2013 opportunities

Puma Biotechnology, Inc.
2013 Annual Report

Drug	Indication	Pre-Clinical	Phase I	Phase II	Phase III	Registration
PB272 COMBINATION WITH XELODA	Metastatic Breast Cancer					
PB272 COMBINATION WITH TORISEL	Metastatic Breast Cancer					
PB272 SINGLE AGENT/ COMBINATION	Metastatic Breast Cancer with Brain Mets					
PB272 COMBINATION WITH CHEMOTHERAPY	Neoadjuvant Breast Cancer					
PB272 COMBINATION WITH PACLITAXEL	Metastatic Breast Cancer					
PB272 SINGLE AGENT	Adjuvant Breast Cancer					
PB272 (oral) COMBINATION AND SINGLE AGENT	HER2 Mutated NSCLC					
PB272 (oral) SINGLE AGENT	HER2 Mutated Breast Cancer					
PB272 (oral) SINGLE AGENT	HER2 Mutated Solid Tumors					

unfolding

Puma Biotechnology is focused on the clinical development of its lead product candidate PB272, ***neratinib (oral)***, for the treatment of breast cancer, non-small cell lung cancer and other types of solid tumors with a HER2 mutation.

Puma's clinical trial pipeline is summarized in the table above.

Additional information on Puma's clinical trials is available at www.clinicaltrials.gov.

Puma Biotechnology, Inc. is 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 further develop those drug candidates for commercial use.

Our lead drug candidate PB272 *(neratinib (oral))* is a potent irreversible tyrosine kinase inhibitor, which we are developing across a broad range of tumors and indications. We are initially focused on developing PB272 for the treatment of patients with HER2-positive metastatic breast cancer and for patients with non-small cell lung cancer, breast cancer and other solid tumors that have a HER2 mutation.

To Our Stockholders

2013 has been a year of considerable progress and achievement at Puma with the rapid advancement of our Phase III and Phase II clinical programs of PB272 (neratinib). We achieved a significant clinical milestone when we reported strong top line results from the Phase II clinical trial of PB272 for the neoadjuvant treatment of breast cancer (I-SPY 2 TRIAL), and as a result we look forward to the advancement of PB272 in this indication. We believe we are well-positioned to aggressively advance and expand our pipeline and meet our milestones in 2014 and beyond. It is a great pleasure to reflect on our success and accomplishments.

Phase III Clinical Trial in HER2-Positive Metastatic Breast Cancer

In June 2013, we achieved a significant milestone with the initiation of our Phase III clinical trial of PB272 in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments. This is a randomized trial of PB272 plus Xeloda versus Tykerb plus Xeloda in patients with third-line HER2-positive metastatic breast cancer. This indication could represent our first indication for PB272 in the treatment of HER2-positive metastatic breast cancer.

Neratinib in HER2 Mutations

Based on preclinical and clinical data with PB272 in patients with activating HER2 mutations, during 2013 Puma began several clinical trials of PB272 in cancer patients with HER2 mutations. The first of these trials is a Puma-sponsored study of PB272 in patients with HER2 mutated non-small cell lung cancer, a trial in which patients are randomized to receive either PB272 alone or PB272 in combination with Torisel.

We also continued to advance our clinical trial of PB272 in patients with metastatic HER2-negative breast cancer who have a HER2 mutation. In this investigator-sponsored trial, patients with metastatic disease are screened for the presence of the HER2 mutation and if the mutation is present, the patient is administered PB272 monotherapy.

In October 2013, we also announced the initiation of a Phase II clinical trial of PB272 as a single agent in patients with solid tumors who have an activating HER2 mutation (basket trial). This Phase II basket trial includes eight cohorts, or baskets, of patients, including (i) bladder/urinary tract cancer; (ii) colorectal cancer; (iii) endometrial cancer; (iv)

gastric/esophageal cancer; (v) ovarian cancer; (vi) all other solid tumors, including prostate, melanoma and pancreatic cancer; (vii) EGFR mutated and/or amplified primary brain cancer; and (viii) solid tumors with a HER3 mutation. We anticipate that the initial clinical data from this trial will be presented in 2014.

Results from I-SPY 2 TRIAL

During 2013, we were very pleased to announce that PB272 graduated from the I-SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2), which is a randomized Phase II neoadjuvant clinical trial for women with newly diagnosed stage 2 or higher breast cancer. We reported positive top line data from this trial in December 2013. Notably, this represented the first clinical data on PB272 in the neoadjuvant treatment of HER2-positive breast cancer and suggested that the combination of paclitaxel plus PB272 has potent activity for the treatment of HER2-positive breast cancer. We look forward to advancing PB272 in this indication and toward future involvement with the I-SPY 3 Phase III trial.

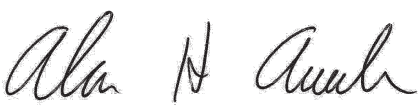
Looking Forward

It is with great pleasure that I lead Puma into a truly exciting time in our Company's history. Puma is uniquely positioned to successfully execute its strategic plan in the upcoming years and build value for its stockholders.

I would like to acknowledge the contribution of Puma's employee, whose skills, experience and commitment enabled us to reach our milestones in 2013 and who diligently strive to continue this momentum in 2014 and beyond.

On behalf of the Company and its Board of Directors, I also would like to take this opportunity to sincerely thank our loyal stockholders for their ongoing support.

Sincerely,



Alan H. Auerbach
Chairman, Chief Executive
Officer and President, Founder

Puma Biotechnology, Inc.
PBYI Daily Closing Prices
April 20, 2012 through April 15, 2014*

*From April 20, 2012 through October 18, 2012, shares of Puma Biotechnology common stock were quoted on the OTC Bulletin Board (OTCBB) under the symbol "PBYI." On October 19, 2012, Puma shares commenced trading on the New York Stock Exchange under the symbol "PBYI" and ceased being quoted on the OTCBB.

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2013

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	**77-0683487**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

10880 Wilshire Boulevard, Suite 2150
Los Angeles, CA 90024
(424) 248-6500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☒ Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2013, was $703,209,481 based upon the closing price of $44.37 per share of the registrant's common stock on the New York Stock Exchange on Friday, June 28, 2013, the last business day of the registrant's most recently completed second fiscal quarter. Shares of common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. As of February 28, 2014, there were 30,117,819 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference:

Portions of the Proxy Statement for the registrant's 2014 Annual Meeting of Stockholders (the "2014 Proxy Statement") are incorporated by reference in Part III of the Form 10-K to the extent stated herein.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions, future events or performance are not historical facts and may be forward-looking. These forward-looking statements include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the regulatory approval of our drug candidates;
- our use of clinical research 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.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Annual Report, including the sections entitled “Item 1. Business” and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II of this Annual Report. These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I of this Annual Report, in the section entitled “Item 1A. Risk Factors,” that could cause our actual results to differ materially from those in the forward-looking statements. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document. The risks discussed in this Annual Report should be considered in evaluating our prospects and future financial performance.

Part I

ITEM 1. BUSINESS

Company Overview

Unless otherwise provided in this Annual Report, references to the "Company," "we," "us," and "our" 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 Ltd., and all references to "Former Puma" refer to Puma Biotechnology, Inc., a privately-held Delaware corporation formed on September 15, 2010, that merged with and into us in October 2011. We refer to this transaction as the "Merger."

We are a development stage biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. We aim to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. Our efforts and resources to date have been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel.

We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients, non-small cell lung cancer patients and patients with HER2 mutation-positive solid tumors;
- 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, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. 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 to the HER2 protein. There are also a number of trials ongoing that involve various combinations of these drugs (for example, Perjeta plus Kadcyla). Based on pre-clinical studies and clinical trials 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 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, or EMA, has also provided follow-on scientific advice, or SA, consistent with that of the FDA regarding our Phase III trial design and endpoints to be used and ability of such design to support the submission of a European Union, or EU, Market Authorization Application, or MAA. We commenced 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 HER 2-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 adjuvant treatment of HER2-positive breast cancer in patients who have completed adjuvant treatment with Herceptin;
- for the treatment of patients with first line HER2-positive metastatic breast cancer who have not previously received treatment in the metastatic setting;
- for the treatment of HER2 mutated non-small cell lung cancer;
- for the treatment of patients with HER2-negative breast cancer that has a HER2 mutation; and
- for the treatment of patients with solid tumors who have an activating HER2 mutation.

We have ongoing 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:

- continue our Phase III clinical trials of neratinib in patients with HER2-positive metastatic breast cancer who have previously failed two or more prior treatments;
- commence a Phase III trial of neratinib for the neoadjuvant treatment of HER2-positive breast cancer and for the neoadjuvant treatment of a subset of patients with HER2-negative breast cancer;
- continue the ongoing Phase II clinical trials of neratinib in the neoadjuvant treatment of HER2-positive breast cancer, the ongoing Phase II trial in patients with HER2-positive metastatic breast cancer that has metastasized to the brain, the ongoing Phase II trial in the treatment of HER2 mutated non-small cell lung cancer, the ongoing Phase II trial in the treatment of patients with HER2-negative breast cancer that have a HER2 mutation, the ongoing Phase II trial in the treatment of solid tumors that have an activating HER2 mutation, the ongoing Phase III trial for the adjuvant treatment of HER2 positive breast cancer in patients who have completed adjuvant treatment with Herceptin, and the ongoing Phase II trial for the treatment of patients with first line HER2-positive metastatic breast cancer who have not previously received treatment in the metastatic setting; 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.

Strategy

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

- *Advance PB272 (neratinib (oral)), our lead drug candidate, toward regulatory approval and commercialization.* We are primarily focused on developing neratinib for the treatment of patients with HER2-positive metastatic breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer who have a HER2 mutation and other solid tumors with an activating mutation in HER2. We have modified the previous clinical development strategy that Pfizer employed by focusing our current and planned Phase II and Phase III clinical trials on the use of neratinib in these patient populations, which we believe may be underserved by current treatment alternatives and where clinical trials have shown substantial levels of activity. We are also focusing on the development of neratinib in the neoadjuvant treatment of patients with HER2-positive breast cancer and in patients with HER2-positive metastatic breast cancer that has metastasized to the brain and in the adjuvant treatment of HER2-positive breast cancer.
- *Expand our product pipeline by pursuing additional applications of neratinib.* We believe there are additional applications for neratinib in the treatment of HER2 mutated non-small cell lung cancer, which we also believe may be underserved by current treatment alternatives; in the treatment of patients with a HER2-negative breast cancer who have a HER2 mutation; and in tumor types where HER2 is over-expressed or mutated. We intend to further evaluate the safety and efficacy of neratinib for treating these cancers.
- *Focus on developing innovative cancer therapies.* We focus on oncology drug candidates in order to capture efficiencies and economies of scale. We believe that drug development for cancer markets is particularly attractive because relatively small clinical trials can provide meaningful information regarding patient response and safety. Furthermore, we believe that our capabilities are well suited to the oncology market and represent distinct competitive advantages.
- *Build a sustainable pipeline by employing multiple therapeutic approaches and disciplined decision criteria based on clearly defined proof of principal goals.* We seek to build a sustainable product pipeline by employing multiple therapeutic approaches and by acquiring drug candidates belonging to known drug classes. In addition, we employ disciplined decision criteria to assess drug candidates, favoring drug candidates that have undergone at least some clinical study. Our decision to license a drug candidate will also depend on the scientific merits of the technology; the costs of the transaction and other economic terms of the proposed license; the amount of capital required to develop the technology; and the economic potential of the drug candidate, should it be commercialized. We believe this strategy minimizes our clinical development risk and allows us to accelerate the development and potential commercialization of current and future drug candidates. We intend to pursue regulatory approval for a majority of our drug candidates in multiple indications.
- *Evaluate the commercialization strategies on a product-by-product basis in order to maximize the value of each.* As we move our drug candidates through development toward regulatory approval, we will evaluate several options for each drug candidate's commercialization strategy. These options include building our own internal sales force; entering into a joint marketing partnership with another pharmaceutical or biotechnology company, whereby we jointly sell and market the product; and out-licensing our product, whereby another pharmaceutical or biotechnology company sells and markets our product and pays us a royalty on sales. Our decision will be made separately for each product and will be based on a number of factors including capital necessary to execute on each option, size of the market to be addressed and terms of potential offers from other pharmaceutical and biotechnology companies. It is too early for us to know which of these options we will pursue for our drug candidates, assuming their successful development.

