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)

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New York, NY 10017
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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 effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific targeted indications. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. Phase III trials, commonly referred to as pivotal studies, are undertaken in an expanded patient population at multiple, geographically dispersed clinical trial centers to further evaluate clinical efficacy and test further for safety by using the drug in its final form. There can be no assurance that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the FDA or an IRB may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Moreover, the FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Post-approval trials are typically referred to as Phase IV clinical trials.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach an agreement on the next phase of development. Sponsors typically use the end of Phase II meeting

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to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug. A sponsor may request a Special Protocol Assessment, or SPA, the purpose of which is to reach an agreement with the FDA that the protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA except in limited circumstances such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

Concurrent with clinical trials, companies usually complete additional animal safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Assuming successful completion of the required clinical testing, the results of pre-clinical studies and of clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. An NDA must be accompanied by a significant user fee, which is waived for the first NDA submitted by a qualifying small business. In July 2012, the Food and Drug Administration Safety and Innovation Act, or FDASIA, was signed into law. Among other things, FDASIA reauthorizes the FDA s authority to collect user fees from industry participants to fund reviews of innovator drugs.

The testing and approval process requires substantial time, effort and financial resources. The FDA will review the NDA and may deem it to be inadequate to support approval, and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically follows such recommendations.

Before approving an NDA, the FDA inspects the facility or the facilities at which the drug and/or its active pharmaceutical ingredient is manufactured and will not approve the product unless the manufacturing is in compliance with cGMPs. If the FDA evaluates the NDA and the manufacturing facilities are deemed acceptable, the FDA may issue an approval letter, or in some cases a Complete Response Letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug s safety or efficacy, or impose other conditions. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Alternatively, the FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, to mitigate risks of the drug, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. Once the FDA approves a drug, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of

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approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

Expedited Review and Approval. The FDA has various programs, including Fast Track, priority review and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and which demonstrate the potential to address an unmet medical need. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious or life-threatening diseases or conditions, including a fast track product, upon a determination that the product has an effect on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials. Pursuant to FDASIA, the FDA is required to issue draft guidance on expedited review and approval programs by July 9, 2013.

Post-Approval Requirements. After a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. In addition, certain changes to an approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA, typically a new NDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

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

Patent Term Restoration and Marketing Exclusivity. Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our U.S. patents may be eligible for limited patent term

extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be requested prior to expiration of the patent. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Data and market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to all of the pre-clinical studies, adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials and approval of foreign countries or economic areas, such as the EU, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In the European Economic Area, or EEA, which is comprised of the 27 member states of the EU, or Member States, plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MAs:

The Community MAs These are issued by the European Commission through the *Centralized Procedure*, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not

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yet authorized in the EEA; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the EU.

National MAs These are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, and are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the *Mutual Recognition Procedure*. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the *Decentralized Procedure*. Under the *Decentralized Procedure*, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State. The competent authority of the Reference Member State prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling or packaging proposed by the Reference Member State, the product is subsequently granted a National MA in all the Member States (i.e., in the Reference Member State and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor s generic product. For example, if any of our products receive marketing approval in the EEA, we expect they will benefit from eight years of data exclusivity and ten years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), we obtain an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product s first marketing authorization in the EU and prevents generics from relying on the marketing authorization holder s pharmacological, toxicological and clinical data for a period of eight years. After eight years, a generic product application may be submitted and generic companies may rely on the marketing authorization holder s data. However, a generic cannot launch until two years later (or a total of 10 years after the first marketing authorization in the EU of the innovator product), or three years later (or a total of 11 years after the first marketing authorization in the EU of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the eight-year data exclusivity period. In Japan our products may be eligible for eight years of data exclusivity. There can be no assurance that we will qualify for such regulatory exclusivity, or that such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies.

When conducting clinical trials in the EU, we must adhere to the provisions of the EU Clinical Trials Directive and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial.

Pricing and Reimbursement

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third-party payors, such as state and federal governments, managed care providers and

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private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and the out-of-pocket obligations of member patients for such products. We may need to conduct pharmacoeconomic studies to demonstrate the cost effectiveness of our products for formulary coverage and reimbursement. Even with such studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

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

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our future business. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, enacted in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, PPACA establishes:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period, or the donut hole; and
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Future legislation, including the current versions being considered at the federal level in the United States, or regulatory actions implementing recent or future legislation may have a significant effect on our business. Our ability to successfully commercialize products depends in part on the extent to which reimbursement for the costs of our products and related treatments will be available in the United States and worldwide from government health administration authorities, private health insurers and other organizations. The adoption of certain proposals could limit the prices we are able to charge for our products, the amounts of reimbursement available for our products, and limit the acceptance and availability of our products. Therefore, substantial uncertainty exists as to the reimbursement status of newly approved health care products by third-party payors.

Sales and Marketing

The FDA regulates all advertising and promotion activities for products under its jurisdiction prior to and after approval, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the

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provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to collect additional data or conduct additional pre-clinical studies and clinical trials. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

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

Outside the United States, our ability to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country.

We may also be subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal health care programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also may be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called responsible corporate officer doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the penalties that may be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government was to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities.

Manufacturing

We do not currently have our own manufacturing facilities. We intend to continue to use our financial resources to accelerate development of our drug candidates rather than diverting resources to establish our own

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manufacturing facilities. We intend to meet our pre-clinical and clinical trial manufacturing requirements by establishing relationships with third-party manufacturers and other service providers to perform these services for us. While our drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. We are currently using the same third-party contractors to manufacture, supply, store and distribute drug supplies for our clinical trials.

Should any of our drug candidates obtain marketing approval, we anticipate establishing relationships with third-party manufacturers and other service providers in connection with commercial production of our products. We have some flexibility in securing other manufacturers to produce our drug candidates; however, our alternatives may be limited due to proprietary technologies or methods used in the manufacture of some of our drug candidates.

Other Laws and Regulatory Processes

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the United States, including laws relating to the oversight activities of the SEC, and, upon the listing of our common stock on the New York Stock Exchange, we will be subject to the regulations of such exchange on which our shares are traded. In addition, the FASB, the SEC, and other bodies that have jurisdiction over the form and content of our accounts, our financial statements and other public disclosure are constantly discussing and interpreting proposals and existing pronouncements designed to ensure that companies best display relevant and transparent information relating to their respective businesses.

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

Research and Development Expenses

Research and development activities, which include personnel costs, research supplies, clinical and preclinical study costs, are the primary source of our overall expenses. Such expenses related to the research and development of our product candidates totaled $23.6 million for the six months ended June 30, 2012, $0.8 million for the year ended December 31, 2011, and $0.8 million from September 15, 2010 (Former Puma s date of inception) through December 31, 2011.

Employees

As of June 30, 2012, we had 41 employees, all of whom are full-time employees. We believe our relations with our employees are good. Over the course of the next year, we anticipate hiring up to 10 additional full-time employees devoted to clinical activities, four additional full-time employees for the regulatory and quality assurance function, and two additional full-time employees for general and administrative activities. In addition, we intend to continue to use clinical research organizations and third parties to perform our clinical studies and manufacturing.

Properties

We lease approximately 13,254 square feet of office space in the building located at 10880 Wilshire Boulevard for use as our corporate headquarters. Our lease commenced in December 2011 and terminates in

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December 2018, with an option to extend for an additional five-year term. We have also signed a lease for additional office space in South San Francisco, California. This lease is for seven years and is expected to commence on or about October 1, 2012. We believe our office space will be adequate to meet current and anticipated future requirements and that additional or substitute space will be available as needed to accommodate any expansions that our operations require.

Legal Proceedings

We are not involved in any pending legal proceedings and are not aware of any threatened or contemplated legal proceedings against us.

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MANAGEMENT AND DIRECTORS

Each executive officer and each member of our board of directors shall serve until his successor is elected and qualified.

Name	Age	Position
Alan H. Auerbach	42	President, Chief Executive Officer and Chairman of the Board
Charles R. Eyler	64	Senior Vice President, Finance and Administration and Treasurer
Richard Phillips, Ph.D.	58	Senior Vice President, Regulatory Affairs, Quality Assurance and Pharmacovigilance
Richard P. Bryce	54	Senior Vice President, Clinical Research and Development
Thomas R. Malley	43	Director
Jay M. Moyes	58	Director

Executive Officers

Alan H. Auerbach. Mr. Auerbach has served as Chairman of our board of directors and as our President and Chief Executive Officer since October 4, 2011. Prior to October 4, 2011, he served in such capacity at Former Puma since its inception in September 2010. Prior to joining Former Puma, Mr. Auerbach founded Cougar Biotechnology, Inc., or Cougar, in May 2003 and served as its Chief Executive Officer, President and a member of its board of directors until July 2009, when Cougar was acquired by Johnson & Johnson. From July 2009 until January 2010, Mr. Auerbach served as the Co-Chairman of the Integration Steering Committee at Cougar (as part of Johnson & Johnson) that provided leadership and oversight for the development and global commercialization of Cougar s lead drug candidate, abiraterone acetate, for the treatment of advanced prostate cancer. Prior to founding Cougar, from June 1998 to April 2003, Mr. Auerbach was a Vice President, Senior Research Analyst at Wells Fargo Securities, where he was responsible for research coverage of small- and middle-capitalization biotechnology companies, with a focus on companies in the field of oncology. Mr. Auerbach has served as a director of Radius Health, Inc., a publicly reporting pharmaceutical company focused on acquiring and developing new therapeutics for the treatment of osteoporosis and other women s health conditions, since May 2011 and its predecessor entity from October 2010 to May 2011. Mr. Auerbach received a B.S. in Biomedical Engineering from Boston University and an M.S. in Biomedical Engineering from the University of Southern California.

Charles R. Eyler. Mr. Eyler has served as our Senior Vice President, Finance and Administration and Treasurer since October 4, 2011. Prior to October 4, 2011, he served in such capacity at Former Puma beginning on September 1, 2011. Prior to joining Former Puma, Mr. Eyler served as Senior Vice President of Finance at Cougar until July 2009, when Cougar was acquired by Johnson & Johnson. He also served as the Treasurer of Cougar from April 2006 to July 2009. From July 2009 until March 2010, Mr. Eyler served on the Integration Steering Committee at Cougar (as part of Johnson & Johnson) and oversaw the integration of Cougar s finance and IT functions with those of Johnson & Johnson. From April 2010 until September 2011, Mr. Eyler explored various entrepreneurial and other opportunities. Prior to joining Cougar, Mr. Eyler served as Chief Financial Officer and Chief Operating Officer of Hayes Medical Inc. from March 1999 to January 2004. Mr. Eyler received his B.S. from Drexel University and his M.B.A. from Saint Francis College.

