PUMA BIOTECHNOLOGY, INC.
Form 424B3
April 12, 2013
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Filed Pursuant to Rule 424(b)(3)
Registration No. 333-178308

PROSPECTUS

Puma Biotechnology, Inc.

10,942,158 Shares

Common Stock

This prospectus relates to the offering and resale by the selling stockholders identified herein of up to 10,942,158 shares of common stock, par value $0.0001 per share. These shares were privately issued to the selling stockholders in connection with a merger transaction and a private placement. We will not receive any proceeds from the sale of these shares by the selling stockholders.

The selling stockholders from time to time may offer and sell the shares held by them directly or through agents or broker-dealers on terms to be determined at the time of sale, as described in more detail in this prospectus and any accompanying prospectus supplements. The prices at which the selling stockholders may sell the shares may be determined by the prevailing market price for the shares at the time of sale, may be different than such prevailing market prices or may be determined through negotiated transactions with third parties. See Plan of Distribution.

Our common stock is traded on the New York Stock Exchange under the symbol PBYI. On April 11, 2013, the closing sale price of our common stock on the New York Stock Exchange was $31.97 per share.

The securities offered by this prospectus involve a high degree of risk.

See Risk Factors beginning on page 5.

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.

The date of this prospectus is April 11, 2013.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, which we refer to as the Securities Act, and Section 21E of the Securities Exchange Act of 1934, which we refer to as the Exchange Act. 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. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. Accordingly, these statements involve estimates, assumptions, risks and uncertainties, including the risks discussed in the section entitled Risk Factors, that could cause actual results to differ materially from those expressed in them. You should not place undue reliance on these forward-looking statements. Although forward-looking statements reflect management s good faith beliefs, reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which may cause the actual results, performance or achievements to differ materially from anticipated future results, performance or achievements expressed or implied by such forward-looking statements. 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 organizations 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.

Discussions containing these forward-looking statements may be found throughout this prospectus. Forward-looking statements speak only as of the date the statements are made. 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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PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus. This summary is not complete and does not contain all of 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 Cautionary Statement Regarding Forward-Looking Statements, Risk Factors 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., together with its wholly-owned subsidiary, Puma Biotechnology Limited, and the term Former Puma refers to Puma Biotechnology, Inc., a private Delaware corporation that merged with and into us in October 2011.

Our Company

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.

We are initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive breast cancer, HER2 mutated non-small cell lung cancer, and HER2-negative breast cancer that has a HER2 mutation. 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), Perjeta (pertuzumab), and Kadcyla (T-DM1), produced by Genentech, and Tykerb (lapatinib), produced by GlaxoSmithKline, given either alone or in combination with chemotherapy, have been developed to improve the treatment of this cancer by binding 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 different site and using a different mechanism than these other drugs.

Currently, the first-line therapy approved by the U.S. Food and Drug Administration, or the FDA, for treatment of HER2-positive metastatic breast cancer is the combination of Perjeta plus Herceptin and taxane chemotherapy. The drug Tykerb, given in combination with the chemotherapy drug capecitabine, is also FDA-approved for the treatment of HER2-positive metastatic breast cancer that has failed prior treatment. 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%.

Results from a Phase II clinical study, where patients with HER2-positive metastatic breast cancer who had failed prior treatments were administered the combination of neratinib and capecitabine, demonstrated a median PFS of 40.3 weeks and an overall response rate of 64%. In February 2013, we announced that we had reached an agreement with the FDA under a Special Protocol Assessment, or SPA, for our planned Phase III clinical trial of PB272 in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments (third-line disease). The European Medicines Agency has also provided follow-on scientific advice consistent with that of the FDA regarding our Phase III trial design and endpoints to be used and ability of such

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design to support the submission of a European Union, or EU, Market Authorization Application, or MAA. We anticipate commencing our Phase III clinical trial of neratinib (oral) for breast cancer patients who have previously failed two or more prior HER2-directed treatments in the second quarter of 2013.

We are also exploring the safety and efficacy of neratinib (oral):

- in combination with temsirolimus in patients with HER2-positive metastatic breast cancer who have failed multiple prior treatments;
- 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 HER2-negative breast cancer that has a HER2 mutation.

We have on-going Phase II clinical trials for each of these indications.

