stock (1)	$ (6,931)	$ (10,232,878)	$ (26,580,876)	$ (38,206)	$ (36,820,685)
Net loss per share of common stock, basic and diluted (1)	$ (0.002)	$ (1.32)	$ (1.326)	$ (0.01)	
Weighted-average shares of common stock outstanding, basic and diluted (1)	4,000,000	7,746,529	20,040,000	4,000,000	

(1) Please see Note 3 to our audited financial statements for the year ended December 31, 3010 and Note 2 to our unaudited financial statements for the six months ended June 30, 2012 included elsewhere in this prospectus for an explanation of the method used to calculate basic and diluted net loss per share of common stock.

	As of		
	December 31, 2010	December 31, 2011	June 30, 2012
Balance Sheet Data:			
Cash and cash equivalents	$	$ 53,381,734	$ 41,001,998
Total assets		55,398,167	44,436,429
Total liabilities		1,025,632	16,397,586
Deficit accumulated during the development stage	(6,931)	(10,239,809)	(36,820,685)
Total stockholders equity		54,372,535	28,038,843

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MANAGEMENT S DISCUSSION AND ANALYSIS

OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those discussed in the forward looking statements as a result of various factors, including, without limitation, those set forth in Risk Factors, Cautionary Statement Regarding Forward-Looking Statements and other matters included elsewhere in this prospectus. The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes thereto included elsewhere in this prospectus.

Overview

We are a development-stage biopharmaceutical company based in Los Angeles, California with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. We aim to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. Our efforts and resources to date have been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. As a development-stage company, we have had no product sales to date and we will have no product sales until we receive approval from the United States Food and Drug Administration, or FDA, or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Developing pharmaceutical products, however, is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety issues during the course of developing our product candidates, we do not expect to receive approval of a product candidate until approximately 2015.

We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients and non-small cell lung cancer patients;
- PB272 (neratinib (intravenous)), which we are developing for the treatment of advanced cancer patients; and
- PB357, which we believe can serve as a backup compound to PB272, and which we plan to evaluate for further development in 2013.

A large portion of our expenses to date have been related to our assuming clinical development of our lead product candidate, PB272 (neratinib (oral)), and the transition of the neratinib program from the licensor. During this transition period, as we built up our infrastructure and assumed responsibility for the neratinib program, a duplication of effort took place that resulted in higher than normal operating expenses. We estimate the duplication of effort had an impact on R&D operating expense of approximately $3 million. The transition, which was the major expense for the second quarter of 2012, has largely been completed. We believe this expense will decrease over subsequent quarters.

Additionally, our expenses to date have been related to hiring staff and the build out of our corporate infrastructure. As we proceed with clinical development of PB272 (neratinib (oral)), and as we further develop PB272 (neratinib (intravenous)) and PB357, our second and third product candidates, respectively, we expect our internal research and development, or R&D, expenses and expenses related to our third party contractors will increase.

To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance research and development will increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance product development. Our major sources of working capital have been proceeds from private sales of our common stock.

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R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for manufacturing of clinical materials and clinical trials. During the three and six months ended June 30, 2012, our R&D expenses consisted primarily of transition costs, as clinical trial responsibilities shifted to us and our outside clinical research organization, or CRO; salaries and related personnel costs; and fees paid to other consultants. We expense our R&D costs as they are incurred.

General and administrative, or G&A, expenses consist primarily of salaries and related personnel costs including stock-based compensation expense, professional fees, business insurance, rent, general legal activities, and other corporate expenses.

Corporate History

We were originally incorporated in the State of Delaware in April 2007 under the name Innovative Acquisitions Corp. We were a shell company registered under the Exchange Act with no specific business plan or purpose until we acquired Former Puma in the Merger. As a result of this transaction, Former Puma become our wholly-owned subsidiary and subsequently merged with and into us, at which time we adopted Former Puma s business plan and changed our name to Puma Biotechnology, Inc.

The Merger was accounted for as a reverse acquisition whereby Former Puma was deemed to be the acquirer for accounting and financial reporting purposes and we were deemed to be the acquired party. Consequently, our financial statements prior to the Merger reflect the assets and liabilities and the historical operations of Former Puma from its inception on September 15, 2010 through the closing of the Merger on October 4, 2011. Our financial statements after completion of the Merger include the assets and liabilities of us and Former Puma, the historical operations of Former Puma, and the operations of us following the closing date of the Merger.

The merger of a private operating company into a non-operating public shell corporation with nominal net assets is considered to be a capital transaction, in substance, rather than a business combination, for accounting purposes. Accordingly, we treated this transaction as a capital transaction without recording goodwill or adjusting any of our other assets or liabilities.

JOBS Act

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies.

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Results of Operations

Six Months Ended June 30, 2012 Compared to Six Months Ended June 30, 2011

General and administrative expenses:

For the six months ended June 30, 2012, G&A expenses were approximately $2.9 million. G&A expenses for the six months ended June 30, 2011, were nominal as we had not commenced meaningful operations during that period. G&A expenses for the six months ended June 30, 2012, were as follows:

General and administrative expenses	
Professional fees	$ 1,155,917
Payroll and related costs	993,679
Facility and equipment costs	279,143
Business taxes and licenses	155,678
Employee stock-based compensation	(35,869)
Other	387,955
	$ 2,936,503

Major expenses incurred in professional fees were legal fees for SEC filings, intellectual property review, contract review and general legal support. We expect to continue to incur significant legal fees in the coming periods. We expect the facility expense to remain at least at comparable levels to the six months ended June 30, 2012, for the next several months; however, we have recently entered into a lease for satellite office space in San Francisco and will have additional rent expense going forward for the term of the lease. Employee stock-based compensation included in G&A expenses for the six months ended June 30, 2012 was approximately $178,000, offset by a reduction in the valuation of the outstanding anti-dilutive warrant held by our CEO and President of approximately $214,000, compared to $0 for the six months ended June 30, 2011. All other costs such as IT support, travel, recruiting and postage were approximately $388,000 for the six months ended June 30, 2012.