Richard Phillips, Ph.D. Dr. Phillips has served as our Senior Vice President, Regulatory Affairs, Quality Assurance and Pharmacovigilance since November 1, 2011. He previously served as a consultant in the Global Regulatory Consultancy Group of PPD, Inc. from March 2011 to October 2011. From March 2010 to March 2011, he worked as an independent consultant with pharmaceutical and biotech companies in the area of regulatory affairs. From January 2007 to July 2009, Dr. Phillips served as Senior Vice President of Regulatory Affairs and Quality Assurance at Cougar Biotechnology, Inc., and following the acquisition of Cougar by Johnson & Johnson, from July 2009 until March 2010, he oversaw the integration of Cougar s regulatory affairs

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and quality assurance function with Johnson & Johnson. Dr. Phillips received a B.S. from the University of California, Irvine in 1976 and a Ph.D. from the University of California, Berkeley in 1982.

Richard P. Bryce MBChB, MRCGP and MFPM. Dr. Bryce has served as our Senior Vice President, Clinical Research and Development since June 20, 2012. Dr. Bryce previously served as Senior Medical Director for Onyx Pharmaceuticals, a biopharmaceutical company, from September 2008 to June 2012, where he oversaw the Phase III clinical trial program of carfilzomib for the treatment of multiple myeloma and the Phase II clinical trial program of sorafenib for the treatment of breast and colorectal cancers. From August 2007 to August 2008, Dr. Bryce served as Senior Medical Director for ICON Clinical Research, a contract research organization, where he was responsible for developing and evaluating oncology protocols, medical monitoring, and overseeing drug safety management activities in connection with the clinical trials of oncology drugs. From May 2005 until July 2007, he served as Executive Vice President of Medical Affairs at Ergomed Clinical Research, a contract research organization, where he worked to establish the company s U.S. operations, had overall responsibility for the global Phase I unit activities, drug safety, medical writing and regulatory affairs, and oversaw the company s provision of consulting services to various oncology-focused biotechnology companies. From April 2003 to May 2005, Dr. Bryce served as International Medical Leader at Roche, where he oversaw the global Phase IV clinical trial program of Xeloda® (capecitabine) for the treatment of breast cancer. Dr. Bryce holds a BSc in Medical Sciences and his primary medical degree (MBChB) from the University of Edinburgh, Scotland. He also holds post-graduate diplomas in Obstetrics and Gynaecology from the Royal College of Obstetricians and Gynaecologists of London and in Child Health and Pharmaceutical Medicine from the Royal College of Physicians of the United Kingdom. He is a member of the Royal College of General Practitioners and the Royal College of Physicians (Faculty of Pharmaceutical Medicine) of the United Kingdom. He is also a member of the American Society of Clinical Oncology, the American Society of Hematology and the European Society of Medical Oncology.

Directors

Alan H. Auerbach. See Executive Officers.

Thomas R. Malley. Mr. Malley has been a director since the closing of the Merger on October 4, 2011. Since May 2007, Mr. Malley has served as President of Mossrock Capital, LLC, a private investment firm. From April 1991 to May 2007, Mr. Malley served with Janus Mutual Funds as an analyst for eight years and as a Vice President and Portfolio Manager for the Janus Global Life Sciences Fund for eight years. Since October 2006, Mr. Malley has served as a director of Synageva BioPharma Corp., a public clinical stage biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for patients with life-threatening rare diseases and unmet medical needs. Mr. Malley previously served as a director of Cougar Biotechnology, Inc. from 2007 to 2009. Mr. Malley received a B.S. in Biology from Stanford University in 1991. Mr. Malley was selected as a director because of his industry and investment experience.

Jay M. Moyes. Mr. Moyes has been a director since April 27, 2012. Mr. Moyes has been a member of the board of directors and chairman of the audit committee of Osiris Therapeutics, Inc., a publicly held stem cell therapeutics company, since May 2006. He has also been a member of the board of directors and the chairman of the audit committee for each of Biocardia, Inc., a privately held cardiovascular regenerative medicine company, and Integrated Diagnostics, Inc., a privately held molecular diagnostics company, since January 2011 and March 2011, respectively. From May 2008 through July 2009, Mr. Moyes served as the Chief Financial Officer of XDx, Inc., a privately held molecular diagnostics company. Prior to that, Mr. Moyes served as the Chief Financial Officer of Myriad Genetics, Inc., a publicly held healthcare diagnostics company, from June 1996 until his retirement in November 2007, and as its Vice President of Finance from July 1993 until July 2005. From 1991 to 1993, Mr. Moyes served as Vice President of Finance and Chief Financial Officer of Genmark, Inc., a privately held genetics company. Mr. Moyes held various positions with the accounting firm of KPMG LLP from 1979 through 1991, most recently as a Senior Manager. He holds an M.B.A. degree from the University of Utah, a B.A. degree in economics from Weber State University, and is formerly a Certified Public Accountant.

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Mr. Moyes also served as a member of the Board of Trustees of the Utah Life Science Association from 1999 through 2006.

None of our directors, nominees or executive officers is related by blood, marriage or adoption to any other director, nominee or executive officer.

Director Independence

Under the listing requirements and rules of the New York Stock Exchange, independent directors must comprise a majority of a listed company s board of directors within a specified period of the completion of this offering. In addition, New York Stock Exchange rules require that, subject to specified exceptions, each member of a listed company s audit, compensation and nominating and corporate governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended. Under New York Stock Exchange rules, a director will only qualify as an independent director if such person is not an executive officer or employee of the listed company and, in the opinion of that company s board of directors, that person does not otherwise have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each of our directors concerning his background, employment and affiliations, including family relationships, our board of directors has determined that Messrs. Malley and Moyes do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is independent as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the New York Stock Exchange. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

We have established an audit committee and, upon the completion of this offering, we will also have a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee provides oversight of our accounting and financial reporting process, the audit of our financial statements and our internal control function. Among other matters, the audit committee assists our board of directors in oversight of the independent registered public accounting firm qualifications, independence and performance; is responsible for the engagement, retention and compensation of the independent auditors; reviews the scope of the annual audit; reviews and discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements including the disclosures in our annual and quarterly reports filed with the SEC; reviews our risk assessment and risk management processes; establishes procedures for receiving, retaining and investigating complaints received

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by us regarding accounting, internal accounting controls or audit matters; approves audit and permissible non-audit services provided by our independent registered public accounting firm; and reviews and approves related person transactions under Item 404 of Regulation S-K. In addition, our audit committee will oversee our internal audit function when it is established.

The members of our audit committee are Mr. Malley, who will be the chair of the committee, and Mr. Moyes. Messrs. Malley and Moyes will continue to serve on the audit committee after this offering. Each of Messrs. Malley and Moyes are independent directors as defined under the applicable rules and regulations of the SEC and the New York Stock Exchange. In accordance with the phase-in rules of the New York Stock Exchange, we will add a third independent director to our audit committee within one year of listing on the New York Stock Exchange. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the New York Stock Exchange. Our board of directors has determined that Mr. Malley is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of the New York Stock Exchange.

Compensation Committee

Our compensation committee will adopt and administer the compensation policies, plans and benefit programs for our executive officers and all other members of our executive team. In addition, among other things, our compensation committee will annually evaluate, in consultation with our board of directors, the performance of our Chief Executive Officer, will review and approve corporate goals and objectives relevant to compensation of our Chief Executive Officer and other executives and will evaluate the performance of these executives in light of those goals and objectives. Our compensation committee also will administer our incentive award plan. Upon the completion of this offering, the members of our compensation committee will be Messrs. Malley and Moyes, with Mr. Moyes serving as the chair of the committee. The members of our compensation committee are independent under the applicable rules and regulations of the SEC and the New York Stock Exchange, and Section 162(m) of the Internal Revenue Code of 1986.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will be responsible for, among other things, making recommendations regarding corporate governance, the composition of our board of directors, identification, evaluation and nomination of director candidates and the structure and composition of committees of our board of directors. In addition, our nominating and corporate governance committee will oversee our corporate governance guidelines, approve our committee charters, oversee compliance with our code of business conduct and ethics, contribute to succession planning, review actual and potential conflicts of interest of our directors and officers other than related person transactions reviewed by the audit committee and oversee the self-evaluation process of our board of directors. Our nominating and corporate governance committee also will be responsible for making recommendations regarding non-employee director compensation to the full board of directors. Upon the completion of this offering, the members of our nominating and corporate governance committee will be Messrs. Malley and Moyes, with Mr. Moyes serving as the chair of the committee. The members of our nominating and corporate governance committee are independent under the applicable rules and regulations of the SEC and the New York Stock Exchange.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that establishes the standards of ethical conduct applicable to all directors, officers and employees of our company. Our code of business conduct and ethics addresses, among other things, conflicts of interest, compliance with disclosure controls and procedures and internal control over financial reporting, corporate opportunities and confidentiality requirements. Our code of business conduct and ethics is available on our corporate website at www.pumabiotechnology.com/about_governance.html. We intend to disclose any future amendments to certain provisions of our code of

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business conduct and ethics, or waivers of provisions required to be disclosed under the rules of the SEC, at the same location on our website identified in the preceding sentence.

Board Leadership Structure and Role in Risk Oversight

Alan H. Auerbach currently serves as our Principal Executive Officer, and Charles R. Eyler currently serves as our Principal Financial and Accounting Officer. Our board of directors is comprised of Messrs. Auerbach, Malley and Moyes, with Mr. Auerbach serving as Chairman. At present, we have determined this leadership structure of having a combined Chairman of the Board and Principal Executive Officer is appropriate due to our small size and limited operations and resources.

We have no policy requiring the combination or separation of the Principal Executive Officer and Chairman roles and our governing documents do not mandate a particular structure. Our directors recognize that the leadership structure and the combination or separation of these leadership roles is driven by our needs at any point in time.

Our directors are exclusively involved in the general oversight of risks that could affect our business and they will continue to evaluate our leadership structure and modify such structure as appropriate based on our size, resources and operations.

Board Meetings

During the fiscal year ended December 31, 2011, our board of directors did not meet and we did not hold an annual meeting. Our board of directors conducted all of its business and approved all corporate action during the fiscal year ended December 31, 2011 by the unanimous written consent of its members, in the absence of formal board meetings.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and officers, and persons who beneficially own more than ten percent (10%) of our common stock, who are hereinafter collectively referred to as the Reporting Persons, to file reports with the SEC of beneficial ownership and reports of changes in beneficial ownership of our common stock on Forms 3, 4 and 5. Reporting Persons are required by applicable SEC rules to furnish us with copies of all such forms filed with the SEC pursuant to Section 16(a) of the Exchange Act. To our knowledge, based solely on our review of the copies of the Forms 3, 4 and 5 received by us during the fiscal year ended December 31, 2011 and written representations that no other reports were required, we believe that all reports required to be filed by such persons with respect to our fiscal year ended December 31, 2011 were timely filed.

Legal Proceedings

We are not aware of any material proceedings in which any of our directors, executive officers or affiliates, any owner of record or beneficially of more than 5% of our common stock, or any associate of any such director, officer, affiliate or security holder is a party adverse to us or any of our subsidiaries or has a material interest adverse to us.

Stockholder Communication with our Board of Directors

Stockholders may send communications to our board of directors by writing to Puma Biotechnology, Inc., 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024, Attention: Board of Directors.

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EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information regarding the compensation earned by our named executive officers for the year ended December 31, 2011. We did not pay any cash or other compensation to our executive officers in 2010.