We licensed 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 our Phase III clinical trials of neratinib in patients with HER2-positive metastatic breast cancer who have previously failed two or more prior treatments;
- continue the on-going Phase II clinical trials of neratinib in the neoadjuvant treatment of HER2-positive breast cancer, in patients with HER2-positive metastatic breast cancer that has metastasized to the brain, in the treatment of HER2 mutated non-small cell lung cancer and in the treatment of patients with HER2-negative breast cancer that have a HER2 mutation; and
- continue to evaluate the application of neratinib in the treatment of other forms of HER2-positive or HER2 mutated cancers where there may be unmet medical needs.

Corporate Information

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 following the Merger, we effected a short-form merger whereby Former Puma merged with and into us, leaving us as the surviving corporation. In connection with the short-form merger, we changed our name to Puma Biotechnology, Inc. and adopted the business of Former Puma.

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.

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THE OFFERING

Common Stock Offered by the Selling Stockholders	Up to 10,942,158 shares
Common Stock Outstanding Prior to and After this Offering:	28,676,666 shares
Use of Proceeds	We will not receive any proceeds from the sale of the shares of common stock offered by the selling stockholders. See Use of Proceeds.
Plan of Distribution	The selling stockholders named in this prospectus, or their pledgees, donees, transferees, assignees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their shares on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. The selling stockholders may resell their shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions, or commissions. For additional information on the methods of sale that may be used by the selling stockholders, see Plan of Distribution.
New York Stock Exchange Symbol	PBYI
Dividend Policy	We do not expect to pay any dividends on our common stock for the foreseeable future.
Risk Factors	You should read the Risk Factors section beginning on page 5 of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.

Unless otherwise noted, the number of shares of our common stock outstanding prior to and after this offering is based on 28,676,666 shares outstanding as of December 31, 2012, and excludes:

- 1,906,334 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2012 at a weighted average exercise price of $8.93 per share;
- 1,611,412 shares of common stock reserved for future issuance under our incentive award plan; and
- 2,116,250 shares of our common stock issuable upon the exercise of a warrant held by Alan Auerbach, our President and Chief Executive Officer, at $16.00 per share.

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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 the 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. 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;
- initiating and conducting sales and marketing activities; and

implementing additional internal systems and infrastructure.

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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 we 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 our clinical studies may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the 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;

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 as a condition to approval;

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- 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.

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 on-going 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

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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.

While we have negotiated a special protocol assessment agreement with the FDA relating to our planned Phase III clinical study of PB272, this agreement does not guarantee approval of PB272 or any other particular outcome from regulatory review of the study or the product candidate.

In February 2013, we announced that we reached agreement with the FDA under a special protocol assessment, or SPA, for our planned Phase III clinical trial of PB272 in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments. The FDA s SPA process is designed to facilitate the FDA s review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III clinical trials that are intended to form the primary basis for determining a drug product s efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor s questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness of the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA. However, an SPA agreement does not guarantee approval of a product candidate, and even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

We cannot assure you that our planned Phase III clinical trial will succeed, will be deemed binding by the FDA under our documented SPA, or will result in any FDA approval for PB272. The trial is expected to enroll approximately 600 patients and we anticipate that enrollment in the study will begin in the second quarter of 2013. We expect that the FDA will review our compliance with the protocol under our SPA agreement and that it will conduct inspections of some of the approximately 150 sites in North America, Europe and Asia-Pacific where the clinical trials will be conducted. We cannot assure you that each of the clinical trial sites will pass such FDA inspections, and negative inspection results could significantly delay or prevent any potential approval for PB272. If the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations.

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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 any of our products 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 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.

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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 on-going 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.

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.

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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;
- 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. In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted

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deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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 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 subject directly or indirectly through our customers, 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.

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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.

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

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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 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 December 31, 2012, we had 49 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.

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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 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, or 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 who 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 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.

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.

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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 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.

Our common stock has been listed on the New York Stock Exchange, or the NYSE, since October 19, 2012. Prior to October 2012, shares of our common stock had 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 the NYSE or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. As of December 31, 2012, we had 28,676,666 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 45.4% 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.

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

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 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.

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.

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Issuance of stock to fund our operations may dilute your investment and reduce your equity interest.