Research and development expenses:

For the six months ended June 30, 2012, R&D expenses were approximately $23.6 million compared to $0 for the six months ended June 30, 2011. R&D expenses for the six months ended June 30, 2012 were as follows:

Research and development expenses	
Outside clinical development services	$ 18,442,898
Regulatory affairs and quality assurance	2,613,217
Internal clinical development	2,018,273
Employee stock-based compensation	283,053
Contract manufacturing	216,848
	$ 23,574,289

Ongoing outside clinical trial cost of approximately $18.4 million during the six months ended June 30, 2012 included approximately $3.0 million of duplicate costs from licensor services for the ongoing clinical trials. When the transition is complete, we expect these duplicate charges to cease. We accrued approximately $5.8 million for licensor services provided during the six months ended June 30, 2012 and approximately $9.4 million for pass-through costs related to the clinical trials. We also incurred approximately $3.2 million for services rendered by a CRO that is taking over operational responsibility for our existing clinical trials. The licensor transition cost represents our estimate of such costs for the six months ended June 30, 2012, and will be adjusted accordingly as the actual costs become known. Other R&D expenses, which include payroll and employee

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related expenses and expenses for travel and other consultant services of approximately $2.0 million, were also incurred in the six months ended June 30, 2012. Regulatory affairs and quality assurance expenses of approximately $2.6 million consisted of approximately $1.8 million of payroll and employee-related expenses, approximately $584,000 of IT and software related expenses, and approximately $94,000 of consultant expenses, with the remaining approximately $146,000 of expenses related to travel, supplies and office facilities. Employee stock-based compensation included in R&D expenses for the six months ended June 30, 2012 was approximately $283,000. Contract manufacturing costs were approximately $217,000, and consisted primarily of employee and employee-related expenses and expenses for travel and consulting services.

While expenditures on current and future clinical development programs, particularly our PB272 program, are expected to be substantial and to increase, they are subject to many uncertainties, including the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our drug candidates; and
- the costs, requirements, timing of, and ability to secure regulatory approvals.

Interest income:

For the six months ended June 30, 2012, we recognized approximately $48,000 in interest income compared to $0 in interest income for the six months ended June 30, 2011. Based on market conditions, we placed our excess funds in money market accounts and high yield savings accounts.

Years Ended December 31, 2011 and 2010

General and administrative expenses:

For the year ended December 31, 2011, general and administrative, or G&A, expenses were approximately $9,319,600 compared to $6,900 for 2010. G&A expenses for the year ended December 31, 2011, were as follows:

General and administrative expenses	
Professional fees	$ 967,900

Payroll and related costs	480,800
Facility and equipment costs	58,700
Business taxes and licenses	6,400
Employee stock-based compensation	7,615,100
Other	190,700
	$ 9,319,600

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During 2011, we incurred professional fees of approximately $967,900 in conjunction with the licensing of three drug compounds, executing the reverse merger, and filing various forms with the SEC in 2011. These professional fees consisted of $851,936 of legal fees, $47,324 of audit and accounting fees, $35,250 of investor relations expenses, $33,390 of consulting expenses, the majority of which was to implement a financial reporting system. Additional G&A expenses associated with employee stock-based compensation was approximately $7,615,100, which included $7,585,600 related to the issuance of an anti-dilutive warrant issued to our CEO (see note 7 of the accompanying financial statements for the year ended December 31, 2011) and $29,500 of stock-based compensation issued to employees. During the fourth quarter of 2011, we began hiring staff and recorded approximately $480,800 of payroll and payroll- related expenses. Rent expense and related facility cost for 2011 was approximately $58,700. We anticipate our rent expense for 2012 to be approximately $550,000. Approximately $6,400 of business taxes and license expenses related to commencing business operations were incurred in 2011. The remaining expenses of approximately $190,700 were associated with the commencement of operations and include such items as business insurance, office supplies, telecommunication cost and banking fees. We expect our G&A expenses, excluding stock-based compensation, to increase significantly for fiscal year 2012 as our cost for 2011 reflects only four months of activity.

Research and development expenses:

For the year ended December 31, 2011, research and development, or R&D, expenses were approximately $826,400 compared to $0 for the prior year. R&D expenses for the year ended December 31, 2011 were as follows:

Research and development expenses	
Regulatory affairs and quality assurance	$ 640,600
Internal clinical development	81,100
Employee stock-based compensation	37,500
Contract manufacturing	67,200
	$ 826,400

Approximately $640,600 of the total expenses incurred were related to regulatory affairs and quality assurance, as we hired support staff and built the infrastructure to transition responsibility for the ongoing clinical trials to our control. Additionally, we incurred approximately $81,100 of internal clinical development costs and $67,200 of contract manufacturing costs primarily related to hiring employees to manage the clinical trial functions. During 2011, approximately $37,500 of stock-based compensation was included in R&D expenses. During 2012, we expect to spend approximately $30 million to $35 million in R&D expenses as we begin to actively manage the existing clinical trials and potentially commence additional clinical trials.

Interest income: For the year ended December 31, 2011, we recognized approximately $3,783 in interest income compared to $0 of interest income for the period from September 15, 2010 (Former Puma s date of inception) to December 31, 2010. Based on market conditions, we placed our excess funds in money market accounts and/or high yield savings accounts.

Other expense: For the year ended December 31, 2011, we incurred other expense of $80,000 compared to $0 for the period from September 15, 2010 (Former Puma s date of inception) to December 31, 2010. In connection with the Merger, we paid our former stockholders $40,000 in exchange for 3,000,000 shares of our common stock pursuant to the Redemption Agreement and we paid their counsel $40,000 for legal fees incurred in connection with the Merger.

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Liquidity and Capital Resources

Operating Activities

We reported a net loss of approximately $26.6 million and negative cash flows from operating activities of approximately $11.6 million for the six months ended June 30, 2012, and a net loss of approximately $10.2 million and negative cash flow from operating activities of approximately $1.8 million for the year ended December 31, 2011. Our net loss from Former Puma s date of inception, September 15, 2010, to June 30, 2012, amounted to approximately $36.8 million, while negative cash flows from operating activities amounted to approximately $13.4 million for the same period.

Net cash used in operating activities for the six months ended June 30, 2012, includes a net loss of $26.6 million, reduced by approximately $15.0 million of adjustments to reconcile net loss to net cash used in operating activities. Adjustments include non-cash items related to expense of approximately $462,000 from the issuance of stock options, adjustments to the warrant valuation of $215,000, depreciation and amortization of approximately $118,000 and an allowance of approximately $236,000 received from the landlord for our corporate headquarters. Other items included in the adjustment of net loss were an increase of approximately $15 million in accounts payable and accrued expenses, an increase of $180,000 in the accrual of deferred rent, and an increase of $715,000 in prepaid expenses and other assets. The increase in accounts payable and accrued expenses reflects charges from transition activities billed to us as we assume clinical trial responsibilities from the licensor of our lead product candidate, of which approximately $3.0 million represents duplication of effort as the licensor transferred clinical trial knowledge and responsibility to us.

Net cash used in operating activities for the year ended December 31, 2011 includes a net loss of $10.2 million adjusted for non-cash items of approximately $7.6 million for the issuance of an anti-dilutive warrant, approximately $0.4 million resulting from an allowance received from the landlord, an increase in accounts payable and accrued expenses of approximately $0.6 million, stock option expense of $0.1 million, and an increase in prepaid expenses and other assets of approximately $0.3 million. The increase in accounts payable and accrued expenses is a direct result of our commencing operations in the fourth quarter of 2011.