Name and Principal Position	Year	Salary ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Alan H. Auerbach President and Chief Executive Officer	2011	$ 156,667 (1)		(2)	$ 156,667
Charles R. Eyler Senior Vice President, Finance and Administration	2011	110,416 (3)	(4)		110,416
Richard Phillips, Ph.D. Senior Vice President, Regulatory Affairs, Quality Assurance and Pharmacovigilance	2011	67,000 (3)	(4)		67,000

(1) We entered into an employment agreement with Mr. Auerbach on January 19, 2012. The employment agreement governs the terms of Mr. Auerbach s employment with us and Former Puma since September 15, 2010. Pursuant to the employment agreement, Mr. Auerbach was entitled to an annual base salary of $470,000, retroactively effective to September 1, 2011.

(2) Mr. Auerbach was issued a warrant on October 4, 2011 that provides Mr. Auerbach with the right to maintain ownership of at least 20% of our common stock in the event that we raise capital in the future through the sale of its securities. The warrant has a ten-year term and will become exercisable upon the closing this offering. For purposes of determining the final fair value of the warrant in accordance with Accounting Standards Codification Topic 718, Compensation Stock Compensation, or ASC 718, the grant date of the warrant will occur on the date of the closing of this offering when the aggregate number of shares exercisable and the price per share will be determined. For accounting purposes, because the requisite service period for the warrant precedes the grant date, the warrant was valued at the time of issuance at approximately $6,900,000 and revalued at December 31, 2011, in accordance with ASC 718. The fair market value of the warrant as of December 31, 2011 was approximately $7,600,000 (See Note 7 to our Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011), which amount was recorded as stock-based compensation expense for the year then ended.

(3) We entered into a letter agreement with (a) Mr. Eyler on October 21, 2011, pursuant to which Mr. Eyler was entitled to an annual base salary of $265,000, retroactively effective to September 1, 2011 and (b) Dr. Phillips on October 21, 2011, pursuant to which Dr. Phillips was entitled to an annual base salary of $268,000, effective as of November 1, 2011. Amounts reflected in the salary column above represent the salary earned by each of the named executive officers during 2011 and also include signing bonuses of $22,083 and $22,333 paid to each of Mr. Eyler and Dr. Phillips, respectively, in connection with entering into his letter agreement. The signing bonus is not considered earned until the one-year anniversary of the effective date of the respective letter agreement and is conditioned upon active service with us through such one-year anniversary. Each of Mr. Eyler and Dr. Phillips is obligated to repay to us his signing bonus in the event his employment with us terminates before the first anniversary of his letter agreement s effective date.

(4) On February 13, 2012, we granted each of Mr. Eyler and Dr. Phillips a stock option to purchase 90,000 shares of our common stock at a price per share of $3.75 pursuant to their respective employment letter agreements with us. The shares of common stock underlying these stock options will vest over a three-year period, with 1/3 of the shares vesting on the one-year anniversary of the letter agreement s effective date and then 1/36 of the shares vesting monthly over the next two years. The vesting period for Mr. Eyler s option grant commenced on his date of hire, September 1, 2011, and we recognized $23,304 of compensation expense for this stock option grant during the fiscal year ended December 31, 2011. The

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vesting period for Dr. Phillips option grant commenced on his date of hire, November 1, 2011, and we recognized $11,495 of compensation expense for this stock option grant during the fiscal year ended December 31, 2011. The grant date fair value for the options granted on February 13, 2012 was computed in accordance with ASC 718.

Pension Benefits and Nonqualified Deferred Compensation

During the fiscal year ended December 31, 2011, neither we nor Former Puma had any plans in place for the payment of retirement benefits or benefits that will be paid primarily following retirement including, but not limited to, tax qualified deferred benefit plans, supplemental executive retirement plans, tax qualified deferred contribution plans and nonqualified deferred contribution plans.

Securities Authorized for Issuance Under Equity Compensation Plans

No options were granted by us or Former Puma during the fiscal year ended December 31, 2011. Upon the consummation of the Merger, we assumed Former Puma s 2011 Incentive Award Plan, or the 2011 Plan. As of December 31, 2011, a total of 3,529,412 shares are reserved for issuance under the 2011 Plan. As of December 31, 2011, no awards had been granted under the 2011 Plan.

The following table sets forth the number of options outstanding under the 2011 Plan as of December 31, 2011:

Plan Category	Number of shares to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in the first column)
Equity compensation plan approved by security holders (1)			3,529,412
Total			3,529,412

(1) On September 15, 2011, the board of directors and stockholder of Former Puma adopted the 2011 Plan. On October 4, 2011, we assumed the 2011 Plan in connection with the Merger.

As of June 30, 2012, pursuant to an employment agreement with our President and Chief Executive Officer and letter agreements with our other executive officers and certain employees, we had granted options to purchase an aggregate of 1,392,500 shares of our common stock under the 2011 Plan.

Administration

Upon the completion of this offering, our board of directors will establish a compensation committee and it will administer the 2011 Plan. Subject to the terms of the 2011 Plan and the board s delegation of its authority under the 2011 Plan to our stock option committee, our compensation committee will have complete authority and discretion to determine the terms of awards under the 2011 Plan. Until the compensation committee is established, our board of directors will administer the 2011 Plan.

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Eligible Recipients

Any of our officers or other employees of us or our affiliates, or an individual that we or an affiliate has engaged to become an officer or employee, or a consultant or advisor who provides services to us or our affiliates, including a non-employee director of the board of directors, is eligible to receive awards under the 2011 Plan.

Grants

The 2011 Plan authorizes the grant to eligible recipients of non-qualified stock options, incentive stock options, restricted stock awards, restricted stock units, performance grants intended to comply with Section 162(m) of the Internal Revenue Code of 1986, as amended, dividend equivalent awards, deferred stock awards, stock payment awards and stock appreciation rights.

Duration, Amendment, and Termination

Our board of directors may amend, suspend or terminate the 2011 Plan without stockholder approval or ratification at any time or from time to time. No change may be made that increases the total number of shares of common stock reserved for issuance pursuant to incentive awards, unless such change is authorized by our stockholders within one year.

Compensation of Directors

No compensation was paid to any of our directors during the fiscal year ended December 31, 2011.

Effective February 2012, our board of directors adopted a non-employee director compensation program under the 2011 Plan. Under this program, each non-employee director will receive an option to purchase 30,000 shares of our common stock under the 2011 Plan upon election or appointment to our board of directors. In addition, each non-employee director who is appointed to serve on a committee of our board of directors in a non-chair capacity will receive an option to purchase 10,000 shares of our common stock under the 2011 Plan upon appointment and each non-employee director who is appointed to serve as the chair of a committee of our board of directors will receive an option to purchase 20,000 shares of our common stock upon appointment. Each option granted pursuant to our non-employee director compensation program will vest over a three-year period from the date of grant, with 1/3 of the shares underlying the option vesting on the one-year anniversary of the grant date and then 1/36 of the shares vesting monthly over the next two years. Each option granted pursuant to our non-employee director compensation program will have an exercise price per share of common stock equal to the fair market value on the date of grant. On February 13, 2012, pursuant to our non-employee director compensation program, Thomas R. Malley was granted an option to purchase 30,000 shares of our common stock in connection with his appointment to our board of directors and an option to purchase 20,000 shares of our common stock in connection with his appointment as the Chairman of our Audit Committee. On April 27, 2012, pursuant to our non-employee director compensation program, Jay M. Moyes was granted an option to purchase 30,000 shares of our common stock in connection with his appointment to our board of directors and an option to purchase 10,000 shares of our common stock in connection with his appointment as a member of our Audit Committee.

Employment Agreements with Our Executive Officers

President and Chief Executive Officer Alan H. Auerbach

On January 19, 2012, we entered into an employment agreement with Alan H. Auerbach, our President and Chief Executive Officer. The employment agreement governs the terms of Mr. Auerbach s employment with us and expires on September 1, 2014, unless earlier terminated, with automatic one-year renewal terms unless

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either we or Mr. Auerbach gives written notice of termination 60 days prior to the end of the term. Pursuant to the employment agreement, Mr. Auerbach will continue to serve as our President and Chief Executive Officer and will have powers and duties customary to those positions and that are assigned to him by our board of directors. The employment agreement also provides that Mr. Auerbach will be nominated for election to our board of directors if the term of his directorship expires during the term of the employment agreement.

The employment agreement provides that Mr. Auerbach will receive an annual base salary of $470,000, retroactively effective to September 1, 2011, and will be eligible to receive an annual discretionary bonus in an amount up to 50% of his base salary (pro-rated for any partial year service), each subject to possible increase in connection with our annual review process. Mr. Auerbach is also eligible under the employment agreement to participate in all benefits offered to our senior executives.

The employment agreement further provides that Mr. Auerbach will receive an option to purchase 200,000 shares of our common stock, which will vest as to 1/3 of the shares underlying the option on January 19, 2013, and as to 1/36 of the shares underlying the option on each monthly anniversary thereafter, subject to Mr. Auerbach s continued employment through the vesting dates. We granted this option to Mr. Auerbach on February 13, 2012.

For a discussion of the payments and other benefits to which Mr. Auerbach is entitled in the event of certain qualifying terminations, including certain terminations in connection with a change in control of us, see Potential Payments Upon a Termination or Change in Control below.

Mr. Auerbach s employment agreement contains customary confidentiality and assignment of inventions provisions that survive the termination of the employment agreement for an indefinite period. The employment agreement also contains non-solicitation and non-disparagement provisions extending until 18 months following the termination of his employment with us.

Other Executive Officers Charles R. Eyler, Richard Phillips, Ph.D. and Richard P. Bryce

We have entered into letter agreements with each of the named executive officers listed in the table below on the date set forth next to such officer s name below. Such named executive officers are at-will employees. The table below also sets forth each officer s initial base salary.

Name	Offer Letter Date	Initial Base Salary
Charles R. Eyler	October 21, 2011	$ 265,000
Richard Phillips, Ph.D.	October 21, 2011	$ 268,000
Richard P. Bryce	May 2, 2012	$ 315,000

Pursuant to the letter agreements, each of these named executive officers is eligible to receive an annual performance bonus in an amount up to a fixed percentage of his base salary, which is targeted to be 30% (but which may be higher or lower), subject to the attainment of performance criteria established and evaluated by us. Each of Mr. Eyler, Dr. Phillips and Dr. Bryce is also eligible to participate in all health, welfare, savings and retirement plans, practices, policies and programs maintained or sponsored by us from time to time for the benefit of similarly situated employees. In addition, pursuant to these letter agreements, we agreed to grant each of Mr. Eyler and Dr. Phillips an option to purchase 90,000 shares of our common stock with an exercise price equal to the fair market value of our common stock on the date of the grant, and agreed to grant Dr. Bryce an option to purchase 105,000 shares of our common stock with an exercise price equal to the fair market value of our common stock on the date of the grant. The shares of common stock underlying the options will vest over a three-year period from the date of grant, with 1/3 of the shares of common stock underlying the option vesting on the one-year anniversary of the letter agreement s effective date and then 1/36 of the shares of common stock underlying the option vesting monthly over the next two years.

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The letter agreements also contain a customary non-solicitation provision and, in connection with their entry into the offer letters, each of the named executive officers listed in the table above entered into our standard proprietary information and inventions agreement.