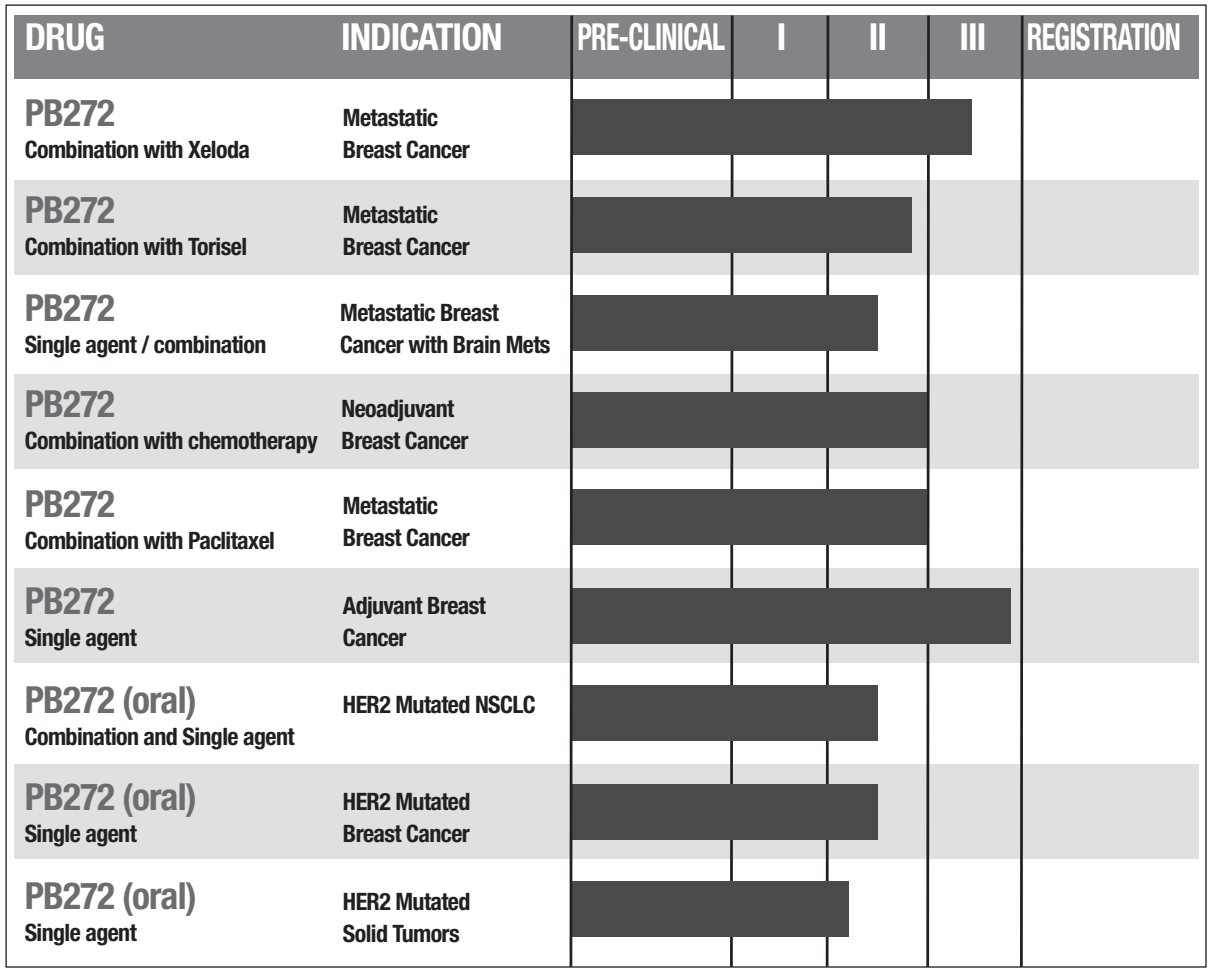
Product Development Pipeline

Breast Cancer Overview

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

Trastuzumab, pertuzumab and T-DM1 are drugs that bind to the HER2 protein and thereby cause the cells to cease reproducing. Trastuzumab and pertuzumab given in combination with chemotherapy is the current first-line standard of care for HER2-positive metastatic breast cancer. Lapatinib is a small molecule that also binds to the HER2 protein and causes the cell to cease reproducing. Lapatinib given in combination with the chemotherapy drug capecitabine is FDA-approved for the treatment of patients who have failed prior treatments. Unfortunately, most patients with HER2-positive breast cancer eventually develop resistance to these treatments, resulting in disease progression. For these reasons, there is a need for alternatives to block HER2 signaling in patients who fail treatment with prior HER2 directed treatments. PB272 is an orally active small molecule that inhibits HER2 at a different site and uses a different mechanism than trastuzumab. As a result, we believe that PB272 may have utility in patients with HER2-positive metastatic breast cancer who have failed treatment with trastuzumab. We believe that there are approximately 36,000 patients in the United States and 34,000 patients in the European Union, or EU, with newly diagnosed HER2-positive breast cancer, representing an estimated total market opportunity between $1 billion and $2 billion. We also believe that there are between 5,000 and 6,000 patients in the United States with third-line or later HER2-positive metastatic breast cancer. In 2013, worldwide sales of Tykerb for this indication were approximately $325 million.

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



PB272 (neratinib (oral))—Breast Cancer

Neratinib is a potent irreversible tyrosine kinase inhibitor, or TKI, that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. We believe neratinib has clinical application in the treatment of several cancers, including breast cancer, non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2.

Advantages of Neratinib

Based on pre-clinical studies and clinical trials to date, we believe that neratinib may offer an advantage over existing treatments that are used in the treatment of patients with HER2-positive metastatic breast cancer who have failed prior treatments, including treatment with trastuzumab, pertuzumab, and T-DM1. Currently, the treatment of metastatic breast cancer patients involves treatment with these agents either alone or in combination with chemotherapy. We believe that by more potently inhibiting HER2 at a different site and acting via a mechanism different from other agents, neratinib may have therapeutic benefits in patients who have failed these existing treatments, most notably due to its increased selectivity and stronger inhibition of the HER2 target enzyme.

PB272 (neratinib (intravenous))—Breast Cancer

We also plan to develop neratinib as an intravenously administered agent. In pre-clinical studies, the intravenous version of neratinib resulted in higher exposure levels of neratinib in pre-clinical models. We believe that this may result in higher blood levels of neratinib in patients, which may translate into better efficacy. We plan to file an Investigational New Drug Application, or IND, for the intravenous formulation of neratinib in 2014.

PB357

PB357 is an orally administered agent that is an irreversible TKI that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. PB357 is structurally similar to PB272. Pfizer had completed single dose Phase I trials of PB357. We are evaluating PB357 and considering options relative to its development in 2014.

Clinical Trials of Neratinib in Patients with Metastatic Breast Cancer

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

The trial involved a total of 136 patients, 66 of whom had received prior treatment with trastuzumab and 70 of whom had not received prior treatment with trastuzumab. The results of the study showed that neratinib was reasonably well-tolerated among both the pretreated patients and the patients who had not received prior treatment with trastuzumab. Diarrhea was the most common side effect, but was manageable with antidiarrheal agents and dose modification. Efficacy results from the trial showed that the objective response rate was 24% for patients who had received prior trastuzumab treatment and 56% for patients with no prior trastuzumab treatment. Furthermore, the median PFS was 22.3 weeks for the patients who had received prior trastuzumab and 39.6 weeks for the patients who had not received prior trastuzumab.

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

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

Data from a third Phase II study, in which patients with confirmed HER2-positive metastatic breast cancer who had failed treatment with trastuzumab and taxane chemotherapy were given PB272 in combination with capecitabine, was presented at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium. The results of the study showed that the combination of PB272 and capecitabine had acceptable tolerability. The efficacy results from the trial showed that for the 61 patients in the trial who had not been previously treated with the HER2 targeted anti-cancer drug lapatinib, there was an overall response rate of 64% and a clinical benefit rate of 72%.

In addition, for the seven patients in the trial who had previously been treated with lapatinib, there was an overall response rate of 57% and a clinical benefit rate of 71%. The median PFS for patients who had not received prior treatment with lapatinib was 40.3 weeks and the median PFS for the patients who had received prior lapatinib treatment was 35.9 weeks.

In February 2013, we announced that we reached agreement with the FDA under an 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 SPA is a written agreement between us, as the trial's sponsor, and the FDA regarding the design, endpoints, and planned statistical analysis of the Phase III trial with respect to the effectiveness of PB272 for the indication to be studied to support a New Drug Application, or NDA. The EMA has also provided follow-on SA consistent with that of the FDA regarding our Phase III trial design and endpoints to be used and ability of such design to support the submission of an MAA in the EU.

Pursuant to the SPA and SA, the Phase III trial is designed as a randomized study of PB272 plus capecitabine versus Tykerb plus capecitabine in patients with third-line HER2-positive metastatic breast cancer. The trial is expected to enroll approximately 600 patients who will be randomized (1:1) to receive either PB272 plus capecitabine or Tykerb plus capecitabine. The trial will be conducted at approximately 150 sites in North America, Europe and Asia-Pacific. The agreed upon co-primary endpoints of the trial are PFS and overall survival. Our plan is to use the PFS data from the trial as the basis for submission of an NDA/MAA for Accelerated/Conditional Approval for PB272 from the regulatory agencies. We commenced patient enrollment in this Phase III trial in the second quarter of 2013.

In 2010, Pfizer also initiated a Phase I/II trial of neratinib in combination with the anti-cancer drug temsirolimus, or Torisel, in patients with HER2-positive metastatic breast cancer who have failed multiple prior treatments. The study enrolled patients with either HER2-positive metastatic breast cancer and disease progression on trastuzumab or with triple-negative breast cancer. The updated Phase II results of this trial were presented at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium. The results of the study showed that the combination of PB272 and temsirolimus had acceptable tolerability. The efficacy results from the trial showed that for the 27 evaluable patients, 12 patients, or 44%, experienced a partial response and one patient, or 4%, experienced prolonged stable disease for greater than six months, which translates to a clinical benefit rate of 48%. Patients who experienced a partial response to the combination of neratinib plus temsirolimus demonstrated a maximum change in the size of their target lesions of between 33% and 83%. Clinical benefit was seen in patients previously treated with trastuzumab as well as lapatinib, T-DM1 and pertuzumab. Enrollment in this trial is continuing and we expect additional data from this trial to be presented in 2014. The Company also intends to progress the combination of PB272 and temsirolimus into Phase III trials and currently anticipates that it will commence Phase III trials of the combination in 2014.

Approximately one-third of the patients with HER2-positive metastatic breast cancer develop metastases that spread to their brain. The current antibody-based treatments, including Herceptin, Perjeta and T-DM1, do not enter the brain and therefore are not believed to be effective in treating these patients. In a Phase II trial with Tykerb given as a single agent, Tykerb demonstrated a 6% objective response rate in the patients with HER2-positive metastatic breast cancer whose disease spread to their brain. In January 2012, a Phase II trial of neratinib as a single agent and in combination with the anticancer drug capecitabine in patients with HER2-positive metastatic breast cancer that has spread to their brain was initiated in conjunction with the Dana Farber Translational Breast Cancer Research Consortium. We anticipate that results from this trial will be presented in 2014.

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

breast and lymph nodes of 27.6%, the patients who received paclitaxel plus lapatinib had a pCR of 20.0% and the patients who received the combination of paclitaxel plus trastuzumab plus lapatinib had a pCR of 46.8%.

Also at the 2010 CTRC-AACR San Antonio Breast Cancer Symposium, the results of the Neo-Sphere study were presented. In this trial, patients with HER2-positive breast cancer were randomized to receive either the combination of docetaxel plus trastuzumab, the combination of docetaxel plus pertuzumab, the combination of trastuzumab plus pertuzumab or the combination of docetaxel plus trastuzumab plus pertuzumab, as a neoadjuvant (preoperative) therapy. The results of the trial demonstrated that the patients who received the combination of docetaxel plus trastuzumab demonstrated a pCR in the breast and lymph nodes of 21.5%, the patients who received docetaxel plus pertuzumab had a pCR of 17.7%, the patients who received pertuzumab plus trastuzumab had a pCR of 11.2% and the patients who received the combination of docetaxel plus trastuzumab plus pertuzumab had a pCR of 39.3%.

In 2010, Pfizer, in collaboration with the National Surgical Adjuvant Breast and Bowel Project, or NSABP, a clinical trials cooperative group supported by the National Cancer Institute, or NCI, initiated a study to investigate the use of neratinib as a neoadjuvant (preoperative) therapy for newly diagnosed HER2-positive breast cancer. In this trial, a total of 129 patients are randomized to receive either neratinib plus the chemotherapy drug paclitaxel or trastuzumab plus paclitaxel prior to having surgery to remove their tumors. The purpose of this study is to test whether adding neratinib to paclitaxel chemotherapy is better than trastuzumab plus paclitaxel chemotherapy before having surgery. This trial was modified in 2012 to include a third treatment arm where patients will receive the combination of neratinib plus trastuzumab plus paclitaxel prior to having surgery to remove their tumors. Enrollment in all three arms of this trial is ongoing and we anticipate that the results of this trial will be presented in 2014.

I-SPY 2 Trial. In 2010, the Foundation for the National Institutes of Health initiated the I-SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2). The I-SPY 2 TRIAL is a randomized Phase II clinical trial for women with newly diagnosed Stage 2 or higher (tumor size at least 2.5 cm) breast cancer that addresses whether adding investigational drugs to standard chemotherapy in the neoadjuvant setting is better than standard chemotherapy. The primary endpoint is pCR in the breast and the lymph nodes at the time of surgery. The goal of the trial is to match investigational regimens with patient subsets on the basis of molecular characteristics, referred to as biomarker signatures, that benefit from the regimen.

In December 2013, we announced top line results from the I-SPY 2 TRIAL. The I-SPY 2 TRIAL involves an adaptive trial design based on Bayesian predictive probability that a regimen will be shown to be statistically superior to standard therapy in an equally randomized 300-patient confirmatory trial. Regimens that have a high Bayesian predictive probability of showing superiority in at least one of 10 predefined signatures graduate from the trial. Regimens are dropped for futility if they show a low predictive probability of showing superiority over standard therapy in all 10 signatures. A maximum total of 120 patients can be assigned to each experimental regimen. A regimen can graduate early and at any time after having 60 patients assigned to it. The neratinib-containing regimen, which was neratinib plus paclitaxel followed by doxorubicin and cyclophosphamide, graduated from the I-SPY 2 TRIAL based on having a high probability of success in Phase III with a signature of HER2-positive/HR-negative. In this group, treatment with the neratinib containing regimen resulted in a higher pCR rate compared to the control arm, which was standard neoadjuvant chemotherapy: paclitaxel in combination with Herceptin (trastuzumab) followed by doxorubicin and cyclophosphamide. The Bayesian probability of superiority for the neratinib-containing regimen compared to standard therapy was 94.7%, which is analogous to a p-value of 0.053. In addition, the Bayesian predictive probability of showing statistical superiority in a 300-patient Phase III randomized trial of paclitaxel plus neratinib versus paclitaxel plus trastuzumab, both followed by doxorubicin/cyclophosphamide, was 78.1%.

There were 115 patients assigned to neratinib in the trial, including 65 patients who were HER2-positive. For the patients in the trial who were HER2-positive, including those who were either hormone receptor positive or negative, treatment with the neratinib-containing regimen also resulted in a higher pCR rate compared to the

control arm. The Bayesian probability of superiority for the neratinib-containing regimen was 95.3%, which is analogous to a p-value of 0.047. In addition, the Bayesian predictive probability of showing statistical superiority in a 300-patient Phase III randomized trial of paclitaxel plus neratinib versus paclitaxel plus trastuzumab was 72.5%. Based on the results from the I-SPY 2 TRIAL, neratinib is now eligible for the upcoming I-SPY 3 Phase III trial. We intend to provide additional detail regarding the results of the I-SPY 2 TRIAL for PB272 at a scientific meeting during 2014.

Safety Database. Our safety database includes over 3,000 patients that have been treated with neratinib. To date, the most significant grade 3 or higher adverse event associated with neratinib has been diarrhea, which occurs in approximately 30% of patients receiving the drug. Historically, once diarrhea occurred, patients were treated with loperamide and/or a reduction in the dose of neratinib. We have evaluated a prophylactic protocol pursuant to which a high dose of loperamide, approximately 16 mg, is given together with the initial dose of neratinib and then tapered down during the first cycle of treatment. In early 2013, an analysis of 24 patients that had received this loperamide prophylaxis protocol together with neratinib showed that none of the patients had grade 3 or higher diarrhea. We plan to continue evaluating this protocol and expect that this treatment will help significantly reduce the incidence of diarrhea.