We may need to raise capital in the future to fund the development of our drug candidates or for other purposes. Any equity financing may have a significant dilutive effect to stockholders and a material decrease in our existing stockholders equity interest in us. Equity financing, if obtained, could result in substantial dilution to our existing stockholders. At its sole discretion, our board of directors may issue additional securities without seeking stockholder approval, and we do not know when we will need additional capital or, if we do, whether it will be available to us.

Upon the exercise of our outstanding warrant, holders of our common stock may experience immediate dilution and the market price of our common stock may be adversely affected.

Following the October 2011 private placement, Alan H. Auerbach, the Company s founder, President and Chief Executive Officer, held approximately 21% of our outstanding shares of common stock. Pursuant to the terms of the Securities Purchase Agreement for the private placement, we issued an anti-dilutive warrant to Mr. Auerbach. The warrant has a 10-year term expiring in October 2021 for 2,116,250 shares with an exercise price of $16.00 per share.

If any of the outstanding warrant is exercised for shares of our common stock, our stockholders may experience immediate dilution and the market price of our common stock may be adversely affected.

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 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 the NYSE 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 more time-consuming and costly, particularly after we are no longer an emerging growth company. 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 Jumpstart Our Business Startups Act of 2012, or 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:

- not being required to comply with the auditor attestation requirements of Section 404 of 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.

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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. As a result, the information that we provide to our stockholders may be different than information 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 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.

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

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional capital by selling equity or equity-linked securities. Pursuant to the terms of a registration rights agreement, as amended, between us and the selling stockholders, we have prepared and filed, at our expense, this registration statement with the SEC registering the resale of 10,942,158 shares of our common stock. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for investors in our common stock to sell shares of our common stock at times and prices that such investors feel are appropriate. Furthermore, we expect that, because there are a large number of shares registered pursuant to this resale registration statement, the selling stockholders will continue to offer shares covered by this registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from offerings pursuant to this registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

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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.

The trading market for our common stock is and 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 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, 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, even if we attain profitability.

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USE OF PROCEEDS

We are registering these shares in order to satisfy registration rights we have granted to the selling stockholders. We will not receive any proceeds from the resale of any of the shares offered by this prospectus by the selling stockholders.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is only a summary, and is qualified in its entirety by reference to the actual terms and provisions of the capital stock contained in our certificate of incorporation, our bylaws, and other agreements to which we and our stockholders are parties.

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 December 31, 2012, we had 28,676,666 shares of common stock outstanding held of record by 68 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 December 31, 2012, there were outstanding options to purchase 1,906,334 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. 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 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 is exercisable until October 2021. Pursuant to the terms of the warrant, Mr. Auerbach may exercise the warrant to acquire 2,116,250 shares of the Company s common stock at $16.00 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.

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.

Registration Rights

Pursuant to a registration rights agreement, dated October 4, 2011 and amended on November 18, 2011, we have prepared and filed, at our expense, this registration statement, which was initially declared effective by the SEC on February 14, 2012, covering the resale of the shares of our common stock held by the selling stockholders identified herein. If we do not, subject to certain exceptions, maintain the effectiveness of this registration statement until the second anniversary of the date this registration statement is initially declared effective or if we suspend the use of this registration statement in excess of permitted periods, then we will also be required to pay liquidated damages, on a 30-day basis, to each investor equal to 1.0% of the aggregate purchase price paid by the investor for the registrable shares of our common stock then held by the investor; provided, however, that the aggregate amount

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of liquidated damages payable by us to each investor as a result of our suspension or failure to maintain the effectiveness of the registration statement shall not exceed 10.0% of the aggregate purchase price paid by the investor in the private placement. The registration rights agreement, as amended, also gives investors certain co-sale rights with respect to a firm commitment underwritten offering of the shares of our common stock held by Alan H. Auerbach, our President and Chief Executive Officer.

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.

New York Stock Exchange Listing

Our common stock is listed on the New York Stock Exchange under the symbol PBYI.

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SELLING STOCKHOLDERS

This prospectus covers the resale by the selling stockholders identified below of 10,942,158 shares of our common stock. The following table sets forth the number of shares of our common stock beneficially owned by the selling stockholders as of March 15, 2013, and after giving effect to this offering. The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale or other disposition of any of the shares. The shares covered hereby may be offered from time to time by the selling stockholders. In addition, the selling stockholders may sell, transfer or otherwise dispose of, at any time or from time to time, all or a portion of the shares of common stock beneficially owned by the selling stockholders in transactions exempt from the registration requirements of the Securities Act. None of the selling stockholders received any of our securities as compensation for underwriting services. At the time of each purchase by the selling stockholders of the shares offered hereby, each selling stockholder represented that the selling stockholder s shares were purchased for the selling stockholder s own account, for investment and not with a view to the distribution of those shares.