Potential Payments Upon a Termination or Change in Control

At December 31, 2011, we did not have any contracts, agreements, plans or arrangements, whether written or unwritten, that provided for payments to our named executive officers or any other persons following, or in connection with the resignation, retirement or other termination of a named executive officer, or a change in control of us or them or a change in a named executive officer s responsibilities following a change in control.

Alan H. Auerbach. On January 19, 2012, we entered into an employment agreement with Alan H. Auerbach, our President and Chief Executive Officer. Pursuant to the employment agreement, in the event Mr. Auerbach s employment is terminated by us without cause or by Mr. Auerbach for good reason (each as defined in the employment agreement and described below) 60 days prior to, or 18 months following, a change in control, he will be entitled to receive, in addition to any accrued but unpaid compensation and benefits:

- a lump sum payment equal to two times the sum of his base salary and the maximum bonus to which he would be eligible to receive for the year in which the termination occurs;
- all unvested equity-based incentive awards will immediately vest on the later of the change in control and the termination date, and will remain exercisable (as applicable) for a period of up to 12 months from the date of the termination; and
- up to 18 months continuation of healthcare benefits to him and his dependents.

In the event of a change in control of us and an excise tax is imposed as a result of any payments made to Mr. Auerbach in connection with such change in control, we will pay or reimburse Mr. Auerbach an amount equal to such excise tax plus any taxes resulting from such payments.

In the event Mr. Auerbach s employment is terminated by us without cause or by Mr. Auerbach for good reason, in each case outside of the change in control context described above, then Mr. Auerbach will be entitled to receive, in addition to any accrued but unpaid compensation and benefits: (i) an amount equal to the sum of his base salary and the maximum bonus to which he would be eligible to receive for the year in which the termination occurs, payable over a period of one year following such termination in substantially equal installments and (ii) up to 18 months continuation of healthcare benefits to him and his dependents. All severance benefits are contingent upon Mr. Auerbach s execution and non-revocation of a general release of claims in favor of us.

Under the terms of Mr. Auerbach s employment agreement:

- *Cause* is generally defined as (i) the willful failure, disregard or refusal by the executive to perform his duties; (ii) any willful, intentional or grossly negligent act by the executive that injures in a material way our business or reputation; (iii) willful misconduct by the executive in respect of his duties or obligations; (iv) the executive s commission of any felony or a misdemeanor involving moral turpitude (including entry of a nolo contendere plea to any such charge); (v) the determination by us, after a reasonable and good-faith investigation following a written allegation by another employee of us that the executive engaged in some form of harassment prohibited by law, unless the executive s actions were specifically directed by the board; (vi) any misappropriation or embezzlement of our property; (vii) breach by the executive of his obligations with respect to confidentiality, non-solicitation and non-disparagement or of any his representations or warranties under the employment agreement; and (viii) material breach by the executive of any other provision of the employment agreement which is not cured within a specified timeframe.

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Good reason is generally defined as: (i) a material diminution in the executive s base salary, excluding any reduction applicable equally to all of our executive officers following a material decline in our earnings, public image, or performance; (ii) a material diminution in the executive s authority, duties or responsibilities; (iii) a change in the geographic location at which the executive must perform services to a location that is greater than 25 miles from our principal place of business as of the date of the employment agreement; (iv) a direction to the executive to take any action that violates any applicable legal or regulatory requirement; or (v) any other action or inaction that constitutes a material breach by us of our obligations under the employment agreement.

A *change in control* is generally defined as: (a) the consummation of a transaction where any persons become the beneficial owners of Company securities representing more than 50% of the total combined voting power of our securities after such acquisition; (b) a change in the composition of the board such that during any period of two consecutive years, individuals who originally formed our board of directors, together with certain new directors, at the beginning of such period cease for any reason to constitute a majority of the board; (c) us merging, consolidating, reorganizing or combining with another corporation or entity or a sale or other disposition of all or substantially all of our assets or an acquisition of assets or stock of another entity, in each case, where our stockholders prior to the transaction own less than 50% of the outstanding voting securities of the surviving corporation or entity; or (d) our stockholders approving a liquidation or dissolution of us.

Richard Phillips, Ph.D., Charles R. Eyler and Richard P. Bryce. None of our other named executive officers are entitled to any payments from us following, or in connection with such named executive officer s resignation, retirement or other termination, or a change in control of us or a change in such named executive officer s responsibilities following a change in control, except that, under the terms of the 2011 Plan, in the event of a change in control (as defined above), if the successor corporation refuses to assume or substitute any equity award held by Dr. Phillips, Mr. Eyler or Dr. Bryce, such equity awards will immediately vest and, if applicable, become exercisable and be deemed exercised immediately prior to the change in control transaction.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Capital Contributions

Former Puma received $61,983 additional cash capital contributions from Mr. Auerbach during the year ended December 31, 2011, and received $68,514 cash capital contributions from Mr. Auerbach from September 15, 2010 (inception) to December 31, 2011. No additional shares of common stock were issued as a result of these capital contributions. On September 2, 2011, Mr. Auerbach advanced Former Puma $150,000 to fund its operations until such time as Former Puma could complete an equity placement. The advance was converted to an unsecured, non-interest bearing convertible note on September 9, 2011 that would mature in one year. On October 6, 2011, Mr. Auerbach converted the note, in accordance with its terms, into 40,000 shares of our common stock.

Officers

Alan H. Auerbach, our President, Chief Executive Officer and Chairman of the Board, was the President and Chief Executive Officer of Former Puma prior to the Merger, and Mr. Eyler, our Senior Vice President, Finance and Administration and Treasurer, served as the Senior Vice President, Finance and Treasurer of Former Puma prior to the Merger.

Redemption of Common Stock

Pursuant to the Redemption Agreement, the shares of our common stock held by our former stockholders were repurchased by us for an aggregate purchase price of $40,000.

Warrant

Mr. Auerbach holds a warrant that will become exercisable for a ten-year term following the closing of this offering. This warrant will have an exercise price equal to the price paid per share in this offering and will be exercisable for the number of shares of our common stock as would be necessary for Mr. Auerbach to maintain, as calculated under the terms of the warrant, ownership of 20% of our outstanding shares of common stock after this offering. 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, this warrant would entitle Mr. Auerbach to purchase 1,585,000 shares of our common stock at $15.50 per share.

Private Placement

On November 18, 2011, Mr. Malley, one of our directors, purchased 126,551 shares of our common stock in the Subsequent Financing at a price per share of $3.75. This was the same price per share paid by all of the other investors in the Subsequent Financing.

Involvement in Certain Legal Proceedings

To our knowledge, there have been no events under any bankruptcy act, no criminal proceedings and no federal or state judicial or administrative orders, judgments or decrees or findings, no violations of any federal or state securities law, and no violations of any federal commodities law material to the evaluation of the ability and integrity of any our directors (existing or proposed) or executive officers (existing or proposed) during the past ten years.

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Compensation Arrangements, Stock Option Grants and Indemnification for Executive Officers and Directors

We have entered into an employment agreement that, among other things, provides for certain change in control benefits as well as severance benefits for our President and Chief Executive Officer. For a description of these agreements, see Executive Compensation Employment Agreements with Our Executive Officers and Executive Compensation Potential Payments Upon a Termination or Change of Control.

We have entered into agreements with our named executive officers regarding cash bonuses. For a description of these bonuses, see Executive Compensation Employment Agreements with Our Executive Officers.

We have granted stock options to our executive officers and our directors. For a description of these equity awards, see Executive Compensation Securities Authorized for Issuance Under Equity Compensation Plans, Executive Compensation Compensation of Directors and Executive Compensation Employment Agreements with Executive Officers.

We will have entered into indemnification agreements with each of our current directors and executive officers before the completion of this offering. Our amended and restated certificate of incorporation provides that we will indemnify our directors and officers to the fullest extent permitted under Delaware law. See Description of Capital Stock Indemnification of Directors and Officers.

Other than as described above under this section Certain Relationships and Related Person Transactions, since, we have not entered into any transactions, nor are there any currently proposed transactions, between us and a related person where the amount involved exceeds, or would exceed, $120,000, and in which any related person had or will have a direct or indirect material interest. We believe the terms of the transactions described above were comparable to terms we could have obtained in arm s length dealings with unrelated third parties.

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PRINCIPAL STOCKHOLDERS

The following table sets forth the number of shares of our common stock beneficially owned as of October 1, 2012, by (i) each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock, (ii) each of our directors and executive officers and (iii) all officers and directors as a group. Unless otherwise noted below, the address of each stockholder below is c/o Puma Biotechnology, Inc., 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024.

		SHARES BENEFICIALLY OWNED (1) (2)	
NAME	TITLE	NUMBER (#)	PERCENTAGE
Directors and Named Executive Officers			
Alan H. Auerbach (3)	President, Chief Executive Officer and Director	4,040,000	20.16%
Charles R. Eyler (4)	Senior Vice President, Finance and Administration and Treasurer	37,500	*
Richard Phillips, Ph.D (5)	Senior Vice President, Regulatory Affairs and Quality Assurance	32,500	*
Richard Paul Bryce.	Senior Vice President, Clinical Research and Development		
Thomas R. Malley (6)	Director	158,218	*
Jay M. Moyes	Director		
All current executive officers and directors as a group (6 individuals)		4,268,218	21.22%
Stockholders Holding 5% or More			
Adage Capital Partners L.P. (7)		4,432,519	22.12%
Brookside Capital Partners Fund, L.P. (8)		1,666,667	8.32%
Entities affiliated with Fidelity Management & Research Company (9)		1,666,667	8.32%
Foresite Capital II-A, LLC (10)		1,386,666	6.92%
Entities affiliated with Tekla Capital Management LLC (11)		1,106,667	5.52%
The FEZ DE Dynasty Trust (12)		1,066,666	5.32%

* Denotes less than 1.0% of beneficial ownership.

(1) This table is based upon information supplied by our officers, directors, principal stockholders and transfer agent, and information contained in Schedules 13D and 13G filed with the SEC. Unless otherwise noted in the footnotes to this table, we believe each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned, subject to community property laws, where applicable. Applicable percentages are based on 20,040,000 shares of our common stock outstanding as of October 1, 2012, adjusted as required by the rules promulgated by the SEC.

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(2) Beneficial ownership is determined in accordance with SEC rules, and includes any shares as to which the stockholder has sole or shared voting power or investment power, and also any shares which the stockholder has the right to acquire within 60 days of October 1, 2012, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(3) Consists of 4,040,000 shares held of record by Mr. Auerbach and does not include any shares exercisable pursuant to an anti-dilutive warrant held by Mr. Auerbach that will become exercisable following the closing of this offering. 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, this warrant would entitle Mr. Auerbach to purchase 1,585,500 shares of our common stock at $15.50 per share.

(4) Consists solely of stock options to purchase 37,500 shares of our common stock exercisable within 60 days of October 1, 2012.

(5) Consists solely of stock options to purchase 32,500 shares of our common stock exercisable within 60 days of October 1, 2012.

(6) Consists of 146,551 shares held of record by Mr. Malley and stock options to purchase 11,667 shares of our common stock exercisable within 60 days of October 1, 2012.