Discontinued Pfizer Legacy Studies. Pfizer had previously sponsored two additional clinical trials of neratinib. The first trial, referred to as the NEfERTT™ trial, was a Phase II randomized trial of neratinib in combination with the anti-cancer drug paclitaxel versus trastuzumab in combination with paclitaxel for the treatment of patients who have not receive previous treatment for HER2-positive metastatic breast cancer. The second trial, referred to as the ExteNET™ trial, was a Phase III study investigating the effects of neratinib after adjuvant trastuzumab in patients with early stage breast cancer. In October 2011, enrollment in the ExteNET trial was halted at approximately 2,800 patients and the NefERTT trial had completed enrollment at approximately 450 patients. We anticipate that results from the ExteNET and NefERTT trials will be reported in 2014.

PB272 (neratinib (oral))—Other Potential Applications

Approximately 2% to 4% of patients with non-small cell lung cancer have a HER2 mutation in the kinase domain. This mutation is believed to narrow the ATP binding cleft which results in increased tyrosine kinase activity. The mutation is also believed to result in increased PI3K activity and mTOR activation. Published data suggests that patients with HER2 mutated non-small cell lung cancer do not respond to platinum chemotherapy and do not respond to epidermal growth factor receptor inhibitors. Pfizer previously conducted a Phase I trial of neratinib given in combination with the anti-cancer drug temsirolimus in patients with solid tumors. In this trial, seven patients with HER2 mutated non-small cell lung cancer were enrolled in the trial. These patients had received a median of three prior treatments for their disease. The results from the trial were presented at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting and at the 2012 International Association for the Study of Lung Cancer meeting and demonstrated that, for the six evaluable patients, two patients, or 33%, demonstrated a partial radiological response and three patients had stable disease evidenced by tumor shrinkage of between approximately 5% and 28%. We are currently enrolling a Phase II randomized trial of neratinib plus temsirolimus versus neratinib monotherapy in patients with HER2 mutated non-small cell lung cancer. We anticipate that data from this trial will be presented in 2014.

A new HER2 mutation in patients with HER2-negative breast cancer was identified as part of a study performed by the Cancer Genome Atlas Network and published in Cancer Discovery in December 2012. We believe this mutation may occur in an estimated 2% of patients with breast cancer. Pre-clinical data from this publication demonstrated that neratinib was active in pre-clinical models of HER2-negative breast cancer that have this HER2 mutation and that neratinib has more anti-cancer activity than either trastuzumab or lapatinib in cells with this mutation. A Phase II trial of neratinib in HER2-negative breast cancer patients who have a HER2 mutation opened for enrollment in December 2012. We anticipate that data from this trial will be reported in 2014.

Basket Trial for HER2 Mutation-Positive Solid Tumors

Based on the results from the Cancer Genome Atlas Study we estimate that between 2% and 11% of each solid tumor has a mutation in HER2. In the United States, this includes new diagnoses of an estimated 7,000 - 7,500 patients with bladder cancer; 4,000 - 4,500 patients with colorectal cancer; 1,500 - 2,000 patients with glioblastoma; 1,000 patients with melanoma; 4,000 - 5,000 patients with prostate cancer; 1,000 patients with stomach cancer and 1,000 - 2,000 patients with uterine cancer.

In October 2013, we announced that we had initiated a Phase II clinical trial of neratinib as a single agent in patients with solid tumors that have an activating HER2 mutation (basket trial). The Phase II basket trial is an open-label, multicenter, multinational study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating HER2 mutations. The study initially included six cohorts (baskets) of patients, each of which will include one of the following cancers: (1) bladder/urinary tract cancer; (2) colorectal cancer; (3) endometrial cancer; (4) gastric/esophageal cancer; (5) ovarian cancer; and (6) all other solid tumors (including prostate, melanoma and pancreatic cancer). Each basket will initially consist of seven patients. If a certain predetermined objective response rate is seen in the initial cohort of seven patients, the basket will be expanded to include a larger number of patients. Additionally, we expect to add two additional baskets to the basket trial this year to enroll patients with epidermal growth factor receptor mutated brain tumors and patients with HER3 mutations. We anticipate that the initial clinical data from this trial will be presented in 2014.

PB272 (neratinib (intravenous))

We also plan to develop neratinib as an intravenously administered agent. The intravenous version of neratinib resulted in higher exposure levels of neratinib in pre-clinical models. We believe that this may result in higher blood levels of neratinib in patients, and may translate into enhanced efficacy. We plan to file an IND for the intravenous formulation of neratinib in 2014 or 2015.

PB357

PB357 is an orally administered agent that is an irreversible TKI that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. PB357 is structurally similar to PB272. Pfizer completed single-dose Phase I trials of PB357. We are evaluating PB357 and considering options relative to its development in 2014.

Clinical Testing of Our Products in Development

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

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

We have entered into, and may enter into in the future, master service agreements with clinical research organizations, or CROs, with respect to initiating, managing and conducting the clinical trials of our products. These contracts contain standard terms for the type of services provided and contain cancellation clauses that require between 30 and 45 days written notice and that obligate us to pay for any services previously rendered with prepaid, unused funds being returned to us.

Competition

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

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

Intellectual Property and License Agreements

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

In the United States, we have a license to an issued patent, which currently will expire in 2025, for the composition of matter of neratinib, our lead compound. We have a license to an issued U.S. patent covering a family of compounds including neratinib, as well as equivalent patents in the European Union and Japan, that currently expire in 2019. We also have a license to an issued U.S. patent for the use of neratinib in the treatment of breast cancer, which currently expires in 2025, and an issued U.S. polymorph patent for neratinib, which currently expires in 2028. In jurisdictions which permit such, we will seek patent term extensions where possible for certain of our patents. We plan to pursue additional patents in and outside the United States covering additional therapeutic uses and polymorphs of neratinib from these existing applications. In addition, we will pursue patent protection for any new discoveries or inventions made in the course of our development of neratinib.

If we obtain marketing approval for neratinib or other drug candidates in the United States or in certain jurisdictions outside the United States, we may be eligible for regulatory protection, such as five years of new chemical entity exclusivity and, as mentioned above, up to five years of patent term extension potentially available in the United States under the Hatch-Waxman Act. In addition, eight to 11 years of data and marketing exclusivity potentially are available for new drugs in the European Union; up to five years of patent extension are potentially available in Europe (Supplemental Protection Certificate), and eight years of data exclusivity are

potentially available in Japan. There can be no assurance that we will qualify for any such regulatory exclusivity, or that any such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies. See "Government Regulation" below.

The intellectual property portfolio that was licensed from Pfizer in 2011 when we licensed neratinib included issued patents in a number of countries, including in Europe (EP 1848414) as well as pending patent applications in several countries, including the United States relating to methods of treating gefitinib and/or erlotinib resistant cancer. More specifically, the patent that was issued in Europe in April 2011 included specific claims that included a pharmaceutical composition for use in treating cancer in a subject with a cancer having a mutation in epidermal growth factor receptor with a T790M mutation. On November 28, 2011, Boehringer Ingelheim International GmbH filed an opposition to this patent asking for this patent to be revoked. The Oral Proceedings of the European Patent Office were held in Munich, Germany on February 4, 2014. The decision of the European Patent Office was to uphold the granted claims of the European patent that relate to the T790M mutation without any modification. This included specific claims that include claims for the pharmaceutical composition comprising an irreversible epidermal growth factor receptor inhibitor for use in treating cancer in a subject having a T790M mutation, and claims for the pharmaceutical composition for use in the treatment of numerous cancers, including lung cancer and non-small cell lung cancer.

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

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

License Agreements

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

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

license agreement, subject to certain specified exceptions. We are also obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and use commercially reasonable efforts to complete such trial and achieve certain milestones as provided in a development plan. If certain of our out-of-pocket costs in completing such studies exceed a mutually agreed amount, Pfizer will pay for certain additional out-of-pocket costs to complete such studies. We must use commercially reasonable efforts to develop and commercialize products containing these compounds in specified major-market countries and other countries in which we believe it is commercially reasonable to develop and commercialize such products.

As consideration for the license, we are required to make payments totaling $187.5 million upon the achievement of certain milestones if all such milestones are achieved. Should we commercialize any of the compounds licensed from Pfizer or any products containing any of these compounds, we will be obligated to pay to Pfizer incremental annual royalties between approximately 10% and 20% of net sales of all such products, subject, in some circumstances, to certain reductions. Our royalty obligation continues, on a product-by-product and country-by-country basis, until the later of (i) the last to expire valid claim of a licensed patent covering the applicable licensed product in such country, or (ii) the earlier of generic competition for such licensed product reaching a certain level of sales in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that we sublicense the rights granted to us under the license agreement with Pfizer to a third party, the same milestone and royalty payments are required. We can terminate the license agreement at will at any time after April 4, 2013, or for safety concerns, in each case upon specified advance notice. Each party may terminate the license agreement if the other party fails to cure any breach of a material obligation by such other party within a specified time period. Pfizer may terminate the license agreement in the event of our bankruptcy, receivership, insolvency or similar proceeding. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

Government Regulation

United States—FDA Process

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

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

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA's GLP regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices, or cGMPs; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

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

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

Clinical trials involve administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be provided to the FDA as part of a separate submission to the IND. Further, an Institutional Review Board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the study protocol and informed consent information for study subjects for any clinical trial before it commences at that center, and the IRB must monitor the study until it is completed. There are also requirements governing reporting of ongoing clinical trials and clinical trial results to public registries. Study subjects must sign an informed consent form before participating in a clinical trial. Clinical trials necessary for product approval typically are conducted in three sequential phases, but the phases may overlap. Phase I usually involves the initial introduction of the investigational drug into a limited population, typically healthy humans, to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific targeted indications. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. Phase III trials, commonly referred to as pivotal studies, are undertaken in an expanded patient population at multiple, geographically dispersed clinical trial centers to further evaluate clinical efficacy and test further for safety by using the drug in its final form. There can be no assurance that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the FDA or an IRB may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Moreover, the FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Post-approval trials are typically referred to as Phase IV clinical trials.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach an agreement on the next phase of development. Sponsors typically use the end of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug. A sponsor may request an SPA to reach an agreement with the FDA that the protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval, even if the study is subject to an SPA.

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

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

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

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

Expedited Review and Approval. The FDA has various programs, including Fast Track designation, priority review, accelerated approval, and breakthrough therapy designation, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening diseases or conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a designation designed to facilitate the development and expedite the review of drugs to treat serious

or life-threatening diseases or conditions and which demonstrate the potential to address an unmet medical need. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months from the date the application is accepted for filing. Although Fast Track designation and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. The FDA may also initiate review of sections of an NDA before the application is complete for drugs with Fast Track designation. This "rolling review" is available if the applicant provides and the FDA approves a schedule for submission of portions of the application. Accelerated approval provides an earlier approval of drugs to treat serious or life-threatening diseases or conditions, including a Fast Track product, upon a determination that the product has an effect on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials. Breakthrough therapy designation is for drugs intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies receive all the benefits of a Fast Track designation, as well as intensive guidance on efficient drug development and organizational commitment involving senior managers in the FDA. In June 2013, the FDA issued draft guidance on these expedited review and approval programs.

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

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

Patent Term Restoration and Marketing Exclusivity. Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However,

patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be requested prior to expiration of the patent. The U.S. Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

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

Foreign Regulation

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

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

- Community MAs – These are issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the European Union.

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

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

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

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

Coverage and Reimbursement

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third-party payors, such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and the out-of-pocket obligations of member patients for such products. We may need to conduct pharmacoeconomic studies to

demonstrate the cost-effectiveness of our products for formulary coverage and reimbursement. Even with such studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA 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 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, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which 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.

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

Sales and Marketing

The FDA regulates all advertising and promotion activities for products under its jurisdiction prior to and after approval, including standards and regulations for direct-to-consumer advertising, dissemination of off-label

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

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

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

Healthcare Fraud and Abuse Laws

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

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal health care programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also may be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the penalties that may be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or determine that we or our executive officers had violated these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions.

Further, there are new federal requirements under ACA and an increasing number of state laws that require manufacturers to disclose and make reports to the government of any "transfer of value" made or distributed to physicians, teachings and other healthcare providers. Many of these laws contain ambiguities as to what is

required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the applicable state and/or federal authorities.

Our activities could be subject to challenge for the reasons discussed above due to the breadth of these laws and the increasing attention being given to them by law enforcement authorities. The costs of defending such claims, as well as any sanctions imposed or negative public perceptions resulting therefrom, could require us to restructure our operations and have a material adverse effect on our financial performance.

Manufacturing

We do not currently have our own manufacturing facilities. We intend to continue to use our financial resources to accelerate development of our drug candidates rather than diverting resources to establish our own manufacturing facilities. We intend to meet our pre-clinical and clinical trial manufacturing requirements by establishing relationships with third-party manufacturers and other service providers to perform these services for us. While our drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. We are currently using the same third-party contractors to manufacture, supply, store and distribute drug supplies for our clinical trials.

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

Other Laws and Regulatory Processes

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the United States with securities traded on the New York Stock Exchange, or the NYSE, including laws relating to the oversight activities of the Securities and Exchange Commission, or the SEC, and the rules and regulations of the NYSE. In addition, the Financial Accounting Standards Board, or FASB, the SEC, and other bodies that have jurisdiction over the form and content of our accounts, our financial statements and other public disclosure are constantly discussing and interpreting proposals and existing pronouncements designed to ensure that companies best display relevant and transparent information relating to their respective businesses.

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

Research and Development Expenses

Research and development activities, which include personnel costs, research supplies, clinical and pre-clinical study costs, are the primary source of our overall expenses. Such expenses related to the research and development of our product candidates totaled $45.1 million for the year ended December 31, 2013, $49.6 million for the year ended December 31, 2012, $0.8 million for the year ended December 31, 2011, and $95.5 million from September 15, 2010, the date of inception, through December 31, 2013.

Employees

As of December 31, 2013, we had 72 employees, all of whom are full-time employees. We believe our relations with our employees are good. Over the course of the next year, we anticipate hiring up to 30 additional full-time employees devoted to clinical activities, six additional full-time employees for the regulatory and quality assurance function, and three additional full-time employees for general and administrative activities. In addition, we intend to continue to use CROs and third parties to perform our clinical studies and manufacturing.