Name of Selling Stockholder	Number of Shares Owned Before Offering (1)	Percentage of Ownership Before Offering (1)	Number of Outstanding Shares Offered by Selling Stockholder	Number of Shares Owned After Offering (2)	Percentage of Ownership After Offering (2)
Adage Capital Partners L.P. (3)	5,242,519	18.3%	3,200,000	2,042,519	7.1%
Foresite Capital II-A, LLC (4)	1,169,039	4.1%	1,036,666	132,373	*
The FEZ DE Dynasty Trust (5)	1,066,666	3.7%	1,066,666	0	0.0%
Fidelity Select Portfolios: Biotechnology Portfolio (6)	854,701	3.0%	522,668	332,033	1.2%
H&Q Healthcare Investors (7)	762,910	2.7%	762,910	0	0.0%
OrbiMed Private Investments IV, LP (8)	675,000	2.4%	675,000	0	0.0%
Fidelity Contra Fund: Fidelity Advisor New Insights Fund (6)	588,623	2.1%	422,223	166,400	*
T. Rowe Price Health Sciences Fund, Inc. (9)	545,725	1.9%	545,725	0	0.0%
Prudential Sector Funds, Inc. - Prudential Health Sciences Fund d/b/a Prudential Jennison Health Sciences Fund (10)	533,334	1.9%	533,334	0	0.0%
Fidelity Select Portfolios: Health Care Portfolio (6)	400,000	1.4%	370,700	29,300	*
H&Q Life Sciences Investors (7)	342,757	1.2%	342,757	0	0.0%
Fourth Avenue Capital Partners LP (11)	306,622	1.1%	306,622	0	0.0%
Hawkes Bay Master Investors (Cayman) LP (12)	195,400	*	195,400	0	0.0%
Thomas Robert Malley (13)	180,717	*	126,551	54,166	*
Fidelity Select Portfolios: Pharmaceuticals Portfolio (6)	140,233	*	133,333	6,900	*

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Bryan K. White	103,459	*	103,459	0	0.0%
Lindsay A. Rosenwald, MD	66,199	*	66,199	0	0.0%
Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund (6)	61,587	*	32,887	28,700	*
Salthill Partners, L.P. (12)	61,000	*	61,000	0	0.0%
Salthill Investors (Bermuda) L.P. (12)	40,400	*	40,400	0	0.0%
Valic Company I Health Sciences Fund (9)	38,324	*	38,324	0	0.0%
RAQ, LLC (14)	30,000	*	30,000	0	0.0%
PENSCO Trust Company FBO James Tananbaum Roth IRA (15)	28,333	*	13,333	15,000	*
TD Mutual Funds TD Health Sciences Fund (9)	27,500	*	27,500	0	0.0%
John Hancock Variable Insurance Trust Health Sciences Trust (9)	24,087	*	24,087	0	0.0%
John Hancock Funds II Health Sciences Fund (9)	14,156	*	14,156	0	0.0%
Nancy Dubin	13,600	*	13,600	0	0.0%
Borgen GrandC Equity, LLLP (16)	13,340	*	13,340	0	0.0%
Edward F. Keely	13,340	*	13,340	0	0.0%
Jon-Erik Borgen	13,340	*	13,340	0	0.0%
Russell P. Shipman	13,340	*	13,340	0	0.0%
T. Rowe Price Health Sciences Portfolio (9)	12,875	*	12,875	0	0.0%
Leerink Swann Co-Investment Fund LLC (17)	8,000	*	8,000	0	0.0%
Allan Schwartzman	6,800	*	6,800	0	0.0%
David J. Tananbaum and Elizabeth B. Tananbaum	6,800	*	6,800	0	0.0%
Kenneth J. Novack	6,800	*	6,800	0	0.0%
Pallan Family Trust (18)	6,800	*	6,800	0	0.0%
Thomas F. Kearns	6,800	*	6,800	0	0.0%
Borgen Equity III G, LLLP (19)	6,670	*	6,670	0	0.0%
Fagelson Family Trust (20)	6,670	*	6,670	0	0.0%
Daniel J. Belluche and Regan H. Belluche	6,667	*	6,667	0	0.0%
Daniel M. McLaughlin	6,667	*	6,667	0	0.0%
James S. Horvath	6,667	*	6,667	0	0.0%
Robert L. Reynolds	6,667	*	6,667	0	0.0%