(7) Adage Capital Partners GP, LLC, or ACPGP, is the general partner of Adage Capital Partners L.P., or the Adage Fund. Adage Capital Advisors, LLC, or ACA, is the managing member of ACPGP. Each of Robert Atchinson and Phillip Gross is a managing member of ACA. The Adage Fund, ACPGP, ACA, Robert Atchinson and Phillip Gross each have shared voting power and shared dispositive power with respect to the shares. The address for the Adage Fund is 200 Clarendon Street, 52nd Floor, Boston, MA 02116.

(8) Brookside Capital Investors, L.P. is the general partner of Brookside Capital Partners Fund, L.P., or the Brookside Fund, and as such has discretion over the portfolio securities beneficially owned by the Brookside Fund. Brookside Capital Management, LLC is the general partner of Brookside Capital Investors, L.P. Brookside Capital Management, LLC is controlled by an executive committee whose members include Dewey J. Awad, Domenic J. Ferrante, Matthew V. McPherron, William E. Pappendick IV and John M. Toussaint. The address for the Brookside Fund is John Hancock Tower, 200 Clarendon Street, Boston, MA 02116.

(9) Consists of 422,223 shares held of record by Fidelity Contrafund: Fidelity Advisor New Insights Fund, 555,556 shares held of record by Fidelity Select Portfolios: Health Care Portfolio, 522,668 shares held of record by Fidelity Select Portfolios: Biotechnology Portfolio, 32,887 shares held of record by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund, and 133,333 shares held of record by Fidelity Select Portfolios: Pharmaceuticals Portfolio. Fidelity Management & Research Company, or Fidelity, a wholly-owned subsidiary of FMR LLC and an investment adviser registered under the Investment Advisers Act of 1940, acts as investment adviser for the beneficial owners set forth above, or the Funds. Edward C. Johnson 3d, the Chairman of FMR LLC, and his family members, directly or through trust, are parties to a shareholders agreement; and may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC and therefore to be persons with the indirect control of Fidelity. Fidelity has the ability to make decisions with respect to the voting and disposition of the shares set forth above subject to the oversight of the board of trustees (or similar entity) of each Fund. The board of trustees (or similar entity) of each Fund has enacted a policy with respect to the voting of any investment property owned thereby and the shares set forth above are voted for the Funds by Fidelity in accordance with such policies. Under the terms of its management contract with each Fund, Fidelity has overall responsibility for directing the investments of the Fund in accordance with the Fund s investment objective, policies and limitations. Each Fund has one or more portfolio managers appointed by and serving at the pleasure of Fidelity who make the decisions with respect to the disposition of the Shares. The address for Fidelity is 82 Devonshire Street, Boston, MA 02109.

(10) Foresite Capital II-A Management, LLC is the sole managing member of Foresite Capital II-A, LLC, or Foresite. The sole manager of Foresite Capital II-A Management, LLC is James B. Tananbaum, and as such, James B. Tananbaum may be deemed to have sole voting and investment power of the securities held by

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Foresite. James B. Tananbaum disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein. The address for Foresite is c/o Foresite Capital Management, P.O. Box 405, Esparto, CA 95627.

(11) Consists of 763,600 shares held of record by H&Q Healthcare Investors and 343,067 shares held of record by H&Q Life Sciences Investors. Tekla Capital Management LLC is the investment advisor to H&Q Healthcare Investors and H&Q Life Sciences Investors. Daniel R. Omstead, Ph.D., is President of Tekla Capital Management LLC and portfolio manager and, as such, has voting, dispositive and investment control over the securities held by H&Q Healthcare Investors and H&Q Life Sciences Investors. Dr. Omstead disclaims beneficial ownership of these securities. The address for the entities affiliated with Tekla Capital Management LLC is 2 Liberty Square, 9th Floor, Boston, MA 02109.

(12) The trustee of The FEZ DE Dynasty Trust is J.P. Morgan Trust Co. of Delaware. Frank Zavrl has sole voting and investment control over the shares held by The FEZ DE Dynasty Trust. The address of J.P. Morgan Trust Co. of Delaware is 500 Stanton Christiana Road, Newark, DE 19713.

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DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock being registered herein is a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and bylaws, which are included as Exhibits 3.3 and 3.4, respectively, hereto.

General

We currently have authorized capital stock of 100,000,000 shares, which are designated as common stock, par value $0.0001 per share. As of June 30, 2012, we had 20,040,000 shares of common stock outstanding held of record by 129 stockholders. Since many stockholders hold shares in street name, we believe that the number of beneficial owners of shares of our common stock was significantly larger than the number of record holders. In addition, as of June 30, 2012, there were outstanding options to purchase 1,392,500 shares of common stock.

The holders of our common stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Subject to any preferential dividend rights of any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of our common stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. Our amended and restated certificate of incorporation does not provide our common stock with any redemption, conversion or preemptive rights.

Warrants

Mr. Auerbach holds a warrant that will become exercisable for a ten-year term following the closing of this offering. This warrant will have an exercise price equal to the price paid per share in this offering and will be exercisable for the number of shares of our common stock as would be necessary for Mr. Auerbach to maintain, as calculated under the terms of the warrant, ownership of 20% of our outstanding shares of common stock as of the closing of this offering. 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, this warrant would entitle Mr. Auerbach to purchase 1,585,000 shares of our common stock at $15.50 per share.

In addition, 27 of our stockholders previously held warrants that provided them with anti-dilution protection in the event of certain stock issuances by us. These warrants expired unexercised, in accordance with their terms, following the quotation of our common stock on the OTC Bulletin Board.

Registration Rights

Pursuant to the terms of a registration rights agreement, as amended, between us and certain stockholders, we prepared and filed, at our expense, a registration statement with the SEC registering the resale of 16,000,000 shares of our common stock. This registration statement was declared effective by the SEC on February 14, 2012, and we are required to use our reasonable best efforts to keep this registration statement continuously effective until the earlier of the date on which all registrable shares cease to be registrable shares and the second anniversary of the date of effectiveness. We are generally required to pay all expenses incurred in connection with registration of the registrable shares.

Dividend Policy

In the past, we have not distributed earnings to stockholders. Any future decisions regarding dividends will be made by our board of directors. We currently intend to retain and use any future earnings for the development and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Our board of directors has complete discretion on whether to pay dividends. Even if our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the board may deem relevant.

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Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a corporation to grant, and authorizes a court to award, indemnity to officers, directors and other corporate agents. As permitted by Section 102(b)(7) of the Delaware General Corporation Law, our certificate of incorporation includes a provision that eliminates the personal liability of our directors for breach of their fiduciary duty as directors, except that a director shall be liable to the extent provided by applicable law (i) for breach of the director s duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the Delaware General Corporation Law or (iv) for any transaction from which the director derived an improper personal benefit. These indemnification provisions may be sufficiently broad to permit indemnification of our officers and directors for liabilities (including reimbursement of expenses incurred) arising under the Securities Act.

To the extent that indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our Company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. If a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of our company in the successful defense of any action, suit or proceeding) is asserted by any of our directors, officers or controlling persons in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law. This statute regulating corporate takeovers prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for three years following the date that the stockholder became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the interested stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers, and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is any person who, together with such person s affiliates and associates (i) owns 15% or more of a corporation s voting securities or (ii) is an affiliate or associate of a corporation and was the owner of 15% or more of the corporation s voting securities at any time

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within the three-year period immediately preceding a business combination of the corporation governed by Section 203. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage takeover attempts that might result in a premium over the market price, once a market exists, for the shares of common stock held by our stockholders.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Wells Fargo Bank, N.A. The transfer agent s address is Wells Fargo Shareowner Services, 1110 Centre Pointe Curve, Suite 101, Mendota Heights, Minnesota 55120, and its telephone number is (800) 468-9716.

Book Entry; Uncertificated Shares

The common stock sold in this offering will be issued in book-entry form through the direct registration system. Under this system, unless a common stockholder requests a physical stock certificate, ownership of our common stock is reflected in account statements periodically distributed to our common stockholders by our transfer agent, who will hold the book-entry shares on behalf of our common stockholders. However, any holder of our common stock who wishes to receive a physical stock certificate evidencing his, her or its shares of our common stock may at any time obtain a stock certificate at no charge by contacting our transfer agent.

New York Stock Exchange Listing

Our shares currently trade on the OTC Bulletin Board and the OTCQB under the symbol PBYI. In connection with this offering, our common stock has been approved for listing on the New York Stock Exchange under the symbol PBYI.

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, shares of our common stock have been quoted for trading on the OTC Bulletin Board and OTCQB Market. In connection with this offering, our common stock has been approved for listing on the New York Stock Exchange. Future sales of our common stock, including shares issued upon the exercise of outstanding options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, certain of the shares of our common stock will not be available for sale in the public market for a period of several months after consummation of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

As of June 30, 2012, we had outstanding 20,040,000 shares of common stock. Of these shares, 16,000,000 have previously been registered with the SEC and the remaining 4,040,000 shares are restricted securities.

Based on the number of shares of our common stock outstanding as of June 30, 2012, upon the closing of this offering and assuming (1) the sale of 6,500,000 shares of our common stock in this offering, (2) no exercise of the underwriters option to purchase additional shares of common stock to cover over-allotments and (3) no exercise of outstanding options or warrants, we will have outstanding an aggregate of approximately 26,540,000 shares of common stock. Of these shares, all of the shares of common stock to be sold in this offering, any shares sold upon exercise of the underwriters option to purchase additional shares, and 16,000,000 shares of our common stock will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our affiliates as such term is defined in Rule 144 of the Securities Act. All remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering will be restricted securities as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

Lock-Up Agreements

In connection with this offering, we, our directors and our executive officers have agreed, subject to certain exceptions, with the underwriters not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date 90 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,

request or demand that we file a registration statement related to the common stock, or

enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

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Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies

Rule 144 is not available for resale of securities issued by any shell companies (other than business combination-related shell companies) or any issuer that has been at any time previously a shell company. The SEC has provided an exception to this prohibition, however, if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and materials required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

Rule 144 became available to our stockholders on October 12, 2012. Our stockholders also may currently resell their shares of our common stock pursuant to a registration statement that has been declared effective under the Securities Act or pursuant to another exemption from registration.

In general, under Rule 144, a person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of ours at any time during the three months preceding the sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months (including any period of consecutive ownership of preceding non-affiliates) would be entitled to sell those shares, subject only to the availability of current public information about us. A non-affiliated person who has beneficially owned restricted securities within the meaning of Rule 144 for at least one year would be entitled to sell those shares without regard to the provisions of Rule 144.

In general, under Rule 144, a person (or persons whose common stock is required to be aggregated), who is an affiliate, and who has beneficially owned our common stock for at least six months is entitled to sell in any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares then outstanding, which will equal approximately 265,400 shares immediately after consummation of this offering, assuming no exercise of the underwriters over-allotment option; or
- the average weekly trading volume in our shares on the New York Stock Exchange during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such a sale, subject to restrictions.