Corporate Information and History

Our principal executive offices are located at 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024 and our telephone number is (424) 248-6500. Our internet address is *www.pumabiotechnology.com*. Our annual, quarterly and current reports, and any amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 may be accessed free of charge through our website after we have electronically filed or furnished such material with the SEC. We also make available free of charge on or through our website our Code of Business Conduct and Ethics, Corporate Governance Guidelines, Audit Committee Charter, Compensation Committee Charter and Nominating and Corporate Governance Committee Charter. The reference to www.pumabiotechnology.com (including any other reference to such address in this Annual Report) is an inactive textual reference only, meaning that the information contained on or accessible from the website is not part of this Annual Report on Form 10-K and is not incorporated in this report by reference.

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

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

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

In November 2012, we established and incorporated Puma Biotechnology Ltd, a wholly owned subsidiary, for the sole purpose of serving as our legal representative in the United Kingdom and the European Union in connection with our clinical trial activity in those countries.

ITEM 1A. RISK FACTORS

In addition to the other information contained in this Annual Report, the following risk factors should be considered carefully in evaluating our company. Our business, financial condition, liquidity or results of operations could be materially adversely affected by any of these risks.

Risks Related to our Business

We currently have no product revenues and no products approved for marketing, and will need to raise additional capital to operate our business.

To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities overseas for one or more of our drug candidates, we cannot market or sell our products and will not have product revenues. Currently, our only drug candidates are neratinib (oral), neratinib (intravenous) and PB357, and none of these products has been approved by the FDA for sale in the United States or by other regulatory authorities for sale outside the United States. Moreover, each of these drug candidates is in clinical 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 beyond 2015. 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.

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) or any of our drug candidates in the United States until they receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until they receive 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 trials 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 trials;
- the clinical research organization, or CRO, that we retain to conduct clinical trials or any other third parties involved in the conduct of trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA may not find the data from pre-clinical studies and clinical trials 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 trials or may require that we conduct additional studies or trials;
- the FDA may not accept data generated at our clinical trial 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 trials, 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 trials, 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;
- 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 can 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:

- imposition of a clinical hold or failure to obtain regulatory authorization or 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 ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the study. Furthermore, any negative results we may report in clinical trials of any of our drug candidates may make it difficult or impossible to recruit and retain patients in other clinical studies of that same drug candidate. Delays or failures in planned patient enrollment and/or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our drug candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our drug candidates for our targeted indications. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a drug candidate and may delay development of other drug candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our drug candidates and generate product revenues.

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

In February 2013, we announced that we reached agreement with the FDA under a special protocol assessment, or SPA, for our Phase III clinical trial of PB272 in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments. We commenced the Phase III clinical trial in June 2013. 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 identified indication. All agreements between the FDA and the sponsor regarding an SPA must be clearly documented in writing, either in the form of an SPA letter or minutes of a meeting between the sponsor and the FDA at which the SPA agreement was reached. 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 Phase III clinical trial will succeed, or that the SPA will ultimately be binding on the FDA or will result in any FDA approval for PB272. The trial is expected to enroll approximately 600 patients. We expect that the FDA will review our compliance with the SPA, evaluate the results of the clinical trials and 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 deem the data insufficient to support regulatory approval, which could materially adversely affect our business, financial condition and results of operations.

Physicians and patients may not accept and use our drugs.

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

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug;
- cost-effectiveness of our products relative to competing products;
- availability of coverage and 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 studies 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 studies 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 manufacturer. This approval would require new testing and compliance inspections. In addition, a new manufacturer would

have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, similar non-U.S. regulatory agencies 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 our clinical trials, the approval, if any, of our drug candidates by the FDA or 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.

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 profitably sell our products, if and when they are approved. 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 Reconciliation Act, or collectively, ACA, became law in the United States. ACA 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 ACA, 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;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- 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;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, which began 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;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- 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 ACA 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 ACA 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 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, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or

ATRA, which, 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 ACA, 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 will 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.

We may also be subject to federal criminal healthcare fraud statutes that were created by the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. The HIPAA health care fraud statute prohibits,

among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

The ACA, 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 ACA 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.

The ACA also enacted new provisions that require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations. Manufacturers were required to begin collecting data on August 1, 2013 and will be required to submit reports to the government by March 31, 2014, and by the 90th day of each subsequent calendar year. In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians. Certain states mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices, and/or the tracking and reporting of gifts, compensation and other remuneration to physicians.

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, any 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 coverage or 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 coverage and reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if one of our drug candidates is approved by the FDA, insurance coverage may not be available, or reimbursement levels may be inadequate to cover such drug. If government and other healthcare payors do not provide adequate coverage and reimbursement for any 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, 2013, we had 72 employees, including our Chief Executive Officer and President. Our future success depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled scientific, technical, marketing, managerial and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite their collective efforts. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial and financial personnel would have a material adverse effect on our business, prospects, financial condition and results of operations.

We may not successfully manage our growth.

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

We may be adversely affected by the current economic environment.

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

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

Our investments in marketable securities are subject to market, interest and credit risk that may reduce their value.

The value of our investments in marketable securities may be adversely affected by changes in interest rates, downgrades in the creditworthiness of bonds we hold, turmoil in the credit markets and financial services industry and by other factors which may result in other than temporary declines in the value of our investments. Decreases in the market value of our marketable securities could have an adverse impact on our statements of financial position, results of operations and cash flow.

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. 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.

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

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

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

presumption of validity enjoyed by issued patents. If we are found to infringe a third-party patent, we may need to cease the commercial sale of our products.

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

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

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

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

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

Risks Related to 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 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 be sufficient to maintain 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, 2013, we had 28,991,289 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 53.7% 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 regarding results of any clinical trials relating to our drug candidates;
- 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.

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 an October 2011 private placement, Alan H. Auerbach, our 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 portion 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 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. 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.

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. We are required to comply with these requirements beginning with this Annual Report on Form 10-K. 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 a registration statement could adversely affect the market price of our common stock in the public market, should one develop, which result would in turn negatively affect our ability to raise additional equity capital.

The sale, or availability for sale, of our common stock in the public market 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 certain of our stockholders, we maintain an effective registration statement registering the resale of shares of our common stock by certain of our stockholders. As of April 2013, the most recent effective date of the registration statement, approximately 10,942,158 shares of our common stock remained available for resale under the registration statement. 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 the resale registration statement, the selling stockholders identified in such registration statement will continue to offer shares covered by such 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 the 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.

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 and research and development credit carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Sections 382 and 383 of the Code. Furthermore, our ability to utilize NOLs and research and development credit carryforwards of any companies we may acquire in the future may be subject to limitations, in accordance with Sections 382 and 383 of the Code. 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 and research and development credit carryforwards, even if we attain profitability.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 22,800 square feet of office space in the building located at 10880 Wilshire Boulevard, Los Angeles, California for use as our corporate headquarters. This lease commenced in December 2011 and terminates in December 2018, with an option to extend for an additional five-year term. We also lease approximately 9,500 square feet of office space in the building located at 701 Gateway Blvd, South San Francisco, California. The lease for the South San Francisco facility commenced in October 2012 and terminates in October 2019, with an option to extend for an additional five-year term. We believe that our existing office space is adequate to meet current and anticipated future requirements and that additional or substitute space will be available as needed to accommodate any expansions that our operations require.

ITEM 3. LEGAL PROCEEDINGS

We are not involved in any material pending legal proceedings. Additionally, we are not aware of any contemplated proceedings against us by any governmental authority.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

Part II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Common Stock

From April 20, 2012, through October 18, 2012, shares of our common stock were quoted on the OTC Bulletin Board, or OTCBB*, under the symbol "PBYI." On October 19, 2012, shares of our common stock commenced trading on the NYSE under the symbol "PBYI" and ceased being quoted on the OTCBB. The high and low bid quotations of our common stock on the OTCBB and the high and low sales prices of our common stock on the NYSE are set forth below:

2013	**High**	**Low**
First quarter	$ 34.98	$18.47
Second quarter	45.69	27.40
Third quarter	62.66	44.39
Fourth quarter	112.46	33.70
2012		
First quarter	—	—
Second quarter	14.03	10.00
Third quarter	15.00	11.00
Fourth quarter	23.25	15.00
OTCBB: October 1—18	17.25	15.00
NYSE: October 19—December 31	23.25	16.08

* The OTCBB is a quotation medium for subscribing members, not an issuer listing service. OTCBB securities are traded by a community of market makers that enter quotes and trade reports through a closed computer network.

On February 28, 2014, the last reported sale price for our common stock on the NYSE was $116.26 per share.

Record Holders

On February 25, 2014, we had 43 holders of record of our common stock. We believe approximately 14,100 additional owners held our common stock in "Street Name" as of that date.

Dividends

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

Securities Authorized for Issuance Under Equity Compensation Plans

The information included under Item 12 of Part III of this Annual Report, "Securities Authorized for Issuance Under Equity Compensation Plans," is hereby incorporated by reference into this Item 5 of Part II of this Annual Report.

Recent Sales of Unregistered Securities

We did not make any sales of unregistered securities during fiscal year 2013.

Use of Proceeds from Registered Securities

On October 18, 2012, our Registration Statement on Form S-1, as amended (File No. 333-184187), was declared effective for our first registered offering, pursuant to which we registered the offering and sale of an aggregate of 8,625,000 shares of common stock, par value $0.0001 per share, at a price of $16.00 per share. Included in the above amount is the underwriters' overallotment of 1,125,000 shares of common stock, which overallotment was exercised on October 19, 2012. The offering, which closed on October 24, 2012, did not terminate until after the sale of all of the shares registered on the registration statement. Merrill Lynch, Pierce Fenner & Smith Incorporated and Leerink Swann LLC acted as joint book-running managers for the offering, and Stifel Nicolaus & Company, Incorporated, Cowen and Company, LLC, and UBS Securities LLC acted as co-managers for the offering.

As a result of the offering, we received net proceeds of approximately $129.2 million, which is comprised of gross proceeds of approximately $138 million, offset by the underwriting discount and estimated offering expenses of $8.8 million payable by us. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

We placed the net proceeds of approximately $129.2 million from this offering in a money market account and invested a portion of the net proceeds in short-term, investment-grade, interest-bearing securities based on our projected cash needs and pending the application of the net proceeds as described below. We intend to continue using these proceeds for the overall development of our drug candidates in 2014 and beyond, including, but not limited to, research and development and clinical trial expenditures, and for general corporate and working capital purposes. There has been no material change in the planned use of proceeds from our offering from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on October 19, 2012.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any "affiliated purchasers" within the definition of Rule 10b-18(a)(3) made any purchases of our equity securities during the fourth quarter of 2013.

ITEM 6. SELECTED FINANCIAL DATA

The following financial data should be read in conjunction with our consolidated financial statements and the related notes thereto appearing elsewhere in this Annual Report and with the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

The Consolidated Statements of Operations data for the years ended December 31, 2013, 2012, 2011 and for the period since our inception on September 15, 2010 through December 31, 2013, and the balance sheet data as of December 31, 2013 and 2012 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report. The Consolidated Statement of Operations data for the year ended December 31, 2010, and the Consolidated Balance Sheet data as of December 31, 2011 and 2010, are derived from our audited consolidated financial statements not included herein. Historical results are not necessarily indicative of the results to be expected in the future, and the results for the years presented should not be considered indicative of our future results of operations.

	Years ended December 31,				September 15, 2010 (date of inception) through December 31, 2013
	2013	2012	2011	2010	
	(in millions, except share data)				
Statement of Operations Data:					
Expenses:					
General and administrative	$ 9.8	$ 24.8	$ 9.3	$ —	$ 43.9
Research and development	45.0	49.6	0.8	—	95.6
Operating loss	(54.8)	(74.4)	(10.1)	—	(139.5)
Interest income	0.2	0.1	—	—	0.2
Other income	—	—	(0.1)	—	—
Totals	0.2	0.1	(0.1)	—	0.2
Net loss	(54.6)	(74.3)	(10.2)	—	(139.3)
Net loss attributable to common stock	(54.6)	(74.3)	(10.2)	—	(139.3)
Net loss per common share—basic and diluted	(1.90)	(3.42)	(1.32)	—	
Weighted-average common shares outstanding—basic and diluted	28,696,573	21,725,986	7,746,529	4,000,000	

	December 31,			
	2013	2012	2011	2010
	(in millions, except share data)			
Balance Sheet Data:				
Total assets	$ 104.4	$ 151.7	$ 55.4	$ —
Total liabilities	20.4	22.8	1.0	—
Total stockholders' equity	84.0	128.9	54.4	—

	Years ended December 31,			
	2013	2012	2011	2010
	(in millions, except share data)			
Other Financial Data:				
Net cash used in operating activities	$ (55.0)	$ (44.0)	$ (1.8)	$ —
Net cash used in investing activities	(41.5)	(1.2)	(1.7)	—
Net cash provided by financing activities	2.2	129.3	57.0	—

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Annual Report on Form 10-K contains forward-looking statements within the meanings of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of Part I of this Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

Overview

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

We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients, non-small cell lung cancer and patients with HER2 mutation-positive solid tumors;
- 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.

A large portion of our expenses to date have been related to the clinical development of our lead product candidate, PB272 (neratinib (oral)), and the transition of the neratinib program from the licensor. During this transition period, as we built up our infrastructure and assumed responsibility for the neratinib program, a duplication of effort took place that resulted in higher than normal operating expenses. We estimate the duplication of effort had an impact on research and development, or R&D, operating expense for the years ended December 31, 2013 and December 31, 2012, of approximately $0.3 million and $5.1 million, respectively.

The license agreement for PB272 established a limit for our expenses related to the Pfizer-initiated clinical trials for PB272 that were ongoing at the time of the agreement. This capped our "out-of-pocket" costs incurred in conducting these existing trials beginning January 1, 2012. We reached the cost cap during the fourth quarter of 2012, which resulted in a reduction of our R&D expenses for the fourth quarter of 2012. The licensor will continue to be responsible for these expenses until the licensor legacy trials are completed. Additionally, our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure. As we proceed with clinical development of PB272 (neratinib (oral)), and as we further develop PB272 (neratinib (intravenous)), and PB357, our second and third product candidates, respectively, we expect our R&D expenses and expenses related to our third-party contractors will continue to increase.

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

Summary of Expenses

General and administrative, or G&A, expenses consist primarily of salaries and related personnel costs, including stock-based compensation expense, professional fees, business insurance, rent, general legal activities, and other corporate expenses. Stock-based compensation expense for the year ended December 31, 2012, included approximately $18.2 million of stock-based compensation related to an anti-dilutive warrant issued to our Founder and Chief Executive Officer in 2011, of which the exercise price and the number of underlying shares were established in 2012. We do not expect to incur such additional expense for this warrant in the future.