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Vincent Formato	6,667	*	6,667	0	0.0%
Hans C. Vitzthum IV	6,666	*	6,666	0	0.0%
Pablo G. Legorreta	6,666	*	6,666	0	0.0%
Laurence Chang	5,670	*	5,670	0	0.0%
Westville Holdings, LLC (21)	5,333	*	5,333	0	0.0%
2217 Group LLC (22)	4,800	*	4,800	0	0.0%
David J. Fitzpatrick	4,800	*	4,800	0	0.0%
Michael Blechman and Barry Lind	4,800	*	4,800	0	0.0%
John S. Skok	4,020	*	4,020	0	0.0%
Barbara A. Whiteside Crary Trust (23)	4,000	*	4,000	0	0.0%
Jill Carol Crary-Ross Irrevocable Trust (24)	4,000	*	4,000	0	0.0%
John Langdon Crary Trust (25)	4,000	*	4,000	0	0.0%
Shane Ellen Crary-Ross Irrevocable Trust (26)	4,000	*	4,000	0	0.0%
Vincent A. Trantolo	4,000	*	4,000	0	0.0%
MSB Family Trust (27)	3,400	*	3,400	0	0.0%
El Chichon Partners, LLC (28)	3,393	*	3,393	0	0.0%
Bryan Ritz	3,200	*	3,200	0	0.0%
Kevin Mack	3,000	*	3,000	0	0.0%
Paul Sallwasser	2,500	*	2,500	0	0.0%
James C. Arnold and Susan M. Arnold	1,000	*	1,000	0	0.0%
William Reed and Evelyn Reed	1,000	*	1,000	0	0.0%
William J. Sasiela	1,000	*	1,000	0	0.0%
William C. Brown	500	*	500	0	0.0%

* Denotes less than 1.0% of beneficial ownership.

(1) The information is based on information provided by or on behalf of the selling stockholders and our transfer agent, and information contained in Schedule 13Gs 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 28,676,666 shares of our common stock outstanding as of March 15, 2013, adjusted as required by the rules promulgated by the SEC. 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 if applicable, also any shares which the stockholder has the right to acquire within 60 days of March 15, 2013, 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.

(2) Assumes the sale of all shares offered.

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(3) 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.

(4) 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 Foresite. James B. Tananbaum disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein. Entities affiliated with Foresite Capital II-A Management, LLC, including Foresite, held in the aggregate 1,269,039 shares, or approximately 4.4%, of our common stock outstanding as of March 15, 2013.

(5) The trustee of The FEZ DE Dynasty Trust is J.P. Morgan Trust Co. of Delaware.

(6) Each of Fidelity Contrafund: Fidelity Advisor New Insights Fund, Fidelity Select Portfolios: Health Care Portfolio, Fidelity Select Portfolios: Biotechnology Portfolio, Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund and Fidelity Select Portfolios: Pharmaceuticals Portfolio (each a Fund and, collectively, the Funds) is an investment company registered under Section 8 of the Investment Company Act of 1940 and advised by 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. Edward C. Johnson 3d and FMR LLC, through its control of Fidelity, and the Fund each has sole power to dispose of the securities owned by the Fund. Members of the family of Edward C. Johnson 3d, Chairman of FMR LLC, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d, Chairman of FMR LLC, has the sole power to vote or direct the voting of the shares owned directly by the Fund, which power resides with the Fund s Boards of Trustees. Fidelity carries out the voting of the shares under written guidelines established by the Fund s Boards of Trustees. Each Fund is an affiliate of a broker-dealer. Entities or funds affiliated with Fidelity, including the Funds, held in the aggregate 3,589,744 shares, or approximately 12.5%, of our common stock outstanding as of March 15, 2013.

(7) Hambrecht & Quist 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 Hambrecht & Quist 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. H&Q Healthcare Investors and H&Q Life Sciences Investors held in the aggregate 1,105,667 shares, or approximately 3.9%, of our common stock outstanding as of March 15, 2013.