Investing Activities

Net cash used in investing activities was approximately $821,000 for the six months ended June 30, 2012. Payments of approximately $428,000 for the purchase of computer equipment and systems and approximately $237,000 related to leasehold improvements were included in net cash used in investing activities. Additionally, to secure the office lease located in the San Francisco area, a standby letter of credit was required. As collateral to that standby letter of credit, approximately $157,000 was moved to the restricted cash account held by Wells Fargo Bank, N.A.

Net cash used in investing activities was approximately $1.7 million for the year ended December 31, 2011. The major portion, $1.1 million, represents a high yield savings account that was opened to secure a stand-by letter of credit issued to our landlord as collateral for the lease of our Los Angeles, California office. We invested approximately $0.2 million in computer equipment and systems and approximately $0.4 million in leasehold improvements.

Financing Activities

We did not engage in any financing activities during the six months ended June 30, 2012. During the year ended December 31, 2011, we engaged in two common stock offerings and our founder and Chief Executive Officer converted a note to equity.

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October 2011 Common Stock Offering. Immediately prior to the Merger, pursuant to the Securities Purchase Agreement, Former Puma sold 14,666,733 shares of its common stock to certain institutional and accredited investors at a price per share of $3.75, for aggregate gross proceeds of approximately $55 million. Former Puma also issued a warrant to each investor that provided such investor with anti-dilution protection in regard to certain issuances of securities. These warrants expired unexercised, in accordance with their terms, following the quotation of our common stock on the OTC Bulletin Board.

We reimbursed the lead investor in this private placement $125,000 for all reasonable fees and expenses, including legal fees, associated with the private placement. In addition, in connection with Leerink Swann LLC, or Leerink, acting as Former Puma s placement agent in this private placement, we paid Leerink $2,338,215 as compensation for its services and $75,000 for reimbursable expenses.

November 2011 Common Stock Offering. On November 18, 2011, we entered into subscription agreements with 139 accredited investors, pursuant to which we sold in a private placement an aggregate of 1,333,267 shares of common stock at a price per share of $3.75 per share, for aggregate gross proceeds of approximately $5.0 million. Leerink Swann LLC acted as lead placement agent and National Securities Corporation acted as co-placement agent in connection with this private placement and received compensation of approximately $84,000 and $150,000, respectively. In addition to the costs noted above, we incurred legal fees and other costs totaling approximately $487,000 associated with the equity raises.

Current and Future Financing Needs

We have incurred negative cash flows from operations since we started our business, and we expect to continue incurring significant losses for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and development efforts. Following this offering, we anticipate that our cash on hand, including our cash equivalents, will be sufficient to enable us to meet our anticipated expenditures for at least the next 24 months. Given the current and desired pace of clinical development of our three product candidates, over the next 12 months we estimate that our research and development spending will be approximately $35 million to $40 million. We will need approximately $6 million to $7 million for general and administrative expenses over the next 12 months. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control.

Our continued operations will depend on whether we are able to raise additional funds through a strategic alliance with a third party concerning one or more of our product candidates, public or private sales of equity or debt and other sources of funds. Through June 30, 2012, a significant portion of our financing was through private placements of our equity securities. After the completion of this offering, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and in light of current economic conditions, including the lack of access to the capital markets being experienced by small companies, particularly in our industry, there can be no assurance that such capital will be available to us on favorable terms or at all. In addition, we can give no assurances that any additional capital raised will be sufficient to meet our needs. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, delay or discontinue the development of one or more of our product candidates or forego attractive business opportunities, and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

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Contractual Obligations

As a smaller reporting company, we are not required to disclose information under this section.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet agreements, as defined by SEC regulations.

Critical Accounting Policies

Research and Development

Research and development expenses are charged to operations as incurred. Research and development expenses consist of salaries, benefits and other personnel related costs, clinical trial and related clinical manufacturing costs, contract and outside service fees, cost of contract research organizations that manage our clinical trials, and cost of contract organizations for pre-clinical development. We account for our clinical trial costs by estimating the total cost to treat a patient in each clinical trial and recognize that cost based on a variety of factors, beginning with preparation for the clinical trial and patient accrual into the clinical trial. The estimated cost includes payments for clinical trial sites and patient-related costs, including laboratory costs related to the conduct of the trial and other costs. We accrue for costs incurred as services are provided for monitoring of the trial and as invoices are received from external service providers. We adjust our accruals in the period when actual costs become known. Cost related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

Investment Securities

Investment securities consist of high-grade marketable debt securities of financial institutions and other corporations. We classify all investment securities (short-term and long-term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management s strategies. These securities are carried at fair value, with the unrealized gains and losses, if material, reported as a component of accumulated other comprehensive income (loss) in stockholders equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

Several methods are used to determine the fair value of our investment securities. For securities that generally have market prices from multiple sources, a weighted average price for each security is determined. Market prices are received from a variety of industry standard data providers, security master files from large financial institutions, and other third-party sources. The prices are input into a distribution curve-based algorithm to determine the daily market value. Securities with a structure that implies a standard expected market price are priced at the expected market price. For example, an open-ended money market fund expected to maintain a Net Asset Value of $1 per share would be priced at the expected market price. Securities with short maturities and infrequent secondary market trades are priced using mathematical calculations. In the case of a certain issue of commercial paper, in the absence of any observable transactions, we may accrete from purchase price at purchase date to face value at maturity. In the event that a transaction is observed on the same security in the marketplace, the price on that subsequent transaction would reflect the market price on that day and we would adjust the price to the observed transaction price.

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Warrants Issued with Private Placement:

In connection with the October 2011 Securities Purchase Agreement, we issued anti-dilutive warrants to 27 investors (see Note 6 of the accompanying financial statements for the year ended December 31, 2011), which subsequently expired unexercised, in accordance with their terms, following our quotation on the OTC Bulletin Board. The fair value of warrants were estimated at the date of issuance using the Monte Carlo Simulation method. As we had no trading history at that time, we calculated the expected volatility based on the historical volatilities of nine companies with similar attributes to us including industry, stage of life cycle, size and financial leverage. The risk-free interest rate was based on the U.S. Treasury yield curve covering the term of the warrants.

The fair value of the warrants issued was determined using the Monte Carlo Simulation method with the following assumptions:

	2011
Dividend yield	0%
Expected volatility	84.4%
Risk-free interest rate	1.81%
Common stock price on date of issuance	$ 3.75
Exercise price	$ 0.01
Warrant term in years	10

Using the above assumptions, the portion of the private placement proceeds attributed to the fair value of the warrants was determined to be $1,758,338 and is recorded as additional paid-in capital.