Sales by our affiliates under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. An affiliate is a person that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with an issuer.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan

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or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, under Rule 701 persons who are not our affiliates, as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our affiliates may resell those shares without compliance with Rule 144 s minimum holding period requirements (subject to the terms of the lock-up agreement referred to below, if applicable).

Stock Options

As of June 30, 2012, options to purchase a total of 1,392,500 shares of common stock were outstanding. All of the shares subject to options are subject to the terms of the lock-up agreements with the underwriters. An additional 2,136,912 shares of common stock are available for future option grants under our incentive award plan and we have filed a registration statement on Form S-8 under the Securities Act covering all shares of common stock subject to outstanding options or issuable pursuant to our incentive award plan. Accordingly, shares registered under such registration statement are available for sale in the open market following the effective date, subject to vesting restrictions with us, Rule 144 restrictions applicable to our affiliates or the lock-up restrictions described above.

Warrant

Mr. Auerbach holds a warrant that will become exercisable for a ten-year term following the closing of this offering. This warrant will have an exercise price equal to the price paid per share in this offering and will be exercisable for the number of shares of our common stock as would be necessary for Mr. Auerbach to maintain, as calculated under the terms of the warrant, ownership of 20% of our outstanding shares of common stock after this offering. If this warrant is exercised following this offering, it would result in the issuance of an aggregate of 1,585,000 shares of common stock, assuming the sale of 6,500,000 shares of our common stock 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. Any shares acquired upon the exercise of this warrant may be sold in the public market, subject to Rule 144 restrictions and the lock-up restrictions described above.

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MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) relevant to the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change may be applied retroactively in a manner that could adversely affect a non-U.S. holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to non-U.S. holders that hold our common stock as a capital asset within the meaning of Section 1221 of the Code (property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder s particular circumstances, including the impact of unearned income Medicare contribution tax. In addition, it does not address consequences relevant to non-U.S. holders subject to particular rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities;
- controlled foreign corporations, passive foreign investment companies, and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships, or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and

tax-qualified retirement plans.

If a partnership (or other entity taxed as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, upon the activities

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of the partnership, and upon certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the specific U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS TAX ADVICE. YOU SHOULD CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR SITUATION AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, NON-U.S. OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is a beneficial owner that is not any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons, or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a U.S. person.

Distributions

As described in the section entitled Dividend Policy, we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions on our common stock, such distributions of cash or property on our common stock (other than distributions in redemption of our common stock described in Section 302(b) of the Code) will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a non-U.S. holder s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our common stock.

Subject to the discussion below on backup withholding and foreign accounts, dividends paid to a non-U.S. holder of our common stock that are not effectively connected with the non-U.S. holder s conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders may be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding our common stock in connection with the conduct of a trade or business within the United States and dividends being paid in connection with that trade or business within the United States. To claim such a reduction or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN claiming an exemption from or reduction of the withholding tax under the benefit of an income

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tax treaty between the United States and the non-U.S. holder s country of residence, or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the United States, as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent the required certification, but that qualify for a reduced income tax treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Subject to the discussion below on backup withholding and foreign accounts, if dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated U.S. federal income tax rates. In addition, if the non-U.S. holder is a corporation, the non-U.S. holder may be subject to a branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Sale or Other Taxable Disposition

Subject to the discussion below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) of a portion of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the sale, which may be offset by certain U.S. source capital losses of the non-U.S. holder, subject to certain limitations.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our

common stock will not be subject to U.S. federal income tax if such class of stock is regularly traded, as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually or constructively, 5% or less of such class of our stock throughout the shorter of the five-year period ending on the date of the sale or other disposition or the non-U.S. holder s holding period for such stock.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Subject to the discussion below on foreign accounts, a non-U.S. holder generally will not be subject to backup withholding with respect to payments of dividends on our common stock we make to the non-U.S. holder, provided we (or another applicable withholding agent) do not have actual knowledge or reason to know such holder is a United States person, within the meaning of the Code, and the holder certifies its non-U.S. status under penalty of perjury, such as by providing a valid IRS Form W-8BEN or W-8ECI, or other applicable certification. However, we must report annually to the IRS and to each non-U.S. holder the amount of dividends on our common stock paid to such holder, the name and address of the recipient, and the amount of any tax withheld with respect to those dividends. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale of our common stock within the United States, and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale of our common stock outside the United States conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a United States person) or such owner otherwise establishes an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under the Foreign Account Tax Compliance Act (FATCA) on certain types of payments made to foreign financial institutions (as defined in the Code) and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign financial institution or to a non-financial foreign entity (as defined in the Code), unless (a) the foreign financial institution undertakes certain diligence and reporting obligations, (b) the non-financial foreign entity either certifies it does not have any substantial United States owners (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (c) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (a) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities (as defined in the Code), annually report certain information about such accounts, and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders.

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Although the withholding rules described above currently apply to applicable payments made after December 31, 2012, proposed Treasury Regulations provide such rules will apply to payments of dividends on our common stock made on or after January 1, 2014 and to payments of gross proceeds from the sale or other disposition of such stock on or after January 1, 2015.

However, the proposed Treasury Regulations described above will not be effective until they are issued in their final form and, as a result, it is not certain that the provisions under the proposed Treasury Regulations will become effective in their current form. Prospective investors should consult their tax advisors regarding these withholding provisions.

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UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
Leerink Swann LLC	
Stifel, Nicolaus & Company, Incorporated	
Cowen and Company, LLC	
UBS Securities LLC	
Total	6,500,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer s certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

The expenses of the offering, not including the underwriting discount, are estimated at approximately $630,000 and are payable by us.

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Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 975,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter s initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 90 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

offer, pledge, sell or contract to sell any common stock,

sell any option or contract to purchase any common stock,

purchase any option or contract to sell any common stock,

grant any option, right or warrant for the sale of any common stock,

lend or otherwise dispose of or transfer any common stock,

request or demand that we file a registration statement related to the common stock, or

enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

New York Stock Exchange Listing

Prior to this offering shares of our common stock have been quoted for trading on the OTC Bulletin Board and the OTCQB Market under the symbol PBYI. In connection with this offering our common stock has been approved for listing on the New York Stock Exchange under the symbol PBYI. In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Price Stabilization and Short Positions

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

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In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. Naked short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the New York Stock Exchange, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

Leerink Swann LLC, or Leerink, acted as our placement agent in our October 2011 private placement, in which we raised gross proceeds of approximately $55.0 million and paid Leerink placement agent fees in the amount of $2,338,215 and reimbursed Leerink expenses of $75,000 and in our November 2011 private placement, in which we raised gross proceeds of approximately $5.0 million and paid Leerink placement agent fees in the amount of $84,000. In the October 2011 and November 2011 private placements, persons related to Leerink acquired a pecuniary interest in an aggregate of 141,604 shares of our common stock through direct purchases or purchases by related entities on the same terms as other investors.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

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Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date), no offer of shares may be made to the public in that Relevant Member State other than:

A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;

B. to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require us or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State (other than a Relevant Member State where there is a Permitted Public Offer) who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that (a) it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive, and (b) in the case of any shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, the shares acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors as defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives has been given to the offer or resale. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression an offer to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the

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Prospectus Directive in the Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are qualified investors (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus supplement relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus supplement is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for the prospectus supplement. The shares to which this prospectus supplement relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus supplement you should consult an authorized financial advisor.

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WHERE YOU CAN FIND MORE INFORMATION

Federal securities law requires us to file information with the SEC concerning our business and operations. Accordingly, we file annual, quarterly, and special reports, proxy statements and other information with the SEC. You can inspect and copy this information at the Public Reference Facility maintained by the SEC at 100 F Street, N.E., Washington, DC 20549. You can receive additional information about the operation of the SEC s Public Reference Facilities by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site at http://www.sec.gov that contains reports, proxy and information statements and other information regarding companies that, like us, file information electronically with the SEC.

VALIDITY OF COMMON STOCK

Legal matters in connection with the validity of the shares offered by this prospectus will be passed upon by Latham & Watkins LLP, Costa Mesa, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

EXPERTS

The financial statements of Puma at December 31, 2011 and 2010, appearing in this prospectus and registration statement have been audited by PKF Certified Public Accountants, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report, given on the authority of such firm as experts in accounting and auditing.

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

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Audited Financial Statements

Unaudited Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Puma Biotechnology, Inc.

We have audited the accompanying balance sheets of Puma Biotechnology, Inc. (A Development Stage Company) (the Company) as of December 31, 2011 and 2010, and the related statements of operations, changes in stockholders equity, and cash flows for the year ended December 31, 2011, for the period September 15, 2010 (date of inception) through December 31, 2010, and for the period September 15, 2010 (date of inception) through December 31, 2011. Puma Biotechnology, Inc. s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatements. The Company is not required to have, nor were we engaged to perform, an audit of its internal controls over financial reporting. Our audits included consideration of internal controls over financial reporting as a basis for designing audit procedures that are appropriate in the circumstance, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Puma Biotechnology, Inc. (A Development Stage Company) as of December 31, 2011 and 2010, and the results of its operations and its cash flows for the year ended December 31, 2011, for the period September 15, 2010 (date of inception) through December 31, 2010, and for the period September 15, 2010 (date of inception) through December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

/s/ PKF

San Diego, California
March 29, 2012

PKF
Certified Public Accountants

A Professional Corporation

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

BALANCE SHEETS

DECEMBER 31, 2011 AND 2010

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,381,734	$
Prepaid expenses and other assets	281,096	
Total current assets	53,662,830	
Property and equipment, net	682,053	
Restricted cash	1,053,284	
Total assets	$ 55,398,167	$
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 86,669	$
Accrued expenses	499,542	
Total current liabilities	586,211	
Deferred rent	439,421	
Total liabilities	1,025,632	
Commitments and contingencies (Note 10)		
Stockholders equity:		
Common stock $.0001 par value; 100,000,000 shares authorized; 20,040,000 and 4,000,000 shares issued and outstanding at December 31, 2011 and 2010, respectively	2,004	400
Additional paid-in capital	64,610,340	6,531
Deficit accumulated during the development stage	(10,239,809)	(6,931)
Total stockholders equity	54,372,535	
Total liabilities and stockholders equity	$ 55,398,167	$

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS

	Year ended December 31, 2011	Period from September 15, 2010 (date of inception) to December 31, 2010	Period from September 15, 2010 (date of inception) to December 31, 2011
Operating expenses:			
General and administrative	$ 9,319,587	$ 6,931	$ 9,326,518
Research and development	826,372		826,372
Depreciation and amortization	10,702		10,702
Totals	10,156,661	6,931	10,163,592
Loss from operations	(10,156,661)	(6,931)	(10,163,592)
Other income (expenses):			
Interest income	3,783		3,783
Other income (expense)	(80,000)		(80,000)
Totals	(76,217)		(76,217)
Net loss	$ (10,232,878)	$ (6,931)	$ (10,239,809)
Net loss applicable to common stock	$ (10,232,878)	$ (6,931)	$ (10,239,809)
Net loss per common share basic and diluted	$ (1.321)	$ (0.002)	
Weighted-average common shares outstanding basic and diluted	7,746,529	4,000,000	