(8) OrbiMed Capital GP IV LLC is the general partner of OrbiMed Private Investments IV, LP. OrbiMed Advisors LLC, a registered investment adviser under the Investment Advisers Act of 1940, as amended, is the managing member of OrbiMed Capital GP IV LLC. Samuel D. Isaly, a natural person, is the managing member of and owner of a controlling interest in OrbiMed Advisors LLC and may be deemed to have voting and investment power over the securities held by OrbiMed Private Investments IV, LP. Each of OrbiMed Capital GP IV LLC, OrbiMed Advisors LLC and Samuel D. Isaly disclaims beneficial ownership of these securities except to the extent of its or his pecuniary interest therein, if any.

(9) T. Rowe Price Associates, Inc., or TRPA, serves as investment advisor with power to direct investments and/or sole power to vote the securities owned by T. Rowe Price Health Sciences Fund, Inc., TD Mutual Funds TD Health Sciences Fund, Valic Company I Health Sciences Fund, T. Rowe Price Health Sciences Portfolio, John Hancock Variable Insurance Trust Health Sciences Trust, and John Hancock Funds II Health Sciences Fund, or collectively the TRPA Advisory Funds. For purposes of reporting requirements of the Exchange Act, TRPA may be deemed to be the beneficial owner of all of the shares

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held by the TRPA Advisory Funds; however, TRPA expressly disclaims that it is, in fact, the beneficial owner of such securities. TRPA is a wholly-owned subsidiary of T. Rowe Price Group, Inc., which is a publicly traded financial services holding company. T. Rowe Price Investment Services, Inc. (TRPIS), a registered broker-dealer, is a subsidiary of T. Rowe Price Associates, Inc., the investment adviser to the TRPA Advisory Funds. TRPIS was formed primarily for the limited purpose of acting as the principal underwriter of shares of the funds in the T. Rowe Price fund family. TRPIS does not engage in underwriting or market-making activities involving individual securities. The T. Rowe Price Proxy Committee develops positions on all major corporate issues, creates guidelines, and oversees the voting process. Once the Proxy Committee establishes its recommendations, they are distributed to the firm s portfolio managers as voting guidelines. The portfolio manager of each fund (including each TRPA Advisory Fund) has ultimate responsibility for the voting decisions for proxies relating to voting securities held by the fund (including each TRPA Advisory Fund). The TRPA Advisory Funds held in the aggregate 662,667 shares, or approximately 2.3%, of our common stock outstanding as of March 15, 2013.

(10) Jennison Associates LLC, or Jennison, is an investment adviser under the Investment Advisers Act of 1940, as amended, and serves as sub-adviser with power to direct investments and/or power to vote the shares owned by Prudential Sector Funds, Inc. Prudential Health Sciences Fund d/b/a Prudential Jennison Health Sciences Fund, or the Prudential Fund. Jennison, in such capacity, may be deemed to beneficially own the shares held by the Prudential Fund. Jennison expressly disclaims beneficial ownership of such shares. Jennison is a wholly-owned subsidiary of Prudential Financial, Inc., which is a publicly-traded financial services firm. The Prudential Fund is an investment company registered under the Investment Company Act of 1940. By virtue of their positions with Jennison, the portfolio managers to the Prudential Fund, have authority to vote or dispose of the securities held by the Prudential Fund. The Prudential Fund s principal underwriter is a broker-dealer that is an affiliate of Jennison.

(11) Fourth Avenue Capital Partners GP LLC is the general partner of Fourth Avenue Capital Partners LP, and as such, Fourth Avenue Capital Partners GP LLC may be deemed to beneficially own the shares held by Fourth Avenue Capital Partners LP. The managing members of Fourth Avenue Capital Partners GP LLC are Daniel Gold, Tracy Fu, Nicholas Brumm and Arthur Chu, each of whom disclaims beneficial ownership of the shares held by Fourth Avenue Capital Partners LP.

(12) Wellington Management Company, LLP, or Wellington Management, is an investment adviser registered under the Investment Advisors Act of 1940, as amended. Wellington, in such capacity, may be deemed to share beneficial ownership over the shares held by its client accounts: Hawkes Bay Master Investors (Cayman) LP, Salthill Investors (Bermuda) L.P. and Salthill Partners, L.P., or collectively the Wellington Funds. Each of the Wellington Funds is an affiliate of a broker-dealer. The Wellington Funds held in the aggregate 296,800 shares of our common stock, or approximately 1.0% of our common stock outstanding as of March 15, 2013.