Stock-based Compensation

As required, we adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, or ASC 718, *Compensation Stock Compensation*. ASC 718 requires the fair value of all stock-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Adoption of the fair value method required by ASC 718 will have a material impact on our results of operations, although it will have no impact on our cash flows or our overall financial position. Because of the variability in the assumptions used in the valuation of stock options granted and the variability in the quantity and other terms of stock-based awards we may issue in the future, our ability to predict future stock-based compensation expense is limited. Under ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. We recognize the valuation of each stock option grant over the service period of the grant, which normally commences with the grant date but can precede the grant date. Our 2011 financial statements reflect stock option grants issued to our employees where the service period commenced prior to their grant date in 2012. The amounts recognized in the financial statements related to employee stock-based compensation were approximately $67,000 and $0 for the years ended December 31, 2011 and 2010, respectively, and $462,000 for the six months ended June 30, 2012, and the amounts were included in general and administrative expenses and research and development expenses.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. As allowed by ASC 718 for companies with a short period of publicly traded stock history, management s estimate of expected volatility is based on historical volatilities of a sampling of five companies with similar attributes to our Company, including industry, stage of life cycle, size and financial leverage. As we have only awarded plain vanilla options, as determined by Staff Accounting Bulletin No. 107, we used the simplified method for determining the expected life of the options granted. The risk-free interest rate for periods within the estimated life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. ASC 718 does not allow companies to account for option forfeitures as they occur. Instead,

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estimated option forfeitures must be calculated upfront to reduce the option expense to be recognized over the life of the award and updated upon further information as to the amount of options expected to be forfeited.

The fair value of options granted to employees was estimated using the Black-Scholes option-pricing model, with the following weighted-average assumptions used during the year ended December 31, 2011 and the period ending June 30, 2012:

	2011	Six Months Ended June, 30 2012
Dividend yield	0.0%	0.0%
Expected volatility	86.0%	85.5%
Risk-free interest rate	1.1%	1.1%
Expected life in years	5.81	5.82

The anti-dilutive warrant issued to our CEO and President, Alan H. Auerbach, was valued at approximately $6,900,000 at the time of issuance and recorded in the statement of operations. The warrant was revalued at approximately $7,600,000 on December 31, 2011, in accordance with ASC 718, and was included in stock-based compensation expense for the year ended December 31, 2011, compared to $0 expense in 2010 (see note 7 of the accompanying financial statements for the year ended December 31, 2011). The fair market value of the warrant as of June 30, 2012 was approximately $7,371,000, resulting in an adjustment to the fair value of ($214,591), which is included in general and administrative expense for the six months ended June 30, 2012.

The fair value of the anti-dilutive warrant as of December 31, 2011 and June 30, 2012, was measured using the Monte Carlo Simulation method and recorded as stock-based compensation in our statements of operations. Management s estimate of volatility was based on average volatilities of a sampling of nine companies with similar attributes to us including industry, stage of life cycle, size and financial leverage. The risk-free interest rate is based on a 10-year U.S. Treasury yield. The fair value was estimated based on projected equity raises ranging from $15 million to $100 million in 2013 using weighted probability factors and the following assumptions:

	2011	Six Months Ended June, 30 2012
Dividend yield	0%	0.0%
Risk-free interest rate	1.81%-1.89%	1.67%
Warrant term in years	10	10
Expected volatility	84.4%-85.1%	76.4%
Common stock price	$ 3.75	$ 11.25

We will revalue the warrant each reporting period until such time as the grant date of the warrant is determined. The grant date of the warrant will be the date of the completion of this offering. Assuming we sell 6,500,000 shares in this offering at a public offering price of $15.50 per share, the last reported sale price of our common stock set forth on the cover page of this prospectus, we expect the final fair value of the warrant to be approximately $18.7 million. After December 31, 2012, we will no longer incur stock-compensation expense related to the warrant.

Recently Issued Accounting Standards

We have adopted all recently issued accounting pronouncements. The adoption of the accounting pronouncements is not anticipated to have a material effect on our operations.

In May 2011, FASB issued Accounting Standards Update No. 2011-04, or ASU 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure*

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Requirements in U.S. GAAP and IFRS, which clarifies some existing concepts and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. ASU 2011-04 was effective for us beginning January 1, 2012, and the adoption of ASU 2011-04 did not have a material effect on our financial condition, profitability, and cash flows.

In June 2011, FASB issued ASU 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income,* which requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income, or in two separate but consecutive statements, and eliminates that option to present components of other comprehensive income as part of the statement of equity. In December 2011, FASB issued ASU 2011-12, which deferred guidance on whether to require entities to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement where net income is presented and the statement where other comprehensive income is presented for both interim and annual financial statements. ASU 2011-12 reinstated the requirements for the presentation of reclassifications that were in place prior to the issuance of ASU 2011-05 and did not change the effective date for ASU 2011-05. ASU 2011-05 and ASU 2011-12 were effective for us beginning January 1, 2012, and the adoption of ASU 2011-05 and ASU 2011-12 did not have a material effect on our financial condition.

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BUSINESS

Company Overview

We are a development-stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. We focus on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seek to further develop those drug candidates for commercial use.

We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients and non-small cell lung cancer patients;
- PB272 (neratinib (intravenous)), which we are developing for the treatment of advanced cancer patients; and
- PB357, which we believe can serve as a backup compound to PB272, and which we are evaluating for further development in 2013.

We are initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2, positive metastatic breast cancer. Studies show that approximately 20% to 25% of breast cancer tumors have an over-expression of the HER2 protein. Women with breast cancer that over-expresses HER2, referred to as HER2 positive breast cancer, are at greater risk for disease progression and death than women whose tumors do not over-express HER2. Therapeutic strategies, such as the use of Herceptin (trastuzumab) and Perjeta (pertuzumab), both produced by Genentech, and Tykerb (lapatinib), produced by GlaxoSmithKline, given in combination with chemotherapy have been developed to improve the treatment of this cancer by blocking HER2. Based on pre-clinical and clinical studies to date, we believe that neratinib may offer an advantage over existing treatments by more potently inhibiting HER2 at a site distinct from those targeted by pertuzumab, trastuzumab, and lapatinib and by acting via a mechanism different from those of other HER2 active drugs.

Currently, the FDA approved first-line therapy for treatment of HER2 positive metastatic breast cancer is the combination of Perjeta plus Herceptin and taxane chemotherapy. The current FDA-approved second-line therapy is Tykerb, given in combination with the chemotherapy drug capecitabine. As a single agent in patients who have failed first line treatment, Tykerb has demonstrated an objective response rate of approximately 5% to 7% and a progression free survival of between eight and nine weeks. In a Phase III clinical trial, patients with HER2 positive metastatic breast cancer who received the combination of Tykerb plus capecitabine demonstrated a median progression free survival, or PFS, of 27.1 weeks and a response rate of 23.7%. Another treatment regimen that is used in patients who have failed first line treatment is the combination of the chemotherapy drug vinorelbine given in combination with Herceptin, which has been shown to have an objective response rate of approximately 25% and a progression free survival of 22 weeks.