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF STOCKHOLDERS EQUITY

THE PERIOD FROM SEPTEMBER 15, 2010 (DATE OF INCEPTION) THROUGH DECEMBER 31, 2011

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Balances, beginning		$	$	$	$
Common stock issued for cash at $.0001 per share	4,000,000	400			400
Paid-in capital			6,531		6,531
Net loss				(6,931)	(6,931)
Balance at December 31, 2010	4,000,000	400	6,531	(6,931)	
Paid-in capital			61,983		61,983
Issuance of shares of common stock through private placements at $3.75 per share, net of issuance costs	16,000,000	1,600	56,739,208		56,740,808
Conversion of stockholder notes payable to equity	40,000	4	149,996		150,000
Stock option compensation			67,022		67,022
Anti-dilutive warrant			7,585,600		7,585,600
Net loss				(10,232,878)	(10,232,878)
Balance at December 31, 2011	20,040,000	$ 2,004	$ 64,610,340	$ (10,239,809)	$ 54,372,535

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CASH FLOWS

	Year ended December 31, 2011	Period from September 15, 2010 (date of inception) to December 31, 2010	2011
Operating activities:			
Net loss	$ (10,232,878)	$ (6,931)	$ (10,239,809)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	10,702		10,702
Build out allowance received from landlord	439,421		439,421
Stock option expense	67,022		67,022
Anti-dilutive warrant	7,585,600		7,585,600
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(281,096)		(281,096)
Accounts payable and accrued expenses	586,211		586,211
Net cash used in operating activities	(1,825,018)	(6,931)	(1,831,949)
Investing activities:			
Purchase of property and equipment	(253,334)		(253,334)
Expenditures for leasehold improvements	(439,421)		(439,421)
Restricted cash	(1,053,284)		(1,053,284)
Net cash used in investing activities	(1,746,039)		(1,746,039)
Financing activities:			
Proceeds from issuance of stockholder convertible note payable	150,000		150,000
Net proceeds from issuance of common stock	56,740,808	400	56,741,208
Capital contributions by stockholder	61,983	6,531	68,514
Net cash provided by financing activities	56,952,791	6,931	56,959,722
Net increase in cash and cash equivalents	53,381,734		53,381,734
Cash and cash equivalents, beginning of period			
Cash and cash equivalents, end of period	$ 53,381,734	$	$ 53,381,734
Supplemental disclosures of non-cash investing and financing activities:			
Conversion of stockholders note payable to common stock	$ 150,000	$	$ 150,000

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS

Note 1 Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc. is a development stage biopharmaceutical company based in Los Angeles, California. References in these Notes to Financial Statements to the Company refer to Puma Biotechnology, Inc., a private Delaware company formed on September 15, 2010, for periods prior to the Merger (as defined below), and Puma Biotechnology, Inc., a Delaware company formed on April 27, 2007 and formerly known as Innovative Acquisitions Corp., for periods following the Merger. The Company s strategy is to license and develop novel therapeutics for the treatment of cancer that have previously been tested in clinical trials, enabling it to obtain an initial indication of the drug s safety and biological activity in humans before committing capital to the drug s development.

Basis of Presentation:

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through December 31, 2011, its efforts have been principally devoted to identifying and acquiring, by license or otherwise, drug candidates for the treatment of cancer. Accordingly, the accompanying financial statements have been prepared in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 915, *Development Stage Entities*. The Company has reported a net loss of $10,232,878 and negative cash flows from operating activities of $1,825,018 for the year ended December 31, 2011. The net loss from the date of inception, September 15, 2010, to December 31, 2011, amounted to $10,239,809. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process.

The Company s continued operations will depend on its ability to raise funds through various potential sources such as equity and debt financing. Through December 31, 2011, the Company s financing has been through private equity placements and capital contributions by the Company s founder and CEO. The Company will continue to fund operations through similar sources of capital previously described. The Company can give no assurances that any additional capital that it is able to obtain will be sufficient to meet its needs. Given the current and desired pace of clinical development of its three product candidates, management estimates that the Company has sufficient cash on hand to fund clinical development through 2012 and into 2013. However, the Company may choose to raise additional capital before 2013 in order to fund its future development activities, likely by selling shares of common stock. If it is unable to raise additional capital, the Company will likely be forced to curtail desired development activities, which will delay the development of its product candidates. There can be no assurance that such capital will be available on favorable terms or at all. The Company will need additional financing thereafter until it can achieve profitability, if ever.

Note 2 Merger with Public Company:

On September 29, 2011, the Company entered into an agreement and plan of merger (the Merger Agreement), with Innovative Acquisitions Corp. (IAC) and its wholly-owned subsidiary, IAC Merger Corporation (Merger Sub). On October 4, 2011, the Company completed a reverse merger in which Merger Sub merged with and into the Company and the Company became a wholly-owned subsidiary of IAC (the Merger).

At the effective time of the Merger, the Company s then issued and outstanding 18,666,733 shares of common stock were exchanged for 18,666,733 shares of common stock of IAC. At the effective time of the

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Merger, each share of the Company common stock that was outstanding immediately prior to the effective time was cancelled, with one share of the Company common stock issued to IAC. Concurrently, IAC redeemed all of its shares from its pre-Merger stockholders in exchange for an aggregate consideration of $40,000 paid by the Company. The Company paid $40,000 for IAC s professional fees associated with the Merger, directly to the service providers. Following the Merger and the redemption, the Company s prior stockholders owned the same percentage of IAC s common stock as they held of the Company s common stock prior to the Merger.

Upon completion of the Merger, the Company merged with and into IAC, and IAC adopted the Company s business plan and changed its name to Puma Biotechnology, Inc. Further, upon completion of the Merger, the existing officers and directors of IAC resigned and the existing officers and directors of the Company were appointed officers and directors of IAC.

The Merger was accounted for as a reverse acquisition with the Company as the accounting acquirer and IAC as the accounting acquiree. 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, the Company treated this transaction as a capital transaction without recording goodwill or adjusting any of its other assets or liabilities. The consideration in the amount of $80,000 paid to the former stockholders of IAC and their attorney was recorded as an other expense item and included in the Company s net loss for the year ending December 31, 2011.

As a condition to the Merger, the Company entered into an Indemnity Agreement dated September 29, 2011, with former officers and directors of IAC, pursuant to which IAC agreed to indemnify such former officers and directors for actions taken by such officers and directors in their official capacities relating to the consideration, approval and consummation of the Merger.

Note 3 Significant Accounting Policies:

The significant accounting policies followed in the preparation of these financial statements are as follows:

Use of Estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the balance sheet and reported amounts of expenses for the period presented. Accordingly, actual results could differ from those estimates. Significant estimates include the valuation of the warrant issued to the CEO (Note 7). The value of the warrant includes estimates based on future events which are difficult to predict. It is at least reasonably possible that a change in the estimates used to value the warrant will occur in the near term.

Cash and Cash Equivalents:

The Company considers all highly-liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

Investment Securities:

The Company classifies 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

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revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. 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.

Assets Measured at Fair Value on a Recurring Basis:

ASC 820, *Fair Value Measurement* (ASC 820) provides a single definition of fair value and a common framework for measuring fair value as well as new disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transactions costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.

Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Following are the major categories of assets measured at fair value on a recurring basis as of December 31, 2011, using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3):

	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 53,003,450	$	$	$ 53,003,450

The Company s investments in short-term and long-term investment securities are exposed to price fluctuations. The fair value measurements for short-term and long-term investment securities are based upon the quoted price in active markets multiplied by the number of securities owned, exclusive of any transaction costs and without any adjustments to reflect discounts that may be applied to selling a large block of securities at one time.

Property and Equipment:

Property and equipment are recorded at cost and depreciated over estimated useful lives ranging from three to five years using the straight-line method. Leasehold improvements are recorded at cost and amortized over the shorter of their useful lives or the term of the lease by use of the straight-line method. Maintenance and repair costs are charged to operations as incurred.

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been an impairment, by comparing the asset s carrying value with its fair value, as measured by the anticipated undiscounted net cash

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flows of the asset. Should impairment exist, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through December 31, 2011.

Research and Development Expenses:

Research and development costs are charged to operations as incurred. Research and development expenses include costs associated with services provided by consultants who conduct research on behalf of the Company, contract organizations for manufacturing of clinical materials and clinical trials. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. The Company determines the total cost of a given study based on the terms of the related contract. The Company accrues for costs incurred as services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in that period. Costs 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.

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents. The Company s cash and cash equivalents in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limit at December 31, 2011 were approximately $54,178,000 due to the Temporary Liquidity Guarantee Program. The Company does not believe it is exposed to any significant credit risk.

Stock-Based Compensation:

Stock option awards:

ASC 718, *Compensation-Stock Compensation* (ASC 718), requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. 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, the Company s estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. ASC 718 does not allow companies to account for option forfeitures as they occur; instead, estimated option forfeitures must be calculated when the option is granted to reduce the option expense to be recognized over the life of the award and updated upon receipt of further information as to the amount of options expected to be forfeited. Due to its limited history, the Company uses the simplified method to determine the expected life of the option grants.

Warrants:

Warrants granted to employees are normally valued at the fair value of the instrument on the date of the grant (grant date) and are recognized in the statement of operations over the requisite service period. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Monte Carlo Simulation Method. As allowed by ASC 718 for companies with a short period of publicly traded stock history, the Company s estimate of expected volatility is based on the average volatilities of a sampling of nine companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the warrant is

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based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value, the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair market value of the warrant at the time of issuance as stock based compensation as an equity transaction. The warrant is then revalued each reporting period up to the grant date when the final fair value of the warrant is established and recorded.

Income Taxes:

The Company follows ASC 740, *Income Taxes* (ASC 740), which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are based on the differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. At the date of adoption, and as of December 31, 2011 and 2010, the Company does not have a liability for unrecognized tax uncertainties.

The Company s policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2011 and 2010, the Company had no accrued interest or penalties related to uncertain tax positions.

Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the periods presented as required by ASC 260, *Earnings Per Share*. Diluted earnings per common share have not been presented because the assumed exercise of the Company s outstanding options would have been anti-dilutive. Potentially dilutive securities excluded from the calculations amounted to 670,000 shares issuable upon exercise of options.

Deferred Rent:

The Company has entered into an operating lease agreement for its corporate offices that contain provisions for future rent increases, a leasehold improvement allowance and rent abatement. The Company records monthly rent expense equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between the rent expense recorded and the amount paid is credited or charged to deferred rent, which is reflected as a separate line item in the accompanying balance sheets. Additionally, the Company recorded as deferred rent the cost of the leasehold improvements to the office paid by the landlord which is amortized on a straight-line basis over the term of the lease.

Reclassifications:

Certain amounts for 2010 have been reclassified to conform to the current year s presentation.

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Recently Issued Accounting Pronouncements:

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

In May 2011, the FASB issued Accounting Standards Update (ASU) 2011-04, Fair Value Measurement (Topic 820): *Amendments to Achieve Common Fair Value Measurement and Disclosure 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 will be effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-04 to have a material effect on its 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, the FASB issued ASU 2011-12, which deferred the 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 will be effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-05 and ASU 2011-12 to have a material effect on its financial condition.