(13) Consists of 156,551 shares held of record by Mr. Malley and stock options to purchase 24,166 shares of our common stock exercisable within 60 days of March 15, 2013. Mr. Malley is a director of the Company.

(14) The sole member of RAQ, LLC is Lindsay A. Rosenwald, MD.

(15) PENSCO Trust Company FBO James Tananbaum Roth IRA is a self-directed IRA, with respect to which James B. Tananbaum is the beneficial owner and has the power to make investment decisions.

(16) The manager of Borgen GrandC Equity, LLLP is Bjorn K. Borgen.

(17) The managing members of Leerink Swann Co-Investment Fund LLC are Jeffrey A. Leerink, James P. Boylan, Daniel B. Dubin, Joseph R. Gentile and Donald D. Notman, Jr., and may be deemed to share discretionary voting authority with respect to such shares.

(18) The trustee of the Pallan Family Trust is Richard Pallan.

(19) The general partner of Borgen Equity III G, LLLP is Bjorn K. Borgen.

(20) The trustee of the Fagelson Family Trust is James E. Fagelson, M.D.

(21) The controlling member of Westville Holdings, LLC is Christine Aylward.

(22) The manager of 2217 Group LLC is Barry J. Lind.

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(23) The trustee of the Barbara A. Whiteside Crary Trust is Barbara A. Whiteside Crary.
(24) The trustee of the Jill Carol Crary-Ross Irrevocable Trust is John L. Crary.
(25) The trustee of the John Langdon Crary Trust is John L. Crary.
(26) The trustee of the Shane Ellen Crary-Ross Irrevocable Trust is John L. Crary.
(27) The trustee of the MSB Family Trust is Michael Blechman.
(28) The manager of El Chichon Partners, LLC is Erin Burr.

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PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. The selling stockholders may sell their shares of our common stock pursuant to this prospectus at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter

into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

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The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be underwriters within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are underwriters within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of the second anniversary of the date the registration statement is declared effective by the SEC and such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or Rule 144 of the Securities Act.

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LEGAL MATTERS

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. If the offered securities are distributed in an underwritten offering or through agents, certain legal matters may be passed upon for any agents or underwriters by counsel for such agents or underwriters identified in the applicable prospectus supplement.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2012 have been so incorporated in reliance on the report of PKF Certified Public Accountants, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other documents with the SEC. You may read and copy any document we file at the SEC s public reference room at 100 F Street, N.E., Washington, D.C. 20549. You should call 1-800-SEC-0330 for more information on the public reference room. Our SEC filings are also available to you on the SEC s Internet website at http://www.sec.gov.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our Common Stock, including certain exhibits and schedules. You can obtain a copy of the Registration Statement from the SEC at the address listed above or from the SEC s Internet website.

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INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC permits us to incorporate into this prospectus information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. The information incorporated by reference is considered to be part of this prospectus. Information contained in this prospectus and information that we file with the SEC in the future and incorporate by reference in this prospectus automatically updates and supersedes previously filed information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the sale of all the shares covered by this prospectus or termination of the offering.

Our Annual Report on Form 10-K, filed April 1, 2013;

Our Current Report on Form 8-K filed February 21, 2013;

The description of our common stock contained in our Registration Statement on Form 8-A filed on October 16, 2012, and any subsequent amendment thereto filed for the purpose of updating such description.

Any other filings we make pursuant to the Exchange Act after the date of filing this registration statement and prior to this registration statement (other than any information in such reports that is deemed to have been furnished to, rather than filed with, the SEC in accordance with SEC rules).

A statement contained in a document incorporated by reference into this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, any prospectus supplement or in any other subsequently filed document which is also incorporated in this prospectus modifies or replaces such statement. Any statements so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a copy of these documents, including exhibits, which will be provided to you at no cost, by writing or telephoning us using the following contact information:

Puma Biotechnology, Inc.

10880 Wilshire Boulevard, Suite 2150

Los Angeles, California 90024

Attention: Investor Relations

Telephone: (424) 248-6500

You should rely only on the information contained in this prospectus or on information to which we have referred you. We have not authorized anyone else to provide you with any information.