Data from a recently completed Phase II clinical trial of neratinib administered as a single agent to patients with HER2 positive metastatic breast cancer demonstrated an objective response rate of 24% and median PFS of 22.3 weeks for patients who had previously been treated with trastuzumab, and an objective response rate of 56% and median PFS of 39.6 weeks for patients who had not previously been treated with trastuzumab. Additionally, data from over 3,000 patients treated with neratinib, either as a single agent or in combination with other anti-cancer drugs, also suggests a manageable safety profile. Diarrhea has been the most common side effect, but appears to be manageable with antidiarrheal agents and dose modification.

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We license the exclusive worldwide rights to our current drug candidates from Pfizer Inc., or Pfizer, which had previously been responsible for the clinical trials regarding neratinib. We have modified Pfizer s clinical development strategy and during the next 12 to 18 months plan to:

- commence Phase III clinical trials to evaluate the use of neratinib in combination with chemotherapy and other anti-cancer drugs as a second or third-line treatment for HER2 positive breast cancer;
- initiate Phase II clinical trials to evaluate the use of neratinib for the treatment of HER2 mutated non-small cell lung cancer and in patients with a newly identified breast cancer mutation in HER2 negative breast cancer;
- continue the ongoing Phase II clinical trial of neratinib in the neoadjuvant treatment of HER2 positive breast cancer and the ongoing Phase II trial of neratinib in patients with HER2 positive metastatic breast cancer that has metastasized to the brain; and
- continue to evaluate the application of neratinib in the treatment of other forms of HER resistant cancers where there may be unmet medical needs.

Our President and Chief Executive Officer, Alan Auerbach, has extensive experience in identifying and developing drug candidates for use in the treatment of cancer. He was the founder, President and Chief Executive Officer of Cougar Biotechnology, Inc., or Cougar, where he was responsible for in-licensing and developing abiraterone acetate for the treatment of advanced prostate cancer. Mr. Auerbach progressed abiraterone acetate into two Phase III clinical trials before Cougar was purchased by Johnson & Johnson in 2009.

Our Strategy

Our strategy is to become a leading oncology-focused biopharmaceutical company. The key elements of our strategy are as follows:

- *Advance PB272 (neratinib (oral)), our lead drug candidate, toward regulatory approval and commercialization.* We are primarily focused on developing neratinib for the treatment of patients with HER2 positive metastatic breast cancer. We plan to modify the previous clinical development strategy that Pfizer employed by focusing our planned Phase II and Phase III clinical trials on the use of neratinib as a second- or third-line treatment option, which we believe may be underserved by current treatment alternatives and where clinical trials have shown substantial levels of activity. We are also focusing on the development of neratinib in the neoadjuvant treatment of patients with HER2 positive breast cancer and in patients with HER2 positive metastatic breast cancer that has metastasized to the brain.
- *Expand our product pipeline by pursuing additional applications of neratinib*. We believe there are additional applications for neratinib in the treatment of HER2 mutated non-small cell lung cancer, which we also believe may be underserved by current treatment alternatives, in the treatment of patients with a newly identified breast cancer mutation in HER2 negative breast cancer and in the treatment of tumor types where HER2 is overexpressed, and we intend to further evaluate the safety and efficacy of neratinib for treating these cancers.
- *Focus on developing innovative cancer therapies*. We focus on oncology drug candidates in order to capture efficiencies and economies of scale. We believe that drug development for cancer markets is particularly attractive because relatively small clinical trials can provide meaningful information regarding patient response and safety. Furthermore, we believe that our capabilities are well suited to the oncology market and represent distinct competitive advantages.

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Build a sustainable pipeline by employing multiple therapeutic approaches and disciplined decision criteria based on clearly defined proof of principal goals. We seek to build a sustainable product pipeline by employing multiple therapeutic approaches and by acquiring drug candidates belonging to known drug classes. In addition, we employ disciplined decision criteria to assess drug candidates, favoring drug candidates that have undergone at least some clinical study. Our decision to license a drug candidate will also depend on the scientific merits of the technology; the costs of the transaction and other economic terms of the proposed license; the amount of capital required to develop the technology; and the economic potential of the drug candidate, should it be commercialized. We believe this strategy minimizes our clinical development risk and allows us to accelerate the development and potential commercialization of current and future drug candidates. We intend to pursue regulatory approval for a majority of our drug candidates in multiple indications.

Evaluate the commercialization strategies on a product-by-product basis in order to maximize the value of each. As we move our drug candidates through development toward regulatory approval, we will evaluate several options for each drug candidate s commercialization strategy. These options include building our own internal sales force; entering into a joint marketing partnership with another pharmaceutical company or biotechnology company, whereby we jointly sell and market the product; and out-licensing our product, whereby another pharmaceutical company or biotechnology company sells and markets our product and pays us a royalty on sales. Our decision will be made separately for each product and will be based on a number of factors including capital necessary to execute on each option, size of the market that needs to be addressed and terms of potential offers from other pharmaceutical and biotechnology companies. It is too early for us to know which of these options we will pursue for our drug candidates, assuming their successful development.

Product Development Pipeline

Breast Cancer Overview

Breast cancer is the leading cause of cancer death among women worldwide, with approximately 1 million new cases reported each year and more than 400,000 deaths per year. Approximately 20% to 25% of breast cancer tumors show over-expression of the HER2 protein. Women with breast cancer that overexpresses HER2 are at greater risk for disease progression and death than women whose tumors do not over-express HER2. Therapeutic strategies have been developed to block HER2 in order to improve the treatment of this cancer.

Trastuzumab and pertuzumab are monoclonal antibodies that bind to the HER2 protein and thereby cause the cells to cease reproducing. Trastuzumab and pertuzumab given in combination with chemotherapy is the current first line standard of care for HER2 positive metastatic breast cancer. Lapatinib is a small molecule that also binds to the HER2 protein and causes the cell to cease reproducing. The current FDA-approved second-line therapy is lapatinib given in combination with the chemotherapy drug capecitabine. Unfortunately, most patients with HER2 positive breast cancer eventually develop resistance to these treatments, resulting in disease progression. For these reasons, there is a need for alternatives to block HER2 signaling in patients who fail pertuzumab, trastuzumab and lapatinib. PB272 is an orally active small molecule that inhibits HER2 at a different site and uses a different mechanism than trastuzumab. As a result, we believe that PB272 may have utility in patients with HER2 positive metastatic breast cancer who have failed treatment with trastuzumab.