R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for manufacturing of clinical materials and clinical trials. During the year ended December 31, 2013, our R&D expenses consisted primarily of clinical research organization, or CRO fees; fees paid to consultants; salaries and related personnel costs; stock-based compensation; and facility costs. During the year ended December 31, 2012, our R&D expenses consisted primarily of transition costs, as clinical trial responsibilities shifted from the licensor to us and our outside clinical research organization, or CRO; fees paid to other consultants; salaries and related personnel costs; stock-based compensation; and facility costs. We expense our R&D costs as they are incurred.

Results of Operations

The following summarizes our results of operations for the years ended December 31, 2013, 2012 and 2011.

General and administration expenses:

General and administrative expenses (in thousands)	2013	2012	2011	Annual percentage change 2013/2012	Annual percentage change 2012/2011
Payroll and related costs	$2,530	$ 2,088	$ 481	21%	334%
Professional fees and expenses	2,352	2,071	950	14%	118%
Facility and equipment costs	1,295	792	52	64%	1423%
Employee stock-based compensation expense	2,332	18,706	7,615	-88%	146%
Other	1,278	1,157	233	10%	397%
	$9,787	$24,814	$9,331	-61%	166%

Year ended December 31, 2013 Compared to Year ended December 31, 2012

Total G&A expenses decreased approximately 61% to $9.8 million for the year ended December 31, 2013 from $24.8 million for the year ended December 31, 2012. This decrease was primarily attributable to a decrease in stock-based compensation of approximately $16.4 million, offset by increases in payroll and related costs, facility costs and professional fees. Stock-based compensation expense decreased to $2.3 million in 2013 from $18.7 million in 2012. The approximately $18.7 million of stock-based compensation expense in 2012, included approximately $18.2 million for an anti-dilutive warrant issued to the our Chief Executive Officer (see Note 6 in the accompanying notes to the consolidated financial statements). We had no additional expense for this anti-dilutive warrant in 2013 because it was fully expensed prior to December 31, 2012. We do not expect this level of expense to reoccur in the future. The increase in payroll and related costs primarily related to our adding G&A employees to support increased operations and to increase staffing in other areas such as accounting and human resources. The increase in overall facility and equipment costs was primarily due to additional leased office space

and corresponding equipment to support corporate growth. The increase in professional fees and expenses was incurred primarily in support of meeting the requirements of becoming a large accelerated filer under the Securities Exchange Act of 1934 and the Sarbanes-Oxley Act of 2002. We expect G&A expenses to increase slightly going forward as we support the corporate growth of the Company.

Year ended December 31, 2012 Compared to Year ended December 31, 2011

Total G&A expenses increased approximately 166% to $24.8 million for the year ended December 31, 2012 from $9.3 million for the year ended December 31, 2011. The increase was primarily related to increases in employee stock-based compensation expense, facility and equipment costs, payroll and related costs and professional fees and expenses. Stock-based compensation increased to $18.7 million in 2012 compared to $7.6 million in 2011. This increase primarily related to the change in fair value of a warrant issued to our Chief Executive Officer. In connection with the closing of a public offering on October 24, 2012, the exercise price and number of shares underlying the anti-dilutive warrant issued to our Chief Executive Officer were established (see Note 6 in the accompanying notes to the consolidated financial statements), and accordingly, the final value of the warrant became fixed. The final valuation of the warrant based on the Black-Scholes Option Pricing Method, was approximately $25.8 million and resulted in an adjustment to the fair value of the warrant of $18.2 million, which is included in G&A expenses for 2012, compared to the $7.6 million estimated fair value of the warrant recorded in 2011. The remaining employee stock-based compensation expense represents the fair value of stock option grants to employees applicable to the reporting period. Facility and equipment costs increased to approximately $0.8 million in 2012 from approximately $52,000 in 2011, primarily due to our not having a physical office location until December 2011, and therefore incurring minimal expense in 2011 versus having two office locations in 2012. Payroll and related costs increased to approximately $2.1 million in 2012 from approximately $0.5 million in 2011, due to our having eight fulltime employees at December 31, 2012 versus four at December 31, 2011. Professional fees and expenses increased to approximately $2.1 million in 2012 from approximately $1.0 million in 2011, which resulted primarily from our having limited operations in 2011 prior to October 2011.

Research and development expenses:

Research and development expenses (in thousands)	2013	2012	2011	Annual percentage change 2013/2012	Annual percentage change 2012/2011
Outside CRO/licensor services	$10,601	$34,773	$—	-70%	—
Outside other clinical development	15,403	5,103	38	202%	13329%
Internal regulatory affairs and quality assurance	6,228	4,791	612	30%	683%
Internal clinical development	6,998	3,720	73	88%	4996%
Internal chemical manufacturing	628	326	65	93%	402%
Employee stock-based compensation	5,188	923	38	462%	2329%
	$45,046	$49,636	$826	-9%	5909%

Year ended December 31, 2013 Compared to Year ended December 31, 2012

Total R&D expenses decreased approximately 9% to $45.0 million for the year ended December 31, 2013 from $49.6 million for the year ended December 31, 2012. This decrease is due to an approximately $16.4 million decrease in costs associated with outside CRO/licensor services due to our reaching the cap on expenses for the on-going clinical trials that we assumed from the licensor, which we refer to as our licensor legacy clinical trials (see Note 2 to the accompanying notes to the consolidated financial statements). The license agreement contained a cap on the external costs associated with the licensor legacy clinical trials for which we are responsible. We reached this cost cap in the fourth quarter of 2012 and the above table reflects the outside services incurred by us net of the excess cost billed back to the licensor. As a result of our reaching this cap, the

outside CRO/licensor service costs and other outside clinical development costs pertaining to the licensor legacy clinical trials decreased significantly. This large decrease was offset by the initiation of our company-sponsored clinical trials. During 2013, we incurred increased outside CRO and other clinical development costs and expect these costs to increase significantly in the coming year. The decrease in outside CRO/licensor service expenses was partially offset by an increase in outside other clinical development expenses to approximately $15.4 million in 2013 from approximately $5.1 million in 2012. In 2013, outside other clinical development consisted of approximately $6.2 million in clinical services, which includes data management and our company-sponsored clinical trial specific activities, approximately $5.1 million in chemical manufacturing and controls, approximately $2.9 million in consultant and contract labor and approximately $1.2 million in legal services for clinical trial-related contracts in support of our company-sponsored clinical trials. The increases in 2013 from 2012 in internal chemical manufacturing costs, internal clinical development costs and internal regulatory affairs and quality assurance costs were primarily due to an increase in employee headcount in support of our company-sponsored clinical trials. Employee stock-based compensation included in R&D expenses for the year ended December 31, 2013, was approximately $5.2 million compared to $0.9 million in 2012 and increased as a result of the increase in the number of employees.

Year ended December 31, 2012 Compared to Year ended December 31, 2011

Total R&D expenses increased to $49.6 million for the year ended December 31, 2012 from $0.8 million for the year ended December 31, 2011. This increase was primarily driven by outside CRO/licensor service expenses of approximately $34.8 million in 2012. The majority of these expenses, approximately $31.5 million, were associated with our licensor legacy clinical trials. This included approximately $5.1 million of duplicate costs from contracting a CRO to take over the management of our licensor legacy clinical trials. Outside other clinical development expenses of approximately $5.1 million were incurred during 2012, as we became responsible for expenses and services related to maintaining and managing the licensor legacy clinical trials. The license agreement contained a cap on the external costs associated with the licensor legacy clinical trials for which we are responsible. We reached this cost cap in the fourth quarter of 2012 and the above table reflects the outside services incurred by us net of the excess cost billed back to the licensor. Internal expenses, which include all employee-related costs such as payroll, benefits and travel, were approximately $4.8 million for regulatory affairs and quality assurance, approximately $3.7 million for clinical development, and approximately $0.3 million for internal chemical manufacturing for the year ended December 31, 2012. Employee stock-based compensation included in R&D expenses for the year ended December 31, 2012, was approximately $0.9 million compared to $38,000 in 2011 and increased as a result of the increase in the number of employees.

While expenditures on current and future clinical development programs, particularly our PB272 program, are expected to be substantial and to increase in 2014, they are subject to many uncertainties, including the results of our clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our R&D projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of other factors, including:

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

Interest income:

For the year ended December 31, 2013, we recognized approximately $172,000 in interest income compared to approximately $98,000 and $4,000 of interest income for the years ended December 31, 2012 and 2011, respectively. The increase in interest income reflects excess cash invested in money market accounts, marketable securities and "high yield" savings accounts for a full year and cash invested from a public offering of our common stock completed in October 2012 (see Note 6 in the accompanying notes to consolidated financial statements).

Adjusted Statement of Operations:

The following tables present our operating results, as calculated in accordance the accounting principles generally accepted in the United States, or GAAP, as adjusted to remove the impact of employee stock-based compensation and the outside CRO/licensor services and outside clinical development costs associated with the licensor legacy clinical trials that we are in the process of completing. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures. We believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods.

For the year ended December 31, 2013, stock-based compensation represented approximately 13.7% of our loss from operations. This cost is related to our employee hiring practice and the fair market value of the stock option grant on the day granted. The major component of the stock-based compensation for 2012 was the valuation of an anti-dilutive warrant issued to Mr. Auerbach, our President and Chief Executive Officer. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures. We believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. We believe the issuance of the anti-dilutive warrant was a onetime occurrence and the full value of the warrant has been recorded in our consolidated financial statements.

The majority of the cost associated with the licensor legacy clinical trials during 2012 were related to external costs that we were responsible for but that were subject to a cap. Having reached the cap, the licensor became responsible for all external costs associated with the licensor legacy clinical trials going forward and we had only limited costs associated with our managing these trials during 2013 and expect to have limited cost through to completion of these studies.

Reconciliation of GAAP and Non-GAAP Financial Information
(in thousands except share and per share data)

	GAAP Measure (Reported) Year Ended December 31, 2013	Expense Adjustments		Non-GAAP Measure Year Ended December 31, 2013
		Stock-based compensation	Licensor legacy clinical trials	
Operating expense:				
General and administrative	$ 9,787	(2,332)	$ —	$ 7,455
Research and development	45,046	(5,188)	(275)	39,583
Loss from operations	(54,833)	7,520	275	(47,038)
Other income (expense):				
Interest income	172	—	—	172
Other expense	2	—	—	2
Totals	174	—	—	174
Net loss	$ (54,659)	$ 7,520	$ 275	$ (46,864)
Net loss applicable to common stock	$ (54,659)	$ 7,520	$ 275	$ (46,864)
Net loss per common share—basic and diluted	$ (1.90)	$ 0.26	$ 0.01	$ (1.63)
Weighted-average common shares outstanding—basic and diluted	28,696,573	28,696,573	28,696,573	28,696,573

	GAAP Measure (Reported) Year Ended December 31, 2012	Expense Adjustments		Non-GAAP Measure Year Ended December 31, 2012
		Stock-based compensation	Licensor legacy clinical trials	
Operating expense:				
General and administrative	$ 24,814	$ (18,706)	$ —	$ 6,108
Research and development	49,636	(923)	(37,892)	10,821
Loss from operations	(74,450)	19,629	37,892	(16,929)
Other income (expense):				
Interest income	98	—	—	98
Other expense	—	—	—	—
Totals	98	—	—	98
Net loss	$ (74,352)	$ 19,629	$ 37,892	$ (16,831)
Net loss applicable to common stock	$ (74,352)	$ 19,629	$ 37,892	$ (16,831)
Net loss per common share—basic and diluted	$ (3.42)	$ 0.90	$ 1.74	$ (0.77)
Weighted-average common shares outstanding—basic and diluted	21,725,986	21,725,986	21,725,986	21,725,986

Liquidity and Capital Resources

Operating Activities

We reported a net loss of approximately $54.7 million, $74.4 million, and $10.2 million for the years ended December 31, 2013, 2012 and 2011, respectively. We also reported negative cash flows from operating activities of approximately $55.0 million, $44.0 million and $1.8 million for the years ended December 31, 2013, 2012, and 2011, respectively. Our net loss from Former Puma's date of inception, September 15, 2010, to December 31, 2013, amounted to approximately $139.3 million, while negative cash flows from operating activities amounted to approximately $100.9 million.

Net cash used in operating activities for the year ended December 31, 2013, includes a net loss of $54.7 million adjusted for non-cash items of approximately $7.5 million for stock option expense and $0.4 million for depreciation and amortization of property and equipment. Further adjustments include a decrease in accounts payable and accrued expenses of approximately $2.4 million, a decrease of $0.8 million in licensor receivables, and an increase in prepaid expenses and other assets of approximately $6.7 million. At December 31, 2012, we had a large receivable from the licensor covering costs incurred in the fourth quarter of 2012. The decrease in both accounts payable and accrued expenses reflect the payment of this receivable and subsequent payments for ongoing costs associated with the licensor-initiated clinical trials. The increase in prepaid expenses and other assets reflects up-front payments made to various CROs for company-initiated clinical trials and for various insurance policies.

Net cash used in operating activities for the year ended December 31, 2012, includes a net loss of approximately $74.4 million adjusted for non-cash items of approximately $18.2 million from the issuance of an anti-dilutive warrant, stock option expense of $1.4 million, $0.5 million resulting from an allowance received from the landlord, an increase in accounts payable and accrued expenses of approximately $21.1 million, an increase of $10.6 million in licensor receivables and an increase in prepaid expenses of approximately $0.7 million. The increase in accounts payable and accrued expenses, compared to 2011, is a direct result of us assuming operational and financial responsibility for the clinical trials transferred from the licensor. These accruals and payables consist mainly of fees due to the licensor and CROs for maintaining and managing our clinical trials. The licensor receivable represents costs in excess of a "cap cost" established in the license agreement. The license agreement allows us to bill back any external costs associated with the transferred trials in excess of the cap cost to the licensor. We reached the cap cost during the fourth quarter of 2012.

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

Investing Activities

Net cash used in investing activities was approximately $41.5 million for the year ended December 31, 2013. The major portion of this is comprised of cash used for the purchase of available-for-sale securities of approximately $49.3 million offset by the sale and maturity of available-for-sale securities of $8.4 million. We invest our excess cash in available-for-sale securities. Additionally, approximately $0.6 million of cash used in investing activities was used for the purchase of property and equipment to support corporate growth.

Net cash used in investing activities was approximately $1.2 million for the year ended December 31, 2012. The major portion for 2012, $0.6 million, represents additional computer equipment and infrastructure, along with $0.5 million in leasehold improvements to support our growth in the number of employees and facilities.