Note 4 Property and Equipment:

Property and equipment at December 31 consisted of the following:

	2011	2010
Leasehold improvements	$ 439,421	$
Computer equipment	216,117	
Telephone equipment	33,854	
Furniture and fixtures	3,363	
	692,755	
Less: accumulated depreciation and amortization	(10,702)	
Totals	$ 682,053	$

Note 5 Accrued Expenses:

Accrued expenses at December 31 consisted of the following:

	2011	2010
Accrued legal fees	$ 149,055	$
Accrued compensation	308,936	
Other	41,551	
Totals	$ 499,542	$

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Note 6 Private Placement and Other Offering:

On October 4, 2011, the Company completed a private placement pursuant to a Securities Purchase Agreement with certain institutional and accredited investors. Pursuant to the Securities Purchase Agreement, the Company sold 14,666,733 shares of common stock at $3.75 per share for aggregate gross proceeds of approximately $55 million. The Company also issued a warrant to each investor that provided such investor with anti-dilution protection. The warrants are exercisable only if the Company sells securities at a price below $3.75 per share on or prior to the date on which shares of Company common stock are first quoted in an over-the-counter market or listed for quotation on a national securities exchange or trading system. If shares are issued below $3.75 per share, the warrants will become effective and have a ten-year term and an exercise price of $0.01 per share (see Note 7).

In connection with the Securities Purchase Agreement, the Company entered into an agreement with Leerink Swann LLC (Leerink) whereby Leerink agreed to act as placement agent in connection with the placement of the common shares. In consideration for Leerink s services, the Company agreed to pay Leerink aggregate cash commissions equal to 6% of the gross cash proceeds from the equity placement not to exceed $3.6 million. The Company also agreed to pay Leerink up to $75,000 as a non-accountable reimbursement allowance. The Company paid Leerink $2,338,215 for services and $75,000 for reimbursable expenses for the private placement transaction. In addition, the Company agreed to reimburse an investor in the private placement for all of the reasonable fees and expenses associated with this agreement subject to a maximum aggregate amount of $125,000.

On November 18, 2011, the Company entered into subscription agreements with 139 accredited investors, pursuant to which the Company sold 1,333,267 shares of common stock at a price per share of $3.75 for aggregate gross proceeds of approximately $5 million. In connection with the subscription agreements, the Company entered into an agreement with Leerink and National Securities Corporation, whereby Leerink agreed to act as lead placement agent and National Securities Corporation agreed to act as co-placement agent and received commissions of $84,000 and $150,000, respectively. In addition to the costs noted above, the Company incurred legal fees and other costs totaling approximately $487,000 associated with the equity raises.

Note 7 Stockholder s Equity:

Common Stock:

The Company issued 4,000,000 shares of common stock to its founder and CEO in September 2010 for $400 at $0.0001 per share. Additionally, the CEO contributed capital totaling $61,983 and $68,514 during the year ended December 31, 2011 and from inception to December 31, 2011, respectively.

In connection with the October 2011 private placement, the Company issued 14,666,733 shares of common stock at $3.75 per share. Additionally, in October 2011, 40,000 shares of common stock were issued through debt conversion at $3.75 per share or $150,000 (see Note 8).

In connection with the November 2011 private placement, the Company issued 1,333,267 shares of common stock at $3.75 per share.

Authorized Shares:

At inception, the Company had 1,200,000 shares of stock authorized for issuance, all of which was common stock, par value $0.0001 per share. On September 15, 2011, the total number of shares of common stock the Company was authorized to issue was increased to 25,000,000. Immediately following the increase in authorized shares, the Company executed a four-to-one forward stock split. The share amounts, including earnings per share, stated in the Company s financial statements have been adjusted to reflect the four-to-one stock split.

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Following the Merger, the Company had 110,000,000 shares of stock authorized for issuance, of which 100,000,000 were common stock, par value $0.0001 per share, and 10,000,000 were preferred stock, par value $0.0001 per share. On October 4, 2011, the Board of Directors of the Company and the stockholders owning 100% of the Company s issued and outstanding common stock approved an Amended and Restated Certificate of Incorporation (the Amended Certificate), which eliminated the Company s entire authorized class of preferred stock and reduced the total number of shares of capital stock that the Company may issue from 110,000,000 shares to 100,000,000 shares, all of which are designated as common stock, par value $0.0001 per share. The Amended Certificate became effective on November 14, 2011, upon the filing of the Amended Certificate with the Secretary of State of the State of Delaware.

Warrants:

In connection with the October 2011 Securities Purchase Agreement, the Company issued anti-dilutive warrants to 27 investors (see Note 6). The fair value of warrants is estimated at the date of issuance using the Monte Carlo Simulation method. As the Company has no trading history, the Company calculated the expected volatility based on the historical volatilities of nine companies with similar attributes to the Company including industry, stage of life cycle, size and financial leverage. The risk-free 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 within additional paid-in capital.

Following the October 2011 private placement, Mr. Auerbach, the Company s founder, CEO and President held approximately 21% of the 18,666,733 outstanding shares of the Company s common stock. Pursuant to the terms of the Securities Purchase Agreement, the Company issued an anti-dilutive warrant to Mr. Auerbach, as the Company s founder. The warrant was issued to provide Mr. Auerbach, as the founder of the Company, with the right to maintain ownership of at least 20% of the common stock of Puma in the event that the Company raises capital in the future through the sale of its securities.

The warrant has a ten-year term and is exercisable only in the event of the first subsequent financing, excluding certain types of financings set forth in the warrant, that results in gross cash proceeds to the Company of at least $15 million. The warrant has an exercise price equal to the price paid per share in such financing and is exercisable for the number of shares of the Company s common stock necessary for Mr. Auerbach to maintain ownership of at least 20% of the outstanding shares of Company common stock after such financing. Upon the occurrence of the first subsequent financing of at least $15 million taking place, the warrant may be exercised any time up to the ten year expiration date of October 4, 2021. The grant date of the warrant will occur on the date of the subsequent financing when the aggregate number of shares exercisable and the price per share will be determined.

The Company determined that the warrant has an implied service requisite period that is prior to its grant date. The Company also determined that a market condition subsequent to the implied service period exists

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as the exercise or partial exercise of the warrant can only occur if there is a subsequent financing. The Company has recorded the fair market value as determined by the following assumptions using the Monte Carlo Simulation method, as stock-based compensation in its statement of operations:

	2011
Dividend yield	0%
Expected volatility	84.4%-85.1%
Risk-free interest rate	1.81%-1.89%
Warrant term in years	10

The fair value was estimated based on projected equity raises ranging from $15 million to $100 million in 2013 using weighted probability factors. The warrant was valued at the time of issuance at approximately $6,900,000 and revalued at December 31, 2011, in accordance with ASC 718. The fair market value of the warrant as of December 31, 2011, using the above assumptions, was approximately $7,600,000 and is included in general and administrative expense in the accompanying statement of operations. The Company will revalue the warrant each reporting period until such time as the grant date of the warrant is determined.

Stock-Based Compensation:

The Company s 2011 Incentive Award Plan (the 2011 Plan) was adopted by the Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair market value of such shares on the date of grant. Through December 31, 2011, a total of 3,529,412 shares of the Company s common stock have been reserved for issuance under the 2011 Plan.

In February 2012, the Company granted, in aggregate, 670,000 stock options to employees hired prior to December 31, 2011. The vesting period for the option grants commenced on each employees date of hire. The Company awarded only plain vanilla options as determined by the Securities and Exchange Commission Staff Accounting Bulletin 107, *Share Based Payment*.

The fair value of options granted to employees was estimated using the Black-Scholes option-pricing model (see Note 3); with the following weighted-average assumptions used during the year ended December 31:

	2011
Dividend yield	0.0%
Expected volatility	86.0%
Risk-free interest rate	1.1%
Expected life in years	5.81

During the year ended December 31, 2011, the Company recognized expense (fair value of the stock option grants) of $67,022 of which $29,498 was recorded as general and administrative expense and $37,524 was recorded as research and development expense.

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Activity with respect to options granted under the 2011 Plan is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2010		$		$
Granted in the period ended December 31, 2011	670,000	3.75	10.0	
Outstanding at December 31, 2011	670,000	$ 3.75	10.0	$
Unvested at December 31, 2011	670,000	$ 3.75	10.0	$
Exercisable at December 31, 2011		$		$

At December 31, 2011, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was $1,471,433, which is expected to be recognized over a weighted-average period of 1.5 years. The weighted average grant date fair values of options granted during the year ended December 31, 2011 was $2.66 per share.

Note 8 Stockholder Note Payable:

On September 2, 2011, the Company s CEO and sole stockholder at the time advanced the Company $150,000 to fund its operations until such time as the Company could complete an equity placement. The advance was unsecured, non-interest bearing and due on demand. On September 9, 2011, the advance was converted to an unsecured convertible promissory note. The note was a non-interest bearing note that could be converted into the Company s common stock at the option of the stockholder. The note was due and payable upon demand of the stockholder on or after the one-year anniversary of the date, if not converted prior to the maturity date. The Company s CEO converted the note into 40,000 shares of the Company s common stock on October 6, 2011 at a price of $3.75 per share.

Note 9 Income Taxes:

Temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes (net operating loss carry-forwards) give rise to the Company s deferred income taxes. The components of the Company s deferred tax assets as of December 31, 2011 and 2010 are as follows:

	Federal	State	Total
Deferred tax assets 2011:			
Net operating loss carry forwards	$ 681,100	$ 103,200	$ 784,300
Organization costs	230,000	39,500	269,500
Compensation	2,631,000	451,400	3,082,400
	3,542,100	594,100	4,136,200
Deferred tax liabilities depreciation	(84,100)	(800)	(84,900)
Total deferred tax assets	3,458,000	593,300	4,051,300
Valuation allowance	(3,458,000)	(593,300)	(4,051,300)
Net deferred tax assets	$	$	$

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	Federal	State	Total
Deferred tax assets 2010:			
Organization costs	$ 2,400	$ 400	$ 2,800
Total deferred tax assets	2,400	400	2,800
Valuation allowance	(2,400)	(400)	(2,800)
Net deferred tax assets	$	$	$

As the ultimate realization of the potential benefits of the Company s deferred tax assets is considered unlikely by management, the Company has offset the deferred tax assets attributable to those potential benefits through valuation allowances. Accordingly, the Company did not recognize any benefit from income taxes in the accompanying financial statements of operations to offset its pre-tax losses. The valuation allowance increased $4,045,700 in 2011 and $2,800 in 2010. At December 31, 2011, the Company has federal and state net operating loss carry forwards of approximately $2,000,000 and $1,700,000 which will expire in 2031 and 2021, respectively. Pursuant to the Internal Revenue Code, Sections 382 and 383, use of the Company s net operating loss and credit carry forward could be limited if a cumulative change in ownership of more than 50% occurs within a three-year period.

The provision (credit) for income taxes in the accompanying statements of operations differs from the amount calculated by applying the statutory income tax rate to income (loss) from continuing operations before income taxes. The primary components of such differences are as follows as of December 31:

	2011	2010
Tax computed at the federal statutory rate	$ (3,479,000)	$ (2,400)
State taxes	(593,800)	