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The following chart shows each of our current drug candidates and their clinical development stage:

PB272 (neratinib (oral)) Breast Cancer

Neratinib is a potent irreversible tyrosine kinase inhibitor, or TKI, that blocks signal transduction through the epidermal growth factor receptors, or EGFRs, HER1, HER2 and HER4. We believe neratinib has clinical application in the treatment of several cancers, including breast cancer and non-small cell lung cancer and other tumor types that overexpress HER2. Our initial focus is on the development of neratinib as an oral treatment of patients with HER2 positive metastatic breast cancer.

Advantages of Neratinib

Based on pre-clinical and clinical studies to date, we believe that neratinib may offer an advantage over existing treatments that are used in the treatment of patients with HER2 positive metastatic breast cancer who have failed first-line therapy, including treatment with trastuzumab. Currently, the treatment of metastatic breast cancer patients who have failed first-line therapy with pertuzumab and trastuzumab involves continuing treatment with chemotherapy given in combination with either trastuzumab or lapatinib. We believe that by more potently inhibiting HER2 at a different site and acting via a mechanism different from those of pertuzumab, trastuzumab or lapatinib, neratinib may have potential advantages over these existing treatments, most notably due to its increased selectivity and stronger inhibition of the HER2 target enzyme.

Clinical Trials of Neratinib in Patients with Metastatic Breast Cancer

Trials of Neratinib as a Single Agent. In 2009, Pfizer presented data at the CTRC-AACR San Antonio Breast Cancer Symposium from a Phase II trial of neratinib administered as a single agent to patients with HER2 positive metastatic breast cancer. Final results from this trial were published in the *Journal of Clinical Oncology* in March 2010.

The trial involved a total of 136 patients, 66 of whom had received prior treatment with trastuzumab and 70 of whom had not received prior treatment with trastuzumab. The results of the study showed that neratinib was reasonably well tolerated among both the pretreated patients and the patients who had not received prior treatment with trastuzumab. Diarrhea was the most common side effect, but was manageable with antidiarrheal

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agents and dose modification. Efficacy results from the trial showed that the objective response rate was 24% for patients who had received prior trastuzumab treatment and 56% for patients with no prior trastuzumab treatment. Furthermore, the median PFS was 22.3 weeks for the patients who had received prior trastuzumab and 39.6 weeks for the patients who had not received prior trastuzumab.

Trials of Neratinib in Combination with Other Anti-Cancer Drugs. At the 2010 San Antonio Breast Cancer Symposium, Pfizer presented data from Phase II trials of neratinib when given in combination with other anti-cancer drugs that are currently used for the treatment of HER2 positive metastatic breast cancer. One Phase II trial evaluated the safety and efficacy of neratinib given in combination with the anti-cancer drug paclitaxel in patients with HER2 positive metastatic breast cancer. The results presented showed that for the 66 patients in the trial who had previously been treated with at least one prior line of therapy, the combination of neratinib with paclitaxel was shown to have a favorable safety profile that was similar to that of each drug when given alone. The efficacy results from the trial demonstrated an objective response rate of 74% and PFS of 63.1 weeks.

Pfizer also presented data from a second Phase II trial at the 2010 San Antonio Breast Cancer Symposium, which evaluated the safety and efficacy of neratinib when given in combination with the anti-cancer drug vinorelbine in patients with HER2 positive metastatic breast cancer. In the 56 patients who had not been previously treated with the anti-HER2 therapy lapatinib, treatment with the combination of vinorelbine plus neratinib resulted in an overall response rate of 57% and PFS was 44.1 weeks. For those patients who had received prior treatment with lapatinib, the overall response rate was 50%. The combination of vinorelbine and neratinib was generally well tolerated.

Data from a third Phase II study, in which patients with confirmed ErbB2 positive (HER2 positive) metastatic breast cancer who had failed treatment with trastuzumab and taxane chemotherapy were given PB272 in combination with capecitabine, was presented at the 2011 San Antonio Breast Cancer Symposium. The results of the study showed that the combination of PB272 and capecitabine had acceptable tolerability. The efficacy results from the trial showed that for the 61 patients in the trial who had not been previously treated with the HER2 targeted anticancer drug lapatinib, there was an overall response rate of 64% and a clinical benefit rate of 72%. In addition, for the seven patients in the trial who had previously been treated with lapatinib, there was an overall response rate of 57% and a clinical benefit rate of 71%. The median PFS for patients who had not received prior treatment with lapatinib was 40.3 weeks and the median PFS for the patients who had received prior lapatinib treatment was 35.9 weeks.

Puma anticipates initiating a Phase III trial of neratinib plus capecitabine in HER2 positive metastatic breast cancer patients who have failed first-line therapy in late 2012 or early 2013. We anticipate that this trial will be a randomized trial of neratinib plus capecitabine versus lapatinib plus capecitabine.

In 2010, Pfizer also initiated a Phase I/II trial of neratinib in combination with the anti-cancer drug temsirolimus, or Torisel, in patients with HER2 positive metastatic breast cancer who have failed multiple prior treatments. The study enrolled patients with either HER2 positive metastatic breast cancer and disease progression on trastuzumab or with triple negative breast cancer. The preliminary Phase II results of this trial were presented at the 2011 San Antonio Breast Cancer Symposium. The results of the study showed that the combination of PB272 and temsirolimus had acceptable tolerability. The efficacy results from the trial showed that for the 15 patients with HER2 positive disease, nine patients, or 60%, experienced a partial response and one patient, or 7%, experienced stable disease for greater than six months, which translates to a clinical benefit rate of 67%. Patients who experienced a partial response to the combination of neratinib plus temsirolimus demonstrated a maximum change in the size of their target lesions of between 33% and 83%. None of the five patients with triple-negative breast cancer demonstrated a partial response or stable disease for greater than six months. We anticipate that data from this trial will be presented in the fourth quarter of 2012 and, in the first quarter of 2013, we expect to commence a Phase III trial of neratinib in combination with temsirolimus in patients with HER2 positive metastatic breast cancer who have failed multiple prior treatments.

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Approximately one-third of the patients with HER2 positive metastatic breast cancer develop metastases that spread to their brain. The current antibody based treatments, including Herceptin and Perjeta, do not enter the brain and therefore are not believed to be effective in treating these patients. In a Phase II trial with Tykerb given as a single agent, Tykerb demonstrated a 6% objective response rate in the patients with HER2 positive metastatic breast cancer whose disease spread to their brains. In January 2012, a Phase II trial of neratinib as a single agent in patients with HER2 positive metastatic breast cancer that has spread to their brains was initiated in conjunction with the Dana Farber Translational Breast Cancer Research Consortium. We anticipate that results from this trial will be presented in 2013.