Net cash used in investing activities was approximately $1.7 million for the year ended December 31, 2011. The major investing activity for 2011 was the acquisition of a high yield savings account in the amount of $1.1 million, which was used to secure a stand-by letter of credit issued to our landlord as collateral for our office

lease and leasehold improvements. We also incurred $0.4 million for leasehold improvements and $0.3 million for computers and office furniture in 2011.

Financing Activities

February 2014 Common Stock Offering. On February 14, 2014, we completed an underwritten public offering of 1,126,530 shares of our common stock (including an additional 146,938 shares of our common stock issued and sold pursuant to the underwriters' option to purchase additional shares), par value $0.0001 per share, at a price of $122.50 per share, less the underwriting discount. The net proceeds received by us were approximately $129.3 million after deducting the underwriting discount and estimated offering expenses payable by us.

During the year ended December 31, 2013, the cash provided by financing activities was approximately $2.2 million. This represents proceeds to us from employee stock options exercised during 2013.

October 2012 Common Stock Offering. On October 18, 2012, we entered into an underwriting agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC, as representatives of several underwriters providing for the offer and sale in a firm-commitment underwritten public offering of 7,500,000 shares of our common stock, par value $0.0001 per share at a price of $16 per share, less the underwriting discount. On October 19, 2012, the underwriters exercised the overallotment option granted to the underwriters to purchase an additional 1,125,000 shares of our common stock from us at $16 per share, less the underwriting discount. The transactions were completed on October 24, 2012, and we received net proceeds of approximately $129.2 million, which is comprised of gross proceeds of approximately $138 million, less $8.8 million of underwriting fees and other offering expenses payable by us.

2011 Private Placements. Immediately prior to the Merger, Former Puma entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which it sold 14,666,733 shares of its common stock at a price per share of $3.75, for aggregate gross proceeds of approximately $55 million. Former Puma also issued a warrant to each investor that provided such investor with anti-dilution protection in regard to certain issuances of securities. We assumed these warrants in the Merger and they subsequently terminated unexercised in accordance with their terms upon our quotation on the OTC Bulletin Board in April 2012.

We reimbursed the lead investor in this private placement $125,000 for all of its reasonable fees and expenses, including legal fees, associated with the private placement. In addition, we paid Leerink approximately $2.3 million as compensation for acting as our placement agent in connection with this offering and $75,000 for reimbursable expenses.

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

Current and Future Financing Needs

We have incurred negative cash flows from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our R&D efforts. Given the current and desired pace of clinical development of our three product candidates, over the next 12 months we estimate that our R&D spending will be approximately $50 million to $60 million, excluding stock-based compensation. We will need approximately $7 million to $8 million for general and administrative expenses over the next

12 months, excluding stock-based compensation. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control.

While we believe that the approximately $43.0 million in cash and cash equivalents and $40.9 million in marketable securities as of December 31, 2013, and the $129.3 million raised on February 14, 2014, from our common stock offering, will be sufficient to enable us to meet our anticipated expenditures for at least 2015 and beyond, we may seek to obtain additional capital through the sale of debt or equity securities, if necessary, especially in conjunction with opportunistic acquisitions or licensing arrangements. We expect to continue incurring significant losses for the foreseeable future and our continuing operations will depend on whether we are able to raise additional funds through additional equity or debt financing or entering into a strategic alliance with a third party concerning one or more of our product candidates. Through December 31, 2013, and into 2014, a significant portion of our financing has been through public offerings and private placements of our equity securities. We will continue to fund operations from cash on hand and marketable securities and through the similar sources of capital previously described. We can give no assurances that any additional capital raised will be sufficient to meet our needs. Further, in light of current economic conditions, including the lack of access to the capital markets being experienced by small companies, particularly in our industry, there can be no assurance that such capital will be available to us on favorable terms or at all. If we are unable to raise additional funds in the future, we may be forced to delay or discontinue the development of one or more of our product candidates and forego attractive business opportunities. Any additional sources of financing will likely involve the sale of our equity securities, which will have a dilutive effect on our stockholders.

In addition, we have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

Off-Balance Sheet Arrangements

We do not have any “off-balance sheet arrangements,” as defined by the SEC regulations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Our contractual obligations result from property leases for office space. Although we do have obligations for CRO services, the table below excludes potential payments we may be required to make under our agreements with CROs because timing of payments and actual amounts paid under those agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations, and those agreements are cancelable upon written notice by the Company and therefore, not long-term liabilities. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information.

The following table represents our contractual obligations as of December 31, 2013, aggregated by type (in thousands):

	Payments due by Period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Operating Lease Obligations	$6,990	$1,117	$2,689	$2,876	$308
Total	$6,990	$1,117	$2,689	$2,876	$308

Critical Accounting Policies

Our discussion and analysis of our consolidated financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses, and related disclosure of contingent assets and liabilities reported in our consolidated financial statements. The estimation process requires assumptions to be made about future events and conditions and, as a result, is inherently subjective and uncertain. Actual results could differ materially from our estimates.

The SEC defines critical accounting policies as those that are, in management's view, most important to the portrayal of our financial condition and results of operations and most demanding of our judgment. We consider the following policies to be critical to an understanding of our consolidated financial statements and the uncertainties associated with the complex judgments made by us that could impact our results of operations, financial position, and cash flows.

Property and Equipment:

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

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been an impairment by comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. Should impairment exist, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through December 31, 2013.

Research and Development Expenses:

R&D expenses are charged to operations as incurred. The major components of R&D costs include clinical manufacturing costs; clinical trial expenses; consulting and other third-party costs; salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and CRO costs. In the normal course of business, we contract with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients

and the completion of portions of the clinical trial or similar conditions. Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. The objective of our accrual policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As actual costs become known, we adjust our accruals in that period.

In instances where we enter into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded as prepaid expenses and expensed as services are performed or as the underlying goods are delivered. If we do not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of R&D costs.

Research and Development Reimbursement:

The licensing agreement set a "cap" on the amount of external expenses we would incur, beginning January 1, 2012, in completing the clinical trials transferred from the licensor to the Company. The license agreement stipulates that the licensor would be responsible for all external expenses associated with the transferred clinical trials and that we would invoice for such costs on a quarterly basis. All amounts reimbursed from the licensor represent charges for services provided by third parties and not by us. Accordingly, we have elected to treat the reimbursed costs as a "pass-through" expense billable to the licensor and as an off-set to our actual R&D expenses. Therefore, our R&D expenses are recorded net of any excess cap costs billed to the licensor. We recognized approximately $16.4 million and $10.6 million of excess cap cost billings in the years ended December 31, 2013 and 2012, respectively.

Stock-Based Compensation:

Stock option awards:

Accounting Standards Codification 718, *Compensation-Stock Compensation*, or ASC 718, requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The determination of the fair value using the Black-Scholes Option Pricing Method is affected by our stock price as well as a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option exercise behaviors. As allowed by ASC 718 for companies with a short period of publicly traded stock history, our estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to us, including industry, stage of life cycle, size and financial leverage. The five companies are reviewed quarterly as the volatility has the greatest impact on the calculation. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. ASC 718 does not allow companies to account for option forfeitures as they occur; instead, estimated option forfeitures must be calculated when the option is granted to reduce the option expense to be recognized over the life of the award and updated upon receipt of further information as to the amount of options expected to be forfeited. Due to our limited history, we use the simplified method to determine the expected life of the option grants.

Warrants:

Warrants granted to employees are normally valued at the fair value of the instrument on the grant date and are recognized in the statement of operations over the requisite service period. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the

Monte Carlo Simulation Method. When the terms of the warrant become fixed, the Company values the warrant using the Black-Scholes Option Pricing Method. As allowed by ASC 718 for companies with a short period of publicly traded stock history, the Company's estimate of expected volatility is based on the average volatilities of a sampling of eight to nine companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value, until the terms are fixed the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair value of the warrant at the time of issuance as an equity stock-based compensation transaction. The warrant is revalued each reporting period up to the grant date when the final fair value of the warrant is established and recorded. The grant date is determined when all pertinent information, such as exercise price and quantity are known.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investing activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing the risk of loss. Some of the investable securities permitted under our cash management policy may be subject to market risk for changes in interest rates. To mitigate this risk, we maintain a portfolio of cash equivalents and available-for-sale investments in a variety of securities, which may include investment grade commercial paper, money market funds, government debt issued by the United States of America, state debt, certificates of deposit and investment grade corporate debt. Presently, we are exposed to minimal market risks associated with interest rate changes because of the relatively short maturities of our investments and we do not expect interest rate fluctuations to materially affect the aggregate value of our financial instruments. We manage our sensitivity to these risks by maintaining investments grade short-term investments. Our cash management policy does not allow us to purchase or hold derivative or commodity instruments or other financial instruments for trading purposes. Additionally, our policy stipulates that we periodically monitor our investments for adverse material holdings related to the underlying financial solvency of the issuer. As of December 31, 2013, our investments consisted primarily of U.S. government and agency obligations and corporate obligations. Our results of operations and financial condition would not be significantly impacted by either a 10% increase or 10% decrease in interest rates due mainly to the short-term nature of our investment portfolio. We have not used derivative financial instruments in our investment portfolio. Additionally, we do not invest in foreign currencies or other foreign investments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

All financial statements and supplementary data required by this Item are listed in Part IV, Item 15 of this Annual Report and are presented beginning on Page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives and in

reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of December 31, 2013. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer have concluded that these disclosure controls and procedures were effective as of December 31, 2013.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fourth quarter ended December 31, 2013, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2013. Management based its assessment on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework*. Based on this evaluation and criteria, our management concluded that as of December 31, 2013, our internal control over financial reporting was effective at the reasonable assurance level.

Our internal control over financial reporting as of December 31, 2013 has been audited by PKF Certified Public Accountants, A Professional Corporation, our independent registered public accounting firm, as stated in their report, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2013.

ITEM 9B. OTHER INFORMATION

Not applicable.

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be included in our 2014 Proxy Statement, which will be filed with the SEC, and is incorporated by reference herein.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be included in our 2014 Proxy Statement, which will be filed with the SEC, and is incorporated by reference herein.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be included in our 2014 Proxy Statement, which will be filed with the SEC, and is incorporated by reference herein.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be included in our 2014 Proxy Statement, which will be filed with the SEC, and is incorporated by reference herein.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item will be included in our 2014 Proxy Statement, which will be filed with the SEC, and is incorporated by reference herein.

Part IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Reference is made to the Index to Consolidated Financial Statements beginning on Page F-1 hereof.

Consolidated Financial Statement Schedules

(a) Documents Filed as Part of Report

(1) Consolidated Financial Statements

- Report of Independent Registered Public Accounting Firm F-2
- Consolidated Balance Sheets at December 31, 2013 and 2012 . . . . . F-4
- Consolidated Statements of Operations for the Years Ended December 31, 2013, 2012, 2011 and for the Period from September 15, 2010 (date of inception) through December 31, 2013 . . . . . F-5
- Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2013, 2012, 2011 and for the Period from September 15, 2010 (date of inception) through December 31, 2013 . . . . . F-6
- Consolidated Statements of Stockholders' Equity for the Period from September 15, 2010 (date of inception) through December 31, 2013 . . . . . F-7
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2013, 2012, 2011 and for the Period from September 15, 2010 (date of inception) through December 31, 2013 . . . . . F-8
- Notes to Consolidated Financial Statements F-9

(2) Consolidated Financial Statement Schedules

Consolidated Financial Statement Schedules have been omitted because they are either not required or not applicable, or because the information required to be presented is included in the consolidated financial statements or the notes thereto included in this Annual Report.

(3) Exhibits

The exhibits listed on the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report and such Exhibit Index is incorporated by reference.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 3, 2014.

PUMA BIOTECHNOLOGY, INC.

By: /s/ Alan H. Auerbach

Alan H. Auerbach
President & Chief Executive Officer
(Principal Executive Officer)

KNOWN BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alan H. Auerbach and Charles R. Eyler, or either of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and any documents related to this report and filed pursuant to the Securities Exchange Act of 1934, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes may lawfully do or cause to be done by virtue hereof. This power of attorney shall be governed by and construed with the laws of the State of Delaware and applicable federal securities laws.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Alan H. Auerbach Alan H. Auerbach	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)	March 3, 2014
/s/ Charles R. Eyler Charles R. Eyler	Senior Vice President, Finance and Administration and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 3, 2014
/s/ Thomas R. Malley Thomas R. Malley	Director	March 3, 2014
/s/ Jay M. Moyes Jay M. Moyes	Director	March 3, 2014
/s/ Troy E. Wilson Troy E. Wilson	Director	March 3, 2014

EXHIBIT INDEX

Exhibit No.		Incorporation by Reference		
		Form	Exhibit	Filing Date
2.1	Agreement and Plan of Merger, dated September 29, 2011, by and among Innovative Acquisitions Corp., IAC Merger Corporation, a Delaware corporation and wholly-owned subsidiary of the Company, and Puma Biotechnology, Inc., a Delaware corporation	8-K	2.1	10/4/2011
3.1	Certificate of Merger relating to the merger of IAC Merger Corporation with and into Puma Biotechnology, Inc., filed with the Secretary of State of Delaware on October 4, 2011	8-K	3.1	10/11/2011
3.2	Certificate of Ownership and Merger relating to the merger of Puma Biotechnology, Inc. with and into Innovative Acquisitions Corp., filed with the Secretary of State of the State of Delaware on October 4, 2011	8-K	3.2	10/11/2011
3.3	Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on November 14, 2011	DEF 14C	Appendix 1	10/24/2011
3.4	Bylaws of Puma Biotechnology, Inc.	10-SB	3.2	9/14/2007
4.1	Form of Common Stock Certificate	S-1/A	4.1	2/1/2012
4.2	Warrant to Purchase Shares of Common Stock of Puma Biotechnology, Inc., dated October 4, 2011, issued to Alan H. Auerbach	8-K	4.2	10/11/2011
10.1*	License Agreement, dated August 18, 2011, by and between the Company, as successor to Puma Biotechnology, Inc., and Pfizer Inc.	8-K/A	10.1	12/16/2011
10.2(a)	Puma Biotechnology, Inc. 2011 Incentive Award Plan	8-K	10.4	10/11/2011
10.2(b)	Form of Stock Option Grant Notice and Stock Option Agreement, issued pursuant to the 2011 Incentive Award Plan	10-K	10.5	3/29/2012
10.2(c)	Form of Chief Executive Officer Stock Option Grant Notice and Stock Option Agreement, issued pursuant to the 2011 Incentive Award Plan	10-K	10.6	3/29/2012
10.2(d)	Form of Performance Share Award Agreement, issued pursuant to the 2011 Incentive Award Plan			
10.3(a)	Registration Rights Agreement, dated October 4, 2011, by and among Puma, the investors listed on Exhibit A attached thereto and the Company	8-K/A	10.5	12/16/2011
10.3(b)	Amendment No. 1 to Registration Rights Agreement	8-K	10.2	11/23/2011
10.4	Letter Agreement, dated October 21, 2011, between the Company and Richard Phillips	8-K	10.1	10/27/2011
10.5	Letter Agreement, dated October 21, 2011, between the Company and Charles Eyler	8-K	10.2	10/27/2011

Exhibit No.		Incorporation by Reference		
		Form	Exhibit	Filing Date
10.6(a)	Office Lease by and between the Company and CA – 10880 Wilshire Limited Partnership, executed on December 7, 2011	8-K	10.1	12/13/2011
10.6(b)	First Amendment to the Office Lease, dated as of November 28, 2012, by and between the Company and CA – 10880 Wilshire Limited Partnership	10-K	10.13(B)	4/1/2013
10.6(c)	Second Amendment to the Office Lease, dated as of December 3, 2013, by and between the Company and CA – 10880 Wilshire Limited Partnership			
10.7	Employment Agreement, dated January 19, 2012, by and between the Company and Alan H. Auerbach	8-K	10.1	1/24/2012
10.8	Office Lease by and between DWF III Gateway, LLC and the Company, executed June 7, 2012	8-K	10.1	6/13/2012
10.9	Letter Agreement, dated May 2, 2012, between the Company and Richard P. Bryce	8-K	10.1	6/26/2012
10.10	Form of Indemnification Agreement	S-1/A	10.17	10/15/2012
10.11	Non-Employee Director Compensation Program			
21.1	Subsidiaries			
23.1	Consent of Independent Registered Public Accounting Firm			
24.1	Power of Attorney (included on signature page)			
31.1	Certification of Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002			
31.2	Certification of Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002			
32.1	Certification of Principal Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002			
32.2	Certification of Principal Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002			
101.INS	XBRL Instance Document			
101.SCH	XBRL Taxonomy Extension Schema Document			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document			
101.PRE	XBRL Taxonomy Extension Linkbase Document			

* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Puma Biotechnology, Inc. and Subsidiary (A Development Stage Company) (the "Company") as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years ended 2013, 2012, and 2011, and for the period from September 15, 2010 (date of inception) through December 31, 2013. We also have audited Puma Biotechnology, Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Puma Biotechnology Inc.'s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Puma Biotechnology, Inc. and Subsidiary as of December 31, 2013 and 2012, and the results of its operations, comprehensive loss, changes in stockholders' equity and its cash flows for each of the three years ended 2013, 2012, and 2011, and for the period from September 15, 2010 (date of inception) through December 31, 2013, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, Puma Biotechnology, Inc. and Subsidiary maintained, in all material respects,

effective internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ PKF
PKF
Certified Public Accountants
A Professional Corporation

San Diego, California
March 3, 2014

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	December 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 43,044	$137,408
Marketable securities	40,904	—
Licensor receivable	9,813	10,612
Prepaid expenses and other, current	2,635	952
Total current assets	96,396	148,972
Property and equipment, net	1,684	1,479
Prepaid expenses and other, long-term	5,080	36
Restricted cash	1,214	1,212
Total assets	$ 104,374	$151,699
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,692	$ 482
Accrued expenses	8,579	21,219
Total current liabilities	19,271	21,701
Deferred rent	1,116	1,089
Total liabilities	20,387	22,790
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock—$.0001 par value; 100,000,000 shares authorized; 28,991,289 issued and outstanding at December 31, 2013, and 28,676,666 issued and outstanding at December 31, 2012	3	3
Additional paid-in capital	223,232	213,498
Accumulated other comprehensive income	3	—
Deficit accumulated during the development stage	(139,251)	(84,592)
Total stockholders' equity	83,987	128,909
Total liabilities and stockholders' equity	$ 104,374	$151,699

See Accompanying Notes to the Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except per share data)

	Years Ended December 31,			Period from September 15, 2010 (date of inception) to December 31, 2013
	2013	2012	2011	
Operating expenses:				
General and administrative	$ 9,787	$ 24,814	$ 9,331	$ 43,939
Research and development	45,046	49,636	826	95,508
Totals	54,833	74,450	10,157	139,447
Loss from operations	(54,833)	(74,450)	(10,157)	(139,447)
Other income (expenses):				
Interest income	172	98	4	274
Other income (expense)	2	—	(80)	(78)
Totals	174	98	(76)	196
Net loss	$ (54,659)	$ (74,352)	$ (10,233)	$(139,251)
Net loss applicable to common stock	$ (54,659)	$ (74,352)	$ (10,233)	$(139,251)
Net loss per common share—basic and diluted	$ (1.90)	$ (3.42)	$ (1.32)	
Weighted-average common shares outstanding—basic and diluted	28,696,573	21,725,986	7,746,529	

See Accompanying Notes to the Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Years Ended December 31,			Period from September 15, 2010 (date of inception) to December 31, 2013
	2013	2012	2011	
Net loss	$(54,659)	$(74,352)	$(10,233)	$(139,251)
Other comprehensive income (loss)				
Unrealized gain on available-for-sale securities	3	—	—	3
Comprehensive loss	$(54,656)	$(74,352)	$(10,233)	$(139,248)

See Accompanying Notes to the Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
THE PERIOD FROM SEPTEMBER 15, 2010 (DATE OF INCEPTION) THROUGH DECEMBER 31, 2013
(in thousands except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Development Income	Deficit Accumulated During the Stage	Total
	Shares	Amount				
Balances, beginning	—	$—	$ —	$—	$ —	$ —
Common stock issued for cash at $0.0001 per share	4,000,000	—	—	—	—	—
Paid-in capital	—	—	7	—	—	7
Net loss	—	—	—	—	(7)	(7)
Balance at December 31, 2010	4,000,000	—	7	—	(7)	—
Paid-in capital	—	—	61	—	—	61
Issuance of shares of common stock through private placementsat $3.75 per share, net of issuance costs	16,000,000	2	56,739	—	—	56,741
Conversion of stockholder's note payable to equity	40,000	—	150	—	—	150
Stock option compensation	—	—	67	—	—	67
Anti-dilutive warrant	—	—	7,586	—	—	7,586
Net loss	—	—	—	—	(10,233)	(10,233)
Balance at December 31, 2011	20,040,000	2	64,610	—	(10,240)	54,372
Issuance of shares of common stock through equity placement at $16.00 per share, net of issuance costs	8,625,000	1	129,213	—	—	129,214
Stock option compensation	—	—	1,408	—	—	1,408
Anti-dilutive warrant	—	—	18,222	—	—	18,222
Exercises of stock options	11,666	—	45	—	—	45
Net loss	—	—	—	—	(74,352)	(74,352)
Balance at December 31, 2012	28,676,666	3	213,498	—	(84,592)	128,909
Stock option compensation	—	—	7,519	—	—	7,519
Exercises of stock options	314,623	—	2,215	—	—	2,215
Unrealized gain on available for sale securities	—	—	—	3	—	3
Net loss	—	—	—	—	(54,659)	(54,659)
Balance at December 31, 2013	28,991,289	$ 3	$223,232	$ 3	$(139,251)	$ 83,987

See Accompanying Notes to the Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,			Period from September 15, 2010 (date of inception) to December 31, 2013
	2013	2012	2011	
Operating activities:				
Net loss	$ (54,659)	$ (74,352)	$(10,233)	$(139,251)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	423	265	11	699
Build-out allowance received from landlord	—	464	439	903
Stock option expense	7,519	1,408	67	8,994
Anti-dilutive warrant	—	18,222	7,586	25,808
Changes in operating assets and liabilities:				
Licensor receivable	799	(10,612)	—	(9,813)
Prepaid expenses and other	(6,727)	(707)	(281)	(7,715)
Accounts payable	10,210	395	87	10,692
Accrued expenses	(12,640)	20,719	500	8,579
Accrual of deferred rent	27	186	—	213
Net cash used in operating activities	(55,048)	(44,012)	(1,824)	(100,891)
Investing activities:				
Purchase of property and equipment	(624)	(591)	(254)	(1,469)
Expenditures for leasehold improvements	(4)	(471)	(439)	(914)
Restricted cash	(2)	(159)	(1,053)	(1,214)
Purchase of available-for-sale securities	(49,347)	—	—	(49,347)
Sale/maturity of available-for-sale securities	8,446	—	—	8,446
Net cash used in investing activities	(41,531)	(1,221)	(1,746)	(44,498)
Financing activities:				
Proceeds from issuance of stockholder's convertible notepayable	—	—	150	150
Net proceeds from issuance of common stock	—	129,214	56,741	185,955
Net proceeds from exercise of options	2,215	45	—	2,260
Capital contributions by stockholder	—	—	61	68
Net cash provided by financing activities	2,215	129,259	56,952	188,433
Net (decrease) increase in cash and cash equivalents	(94,364)	84,026	53,382	43,044
Cash and cash equivalents, beginning of period	137,408	53,382	—	—
Cash and cash equivalents, end of period	$ 43,044	$137,408	$ 53,382	$ 43,044
Supplemental disclosures of non-cash investing and financing activities:				
Conversion of stockholder's note payable to common stock	$ —	$ —	$ 150	$ 150

See Accompanying Notes to the Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or Puma, is a development stage biopharmaceutical company based in Los Angeles, California. References in these Notes to Consolidated Financial Statements to the "Company" refer to Puma Biotechnology, Inc., a private Delaware company formed on September 15, 2010, for periods prior to the Merger (as defined below), which took place on October 4, 2011, and Puma Biotechnology, Inc., a Delaware company formed on April 27, 2007, and formerly known as Innovative Acquisitions Corp., for periods following the Merger. The Company is a development stage biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use.

In November 2012, the Company established and incorporated Puma Biotechnology Ltd., a wholly owned subsidiary, for the sole purpose of serving as Puma's legal representative in the United Kingdom and the European Union in connection with Puma's clinical trial activity in those countries.

Basis of Presentation:

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products through December 31, 2013. The Company is 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, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. Accordingly, the accompanying consolidated financial statements have been prepared in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, ASC 915, *Development Stage Entities*. The Company has reported a net loss of $54.7 million and negative cash flows from operations of $55.0 million for the year ended December 31, 2013. The net loss from the date of inception, September 15, 2010, to December 31, 2013, amounted to $139.3 million while the negative cash flows from operations from the date of inception amounted to $100.9 million. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process.

The Company's continued operations will depend on its ability to raise funds through various potential sources, such as equity and debt financing. Through December 31, 2013, and into 2014, the Company's financing was primarily through public offerings of Company common stock and private equity placements. Given the current and desired pace of clinical development of its three product candidates, management estimates that the Company had sufficient cash on hand at December 31, 2013, to fund clinical development through 2015 and beyond. The Company sold additional shares of its common stock through an underwritten public offering in February 2014 (see Note 10). As a result, the Company received net proceeds of approximately $129.3 million. The Company may need additional financing until it can achieve profitability, if ever. There can be no assurance that additional capital will be available on favorable terms or at all or that any additional capital that the Company is able to obtain will be sufficient to meet its needs. If it is unable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

Merger with Public Company:

On September 29, 2011, the Company entered into an agreement and plan of merger, or the Merger Agreement, with Innovative Acquisitions Corp., or IAC, and IAC's wholly-owned subsidiary, IAC Merger Corporation, or Merger Sub. On October 4, 2011, the Company completed a reverse merger in which Merger Sub merged with and into the Company and the Company became a wholly-owned subsidiary of IAC, or the Merger. At the effective time of the Merger, the Company's then issued and outstanding 18,666,733 shares of common stock were exchanged for 18,666,733 shares of common stock of IAC and each share of the Company's common stock that was outstanding immediately prior to the effective time was cancelled, with one share of the Company common stock issued to IAC. Concurrently, IAC redeemed all of its shares from its pre-Merger stockholders in exchange for aggregate consideration of $40,000 paid by the Company. The Company also paid $40,000 for IAC's professional fees associated with the Merger, directly to legal counsel for IAC's former stockholders. Following the Merger and the redemption, the Company's prior stockholders owned the same percentage of IAC's common stock as they held of the Company's common stock prior to the Merger.

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

The Merger was accounted for as a reverse acquisition, with the Company as the accounting acquirer and IAC as the accounting acquiree. The merger of a private operating company into a non-operating public shell corporation with nominal net assets is considered to be a capital transaction, in substance, rather than a business combination for accounting purposes. Accordingly, the Company treated this transaction as a capital transaction without recording goodwill or adjusting any of its other assets or liabilities. Consideration in the amount of $80,000 paid to the former stockholders of IAC and their attorney was recorded as an other expense item and included in the Company's net loss for the year ended December 31, 2011.

Note 2—Significant Accounting Policies:

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

Use of Estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the balance sheet and reported amounts of expenses for the period presented. Accordingly, actual results could differ from those estimates. Significant estimates include accrued expenses for the cost of services provided by consultants who manage clinical trials and conduct research and clinical trials on behalf of the Company that are billed on a delayed basis. As the actual costs become known, the Company adjusts its estimated cost in that period. The value of stock-based compensation includes estimates based on future events which are difficult to predict. It is at least reasonably possible that a change in the estimates used to record accrued expenses and to value the stock-based compensation will occur in the near term.

Principles of Consolidation:

The Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents:

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

Licensor Receivable:

Licensor receivable represents external "out of pocket" clinical trial costs in excess of an agreed upon "cap cost" for clinical trials that were ongoing at the time the licensing agreement with the Licensor (defined below) was entered (see Note 9). The licensing agreement allows the Company to bill the Licensor for all external "out of pocket" costs in excess of the cap cost on a quarterly basis. Licensor receivables include both invoiced and un-invoiced costs in excess of the cap. The Company has not established a reserve against this receivable as it is deemed to be 100% collectable.

Investment Securities:

The Company classifies all investment securities (short term and long term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management's strategies. These securities are carried at fair value, with the unrealized gains and losses, reported as a component of accumulated other comprehensive income (loss) in stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

Assets Measured at Fair Value on a Recurring Basis:

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

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

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

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

Following are the major categories of assets measured at fair value on a recurring basis as of December 31, 2013 and 2012, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

December 31, 2013	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 41,598	$ —	$ —	$ 41,598
Marketable securities—corporate bonds	—	40,904	—	40,904
	$ 41,598	$40,904	$ —	$ 82,502

December 31, 2012	Level 1	Level 2	Level 3	Total
Cash equivalents	$134,867	$ —	$ —	$134,867

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

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents. The Company's cash and cash equivalents in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at December 31, 2013, were approximately $44.2 million. The Company does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held. Pursuant to the Company's internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor's Corporation and Moody's Investor Services at the time of purchase.