At the 2010 San Antonio Breast Cancer Symposium, the results of the Neoadjuvant Lapatinib and/or Trastuzumab Treatment Optimisation) Study, or the Neo-ALTTO study, were presented. In this trial, patients with HER2 positive breast cancer were randomized to receive either the combination of paclitaxel plus trastuzumab, the combination of paclitaxel plus lapatinib or the combination of paclitaxel plus trastuzumab plus lapatinib, and neoadjuvant (preoperative) therapy. The results of the trial demonstrated that the patients who received the combination of paclitaxel plus trastuzumab demonstrated a pathological complete response rate of 29.5%, the patients who received paclitaxel plus lapatinib had a pathological complete response rate of 24.7% and the patients who received the combination of paclitaxel plus trastuzumab plus lapatinib had a pathological complete response rate of 51.3%.

In 2010, Pfizer, in collaboration with the National Surgical Adjuvant Breast and Bowel Project, or NSABP, a clinical trials cooperative group supported by the National Cancer Institute, or NCI, initiated a study to investigate the use of neratinib as a neoadjuvant (preoperative) therapy for newly diagnosed HER2 positive breast cancer. In this trial, a total of 129 patients are randomized to receive either neratinib plus the chemotherapy drug paclitaxel or trastuzumab plus paclitaxel prior to having surgery to remove their tumors. The purpose of this study is to test whether adding neratinib to paclitaxel chemotherapy is better than trastuzumab plus paclitaxel chemotherapy before having surgery. This trial has been modified to include a third treatment arm where patients will receive the combination of neratinib plus trastuzumab plus paclitaxel prior to having surgery to remove their tumors. We anticipate that enrollment in all three arms of this trial will continue through the end of 2012 and that results from this trial will be presented in 2013.

Also in 2010, the Foundation for the National Institutes of Health initiated the I-SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis 2). Patients with newly diagnosed HER2 positive breast cancer are randomized to receive either neratinib plus the chemotherapy drug paclitaxel or trastuzumab plus paclitaxel prior to having surgery to remove their tumors (neoadjuvant therapy). The purpose of this study is to test whether adding neratinib to paclitaxel chemotherapy is better than trastuzumab plus paclitaxel chemotherapy before having surgery. We anticipate that this trial will be modified in 2012 to include a third treatment arm where patients will receive the combination of neratinib plus trastuzumab plus paclitaxel prior to having surgery to remove their tumors. We anticipate that enrollment in all three arms of this trial will continue through the end of 2012.

Discontinued Studies. Pfizer had previously been sponsoring two additional clinical trials of neratinib. The first trial, referred to as the NEfERTT trial, was a Phase II randomized trial of neratinib in combination with the anti-cancer drug paclitaxel versus trastuzumab in combination with paclitaxel for the treatment of patients who have not received previous treatment for HER2 positive metastatic breast cancer. The second trial, referred to as the ExteNET trial, was a Phase III study investigating the effects of neratinib after adjuvant trastuzumab in patients with early stage breast cancer. On October 5, 2011, we announced that enrollment in the ExteNET trial was terminated and that both the NEfERTT and the ExteNET trials were going to be wound down. We anticipate that completion of these wind-down activities will continue in 2012. We are responsible for any activities associated with winding down these trials during 2012 and beyond.

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PB272 (neratinib (oral)) Other Potential Applications

Approximately 2% to 4% of patients with non-small cell lung cancer have a HER2 mutation in the kinase domain. This mutation is believed to narrow the ATP binding cleft which results in increased tyrosine kinase activity. The mutation is also believed to result in increased PI3K activity and mTOR activation. Published data suggests that patients with HER2 mutated non-small cell lung cancer do not respond to platinum chemotherapy and do not respond to EGFR inhibitors. Pfizer previously conducted a Phase I trial of neratinib given in combination with the anticancer drug temsirolimus in patients with solid tumors. In this trial, seven patients with HER2 mutated non-small cell lung cancer were enrolled in the trial. These patients had received a median of three prior treatments for their disease. The results from the trial were presented at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting and at the 2012 International Association for the Study of Lung Cancer meeting and demonstrated that for the six evaluable patients, two (33%) patients demonstrated a partial radiological response and three patients had stable disease evidenced by tumor shrinkage of between approximately 5% and 28%. We anticipate initiating a Phase II randomized trial of neratinib plus temsirolimus in patients with HER2 mutated non-small cell lung cancer in the fourth quarter of 2012.

In September 2012, a new mutation in patients with HER2 negative breast cancer was identified as part of a study performed by the Cancer Genome Atlas Network and published in Nature. We believe this mutation may occur in an estimated 2% of patients with HER2 negative breast cancer. We are aware of results from third party preclinical studies that we believe suggest that neratinib is active in HER2 negative breast cancer cells that have this mutation and that neratinib has more anticancer activity than either trastuzumab or lapatinib in cells with this mutation. We anticipate that this preclinical data will be presented in the fourth quarter of 2012. In the fourth quarter of 2012 or the first quarter of 2013, we anticipate initiating a Phase II trial of neratinib in HER2 negative breast cancer patients who have this newly identified mutation.

PB272 (neratinib (intravenous))

We also plan to develop neratinib as an intravenously administered agent. In pre-clinical studies the intravenous version of neratinib resulted in higher exposure levels of neratinib in pre-clinical models. We believe that this may result in higher blood levels of neratinib in patients, and this may translate into enhanced efficacy. We plan to file the IND for the intravenous formulation of neratinib in 2013.

PB357

PB357 is an orally administered agent that is an irreversible TKI that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2, and HER4. PB357 is structurally similar to PB272. Pfizer completed single dose Phase I trials of PB357. We are evaluating PB357 and considering options relative to its development in 2013.

Plan of Development

We plan to conduct additional clinical trials of neratinib in patients with HER2 positive metastatic breast cancer over the next 12 to 18 months. In one trial we plan to further investigate the efficacy of neratinib when given in combination with chemotherapy in patients with HER2 positive metastatic breast cancer who have previously been treated with at least one prior line of treatment. In another, we plan to investigate the efficacy of neratinib in patients with HER2 positive metastatic breast cancer with brain metastases. We will also continue the ongoing trial of neratinib in combination with the anti-cancer drug temsirolimus in patients with HER2 positive metastatic breast cancer. We are also continuing the development of neratinib in the neoadjuvant treatment of patients with HER2 positive breast cancer.

We also plan to conduct a Phase II clinical trial of neratinib in HER2 mutated non-small cell lung cancer patients and in HER2 negative breast cancer patients with a newly identified mutation during 2012.

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Clinical Testing of Our Products in Development

Each of our products in development, and likely all future drug candidates we in-license, will require extensive pre-clinical and clinical testing to determine the safety and efficacy of the product applications prior to seeking and obtaining regulatory approval. This process is expensive and time consuming. In completing these trials, we are dependent upon third-party consultants, consisting mainly of investigators and collaborators, who will conduct such trials.

We and our third-party consultants conduct pre-clinical testing in accordance with Good Laboratory Practices, or GLP, and clinical testing in accordance with Good Clinical Practice standards, or GCP, which are international ethical and scientific quality standards utilized for pre-clinical and clinical testing, respectively. GCP is the standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials, and is required by the FDA to be followed in conducting clinical trials. Additionally, our pre-clinical and clinical testing completed in the European Union is conducted in accordance with applicable EU standards, such as the EU Clinical Trials Directive (Directive 2001/20/EC of April 4, 2001), or the EU Clinical Trials Directive, and the national laws of the Member Estates of the EU implementing its provisions.

Competition

The development and commercialization of new products to treat cancer is highly competitive, and we expect considerable competition from major pharmaceutical, biotechnology and specialty cancer companies. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new cancer products. Our potential competitors include, but are not limited to, Genentech, GlaxoSmithKline, Roche, Boehringer Ingelheim, Takeda, Array Biopharma and Ambit Biosciences. We are an early-stage company with no history of operations and we only recently acquired the rights to the drug candidates we expect to develop. Many of our competitors have substantially more resources than we do, including both financial and technical. In addition, many of our competitors have more experience than we have in pre-clinical and clinical development, manufacturing, regulatory and global commercialization. We are also competing with academic institutions, governmental agencies and private organizations that are conducting research in the field of cancer. We anticipate that we will face intense competition.

We expect that our products under development and in clinical trials will address major markets within the cancer sector. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors products may be an important competitive factor. Accordingly, the speed with which we can develop products, complete pre-clinical testing, clinical trials and approval processes, and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price, reimbursement and patent position.

Intellectual Property and License Agreements

We hold a worldwide exclusive license under our license agreement with Pfizer to four granted U.S. patents and nine pending U.S. patent applications, as well as foreign counterparts thereof and other patent applications and patents claiming priority therefrom.

In the U.S., we have a license to an issued patent, which currently will expire in 2025, for the composition of matter of neratinib, our lead compound. We have a license to an issued U.S. patent covering a family of compounds including neratinib, as well as equivalent patents in the European Union and Japan, that currently expire in 2019. We also have a license to an issued U.S. patent for the use of neratinib in the treatment of breast cancer, which currently expires in 2025, and an issued U.S. polymorph patent for neratinib, which

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currently expires in 2028. In jurisdictions which permit such, we will seek patent term extensions where possible for certain of our patents. We plan to pursue additional patents in and outside the U.S. covering additional therapeutic uses and polymorphs of neratinib from these existing applications. In addition, we will pursue patent protection for any new discoveries or inventions made in the course of our development of neratinib.

If we obtain marketing approval for neratinib or other drug candidates in the U.S. or in certain jurisdictions outside the U.S., we may be eligible for regulatory protection, such as five years of new chemical entity exclusivity, and as mentioned above, up to five years of patent term extension potentially available in the United States under the Hatch-Waxman Act. In addition, eight to 11 years of data and marketing exclusivity potentially are available for new drugs in the European Union; up to five years of patent extension are potentially available in Europe (Supplemental Protection Certificate), and eight years of data exclusivity are potentially available in Japan. There can be no assurance that we will qualify for any such regulatory exclusivity, or that any such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies. See Government Regulation below.

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, even patent protection may not always afford us with complete protection against competitors who seek to circumvent our patents. See Risk Factors Risks Related to Our Intellectual Property Our proprietary rights may not adequately protect our intellectual property and potential products, and if we cannot obtain adequate protection of our intellectual property and potential products, we may not be able to successfully market our potential products.

We depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how, which is not patentable, and inventions for which patents may be difficult to obtain or enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

License Agreements

In August 2011, Former Puma entered into an agreement pursuant to which Pfizer agreed to grant to Former Puma a worldwide license for the development, manufacture and commercialization of neratinib (oral), neratinib (intravenous), PB357, and certain related compounds. Pursuant to the terms of the agreement, the license would not become effective until Former Puma closed a capital raising transaction in which it raised at least $25 million in aggregate net proceeds and had a net worth of at least $22.5 million. Upon the closing of the financing that preceded the Merger, this condition was satisfied.

We assumed the license agreement, in accordance with its terms, in the Merger. The license is exclusive with respect to certain patent rights owned or licensed by Pfizer. Under the license agreement, Pfizer is obligated to transfer to us certain information, records, regulatory filings, materials and inventory controlled by Pfizer and relating to or useful for developing these compounds and to continue to conduct certain ongoing clinical studies until a certain time. After that time, we are obligated to continue such studies pursuant to an approved development plan, including after the license agreement terminates for reasons unrelated to Pfizer s breach of the license agreement, subject to certain specified exceptions. We are also obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and use commercially

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reasonable efforts to complete such trial and achieve certain milestones as provided in a development plan. If certain of our out-of-pocket costs in completing such studies exceed a mutually agreed amount, Pfizer will pay for certain additional out-of-pocket costs to complete such studies. We must use commercially reasonable efforts to develop and commercialize products containing these compounds in specified major-market countries and other countries in which we believe it is commercially reasonable to develop and commercialize such products.

As consideration for the license, we are required to make payments totaling $187.5 million upon the achievement of certain milestones if all such milestones are achieved. Should we commercialize any of the compounds licensed from Pfizer or any products containing any of these compounds, we will be obligated to pay to Pfizer incremental annual royalties between approximately 10% and 20% of net sales of all such products, subject, in some circumstances, to certain reductions. Our royalty obligation continues, on a product-by-product and country-by-country basis, until the later of (i) the last to expire valid claim of a licensed patent covering the applicable licensed product in such country, or (ii) the earlier of generic competition for such licensed product reaching a certain level of sales in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that we sublicense the rights granted to us under the license agreement with Pfizer to a third party, the same milestone and royalty payments are required.

We can terminate the license agreement at will at any time after April 4, 2013 or for safety concerns, in each case upon specified advance notice. Each party may terminate the license agreement if the other party fails to cure any breach of a material obligation by such other party within a specified time period. Pfizer may terminate the license agreement in the event of our bankruptcy, receivership, insolvency or similar proceeding. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

Government Regulation

United States FDA Process

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Drug Approval Process. None of our drug product candidates may be marketed in the United States until the drug has received FDA approval. The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA s GLP regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;

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satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with cGMPs; and

FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

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

Clinical trials involve administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be provided to the FDA as part of a separate submission to the IND. Further, an IRB for each medical center proposing to conduct the clinical trial must review and approve the study protocol and informed consent information for study subjects for any clinical trial before it commences at that center, and the IRB must monitor the study until it is completed. There are also requirements governing reporting of ongoing clinical trials and clinical trial results to public registries. Study subjects must sign an informed consent form before participating in a clinical trial.

Clinical trials necessary for product approval typically are conducted in three sequential phases, but the phases may overlap. Phase I usually involves the initial introduction of the investigational drug into a limited population, typically healthy humans, to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effec