Property and Equipment:

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

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been impairment by comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. Should impairment exist, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through December 31, 2013.

Research and Development Expenses:

Research and development expenses are charged to operations as incurred. The major components of research and development costs include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and clinical research organization, or CRO, costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors

such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company's accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. The objective of the Company's accrual policy is to match the recording of expenses in the Consolidated Financial Statements to the actual services received and efforts expended. As actual costs become known, the Company adjusts its accruals in that period.

In instances where the Company enters into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded to prepaid expenses and other in the accompanying Consolidated Balance Sheets and expensed as services are performed or as the underlying goods are delivered. If the Company does not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

Research and Development Reimbursement:

The licensing agreement set a "cap" on the amount of external expenses the Company would incur, beginning January 1, 2012, in completing the clinical trials transferred from the Licensor to the Company. The license agreement stipulates that the Licensor would be responsible for all external expenses associated with the transferred clinical trials and that the Company would invoice for such costs on a quarterly basis. All amounts reimbursed by the Licensor represent charges for services provided by third parties and not by the Company; accordingly, the Company has elected to treat the reimbursed costs as a "pass-through" expense billable to the Licensor and as an off set to research and development expenses. Consequently, research and development expenses are recorded net of any excess cap costs billed to the Licensor. The Company recognized approximately $16.4 million and $10.6 million of excess cap cost billed to the Licensor in 2013 and 2012, respectively.

Stock-Based Compensation:

Stock option awards:

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

Warrants:

Warrants granted to employees are normally valued at the fair value of the instrument on the grant date and are recognized in the statement of operations over the requisite service period. When the requisite service period

precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Monte Carlo Simulation Method. When the terms of the warrant become fixed, the Company values the warrant using the Black-Scholes Option Pricing Method. As allowed by ASC 718 for companies with a short period of publicly traded stock history, the Company's estimate of expected volatility is based on the average volatilities of a sampling of eight to nine companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value of the warrant until the terms are fixed, the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair value of the warrant at the time of issuance as an equity stock-based compensation transaction. The warrant is revalued each reporting period up to the grant date when the final fair value of the warrant is established and recorded. The grant date is determined when all pertinent information, such as exercise price and quantity are known.

Income Taxes:

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

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the Consolidated Financial Statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the Consolidated Financial Statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. At the date of adoption, and as of December 31, 2013 and 2012, the Company did not have a liability for unrecognized tax uncertainties.

The Company is subject to routine audits by taxing jurisdictions. As of December 31, 2013, the Company's tax years for 2010, 2011 and 2012 are subject to examination by the authorities. Currently, the Company is under review for the 2011 and 2012 tax years by the Internal Revenue Service. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2013 and 2012, the Company had no accrued interest or penalties related to uncertain tax positions.

Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the periods presented as required by ASC 260, *Earnings per Share*. Diluted earnings per common share are the same as basic earnings per share because the assumed exercise of the Company's outstanding options are anti-dilutive. For the year ended December 31, 2013, potentially dilutive securities excluded from the calculations were 2,604,224 shares issuable upon exercise of options and 2,116,250 shares issuable upon exercise of a warrant. For the years ended December 31, 2012 and 2011, potentially dilutive securities excluded from the earnings per common share calculation were 4,022,584 and 670,000, respectively.

Deferred Rent:

The Company has entered into operating lease agreements for its corporate offices in Los Angeles and South San Francisco that contain provisions for future rent increases, leasehold improvement allowances and rent abatements. The Company records monthly rent expense equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between the rent expense recorded and the amount paid is credited or charged to deferred rent, which is reflected as a separate line item in the accompanying Consolidated Balance Sheets. Additionally, the Company recorded as deferred rent the cost of the leasehold improvements paid by the landlord, which is amortized on a straight-line basis over the term of the lease.

Reclassifications:

Certain amounts for 2012 and 2011 have been reclassified to conform to the current year's presentation.

Note 3—Prepaid Expenses and Other:

Prepaid expenses and other consisted of the following at December 31 (in thousands):

	2013	2012
Current:		
CRO services	$ 863	$365
Other clinical development	1,089	252
Insurance	554	229
Prepaid rent	—	74
Other	129	32
	2,635	952
Long-term:		
CRO services	1,509	—
Other clinical development	3,359	—
Insurance	142	—
Other	70	36
	5,080	36
Totals	$7,715	$988

Note 4—Property and Equipment:

Property and equipment consisted of the following at December 31 (in thousands):

	2013	2012
Leasehold improvements	$ 914	$ 910
Computer equipment	874	535
Telephone equipment	82	34
Furniture and fixtures	513	276
	2,383	1,755
Less: accumulated depreciation and amortization	(699)	(276)
Totals	$1,684	$1,479

Note 5—Accrued Expenses:

Accrued expenses consisted of the following at December 31 (in thousands):

	2013	2012
Accrued CRO/licensor services	$4,801	$19,846
Accrued other clinical development	2,369	389
Accrued legal fees	84	121
Accrued compensation	1,066	787
Other	259	76
	$8,579	$21,219

Accrued CRO/licensor services represent the Company's estimate of such costs as of December 31, 2013, which will be adjusted in the period the actual costs become known.

Note 6—Stockholders' Equity:

Common Stock:

The Company issued 4,000,000 shares of common stock at $0.0001 per share to its Founder and Chief Executive Officer and President, Alan Auerbach, in September 2010 for $400. Additionally, Mr. Auerbach contributed capital totaling $6,531 during the year ended December 31, 2010.

During the year ended December 31, 2011, Mr. Auerbach contributed capital totaling $61,983. Additionally, in October 2011, 40,000 shares of common stock were issued to Mr. Auerbach through debt conversion at $3.75 per share, or $150,000.

October 2011 Common Stock Offering. Immediately prior to the Merger, pursuant to a securities purchase agreement, or the Securities Purchase Agreement, Puma sold 14,666,733 shares of its common stock to certain institutional and accredited investors at a price per share of $3.75, for aggregate gross proceeds of approximately $55 million. Puma also issued a warrant to each investor that provided such investor with anti-dilution protection in regard to certain issuances of securities. The Company assumed these warrants in the Merger and they were exercisable only if the Company sold securities at a price below $3.75 per share on or prior to the date on which shares of Company common stock were first quoted in an over-the-counter market or listed for quotation on a national securities exchange or trading system if the Company had not previously sold securities for less than $3.75 per share. Otherwise, the warrants had a ten-year term and an exercise price of $0.01 per share. The Company's common stock was approved for quotation on April 18, 2012, and began trading on April 20, 2012, on the OTC Bulletin Board, or OTCBB, and the OTCQB under the symbol "PBYI" and the Company did not sell securities at a price below $3.75 per share on or prior to such date. These warrants subsequently terminated unexercised in accordance with their terms.

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

October 2012 Common Stock Offering. On October 18, 2012, the Company entered into an underwriting agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink, as representatives of several underwriters, providing for the offer and sale in a firm-commitment underwritten public offering of 7,500,000 shares of the Company's common stock, par value $0.0001 per share, at a price of $16 per share, less the

underwriting discount. On October 19, 2012, the underwriters exercised the overallotment option granted to the underwriters to purchase an additional 1,125,000 shares of Company common stock from the Company at $16 per share, less the underwriting discount. The transactions were completed on October 24, 2012; the Company received net proceeds of approximately $129.2 million, which is comprised of gross proceeds of approximately $138 million, offset by the underwriting discount and estimated offering expenses of $8.8 million payable by the Company.

The Company issued 314,623 and 11,666 shares of common stock upon exercise of stock options during the years ended December 31, 2013 and 2012, respectively.

Authorized Shares:

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

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

Warrants:

In October 2011, the Company issued anti-dilutive warrants to 27 investors pursuant to a securities purchase agreement. These warrants were exercisable only if the Company sold securities at a price below $3.75 per share on or prior to the date on which the Company's common stock was first quoted in an over-the-counter market or listed for quotation on a national securities exchange or trading system. The Company's common stock was approved for quotation on the OTCBB, on April 18, 2012, and began trading on April 20, 2012 under the symbol "PBYI" and the Company did not sell securities at a price below $3.75 per share on or prior to such date. Accordingly, these warrants subsequently terminated unexercised in accordance with their terms. The fair value of the warrants issued was determined using the Monte Carlo Simulation Method with the following assumptions:

	October 2011
Dividend yield	0%
Expected volatility	84.40%
Risk-free interest rate	1.81%
Common stock price on date of issuance	$ 3.75
Exercise price	$ 0.01
Warrant term in years	10

Using the above assumptions, the portion of the private placement proceeds attributed to the fair value of the warrants was determined to be approximately $1.8 million and recorded within additional paid-in capital.

Following the October 2011 common stock offering, Mr. Auerbach held approximately 21% of the 18,666,733 outstanding shares of the Company's common stock.

Pursuant to the terms of the securities purchase agreement, the Company issued an anti-dilutive warrant to Mr. Auerbach, as the Company's founder. The warrant was issued to provide Mr. Auerbach with the right to maintain ownership of at least 20% of the Company's common stock in the event that the Company raised capital through the sale of its securities in the future.

The warrant has a ten-year term and is exercisable only in the event of the first subsequent financing, excluding certain types of financings set forth in the warrant, that results in gross cash proceeds to the Company of at least $15 million. The warrant has an exercise price equal to the price paid per share in such financing and is exercisable for the number of shares of the Company's common stock necessary for Mr. Auerbach to maintain ownership of at least 20% of the outstanding shares of Company common stock after such financing. Upon the occurrence of the first subsequent financing of at least $15 million, the warrant may be exercised any time up to the ten-year expiration date of October 4, 2021. The grant date of the warrant would occur on the date of the subsequent financing when the aggregate number of shares exercisable and the price per share will be determined. The Company determined that the warrant has an implied service requisite period in 2011 that is prior to its grant date. The Company also determined that a market condition subsequent to the implied service period exists as the exercise or partial exercise of the warrant can only occur if there is a subsequent financing.

In connection with the closing of a public offering on October 24, 2012, the exercise price and number of shares underlying the warrant issued to Mr. Auerbach were established and, accordingly, the final value of the warrant became fixed. 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 per share until October 4, 2021.

The warrant was valued at approximately $6.9 million at the time of issuance, using the Monte Carlo Simulation Method, and recorded to the Consolidated Statements of Operations. The warrant was revalued at approximately $7.6 million on December 31, 2011, using the Monte Carlo Simulation Method. Once the terms of the warrant became fixed, the fair value of the warrant as of October 24, 2012, using the Black-Scholes Option Pricing Method, was approximately $25.8 million and resulted in an adjustment to the fair value of the warrant of $18.2 million in 2012, which is included in general and administrative expense in the accompanying Consolidated Statements of Operations for the year ended December 31, 2012.

The fair value of the warrant at October 24, 2012, was determined by the following assumptions using the Black-Scholes Option Pricing Method:

	October 2012
Common stock price	$ 16.00
Dividend yield	0.00%
Expected volatility	75.50%
Risk-free interest rate	1.81%
Remaining warrant term in years	9

The fair value at December 31, 2011, was determined by the following assumptions using the Monte Carlo Simulation Method:

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

The fair value of the warrant, on December 31, 2011 was estimated based on projected equity raises ranging from $15 million to $100 million in 2013 using weighted probability factors.

Stock-Based Compensation:

The Company's 2011 Incentive Award Plan, or the 2011 Plan, was adopted by the Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. Through December 31, 2013, a total of 3,529,412 shares of the Company's common stock has been reserved for issuance under the 2011 Plan.

The Company awarded only "plain vanilla options" as determined by the SEC Staff Accounting Bulletin 107, or *Share Based Payment*. As of December 31, 2013, 2,604,224 shares of the Company's common stock are issuable upon the exercise of outstanding awards granted under the 2011 Plan and 598,899 shares of the Company's common stock are available for future issuance under the 2011 Plan. The fair value of options granted to employees was estimated using the Black-Scholes Option Pricing Method (see Note 2) with the following weighted-average assumptions used during the years ended December 31:

	2013	2012	2011
Dividend yield	0.0%	0.0%	0.0%
Expected volatility	83.6%	86.4%	86.0%
Risk-free interest rate	1.4%	1.0%	1.1%
Expected life in years	5.85	5.79	5.81

Employee stock-based compensation was as follows for the years ended December 31 (in thousands except per share data):

	2013	2012	2011
Stock-based compensation:			
Options-			
Research and development	$ 5,188	$ 924	$ 38
General and administrative, or G&A	2,331	484	29
Warrants -G&A	—	18,222	7,586
Total share-based compensation expense	$ 7,519	$ 19,630	$ 7,653
Impact on basic and diluted net loss per share	$ 0.26	$ 0.90	$ 0.99
Weighted average shares (basic and diluted)	28,696,573	21,725,986	7,746,529

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2011	—	—		
Options granted in the period ended March 31, 2012 for which compensation was recognized during 2011	670,000	$ 3.75		
Granted during 2012	1,278,000	$11.48		
Forfeited during 2012	(30,000)	$ 3.75		
Exercised during 2012	(11,666)	$ 3.75		$ 190
Outstanding at December 31, 2012	1,906,334	$ 8.93		
Granted during 2013	1,032,375	$44.77		
Forfeited during 2013	(19,862)	$11.60		
Exercised during 2013	(314,623)	$ 7.29		$ 23,525
Outstanding at December 31, 2013	2,604,224	$23.31	8.9	$208,902
Unvested at December 31, 2013	1,838,633	$29.51	9.1	$136,105
Exercisable at December 31, 2013	765,591	$ 8.44	8.3	$ 72,797

At December 31, 2013, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $33.8 million, which is expected to be recognized over a weighted-average period of 2.5 years. The weighted-average grant date fair value of options granted during the years ended December 31, 2013 and 2012, was $29.94 per share and $6.38 per share, respectively.

Stock options	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2012	1,659,399	$ 7.03
Granted	1,032,375	29.94
Vested/Issued	(833,279)	9.85
Forfeited	(19,862)	8.12
Nonvested shares at December 31, 2013	1,838,633	$20.18

Note 7—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately $0.2 million, $0.1 million, and $0 for the years ended December 31, 2013, 2012, and 2011, respectively.

Note 8—Income Taxes:

Temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes (net operating loss carry-forwards) give rise to the Company's deferred income taxes. The components of the Company's net deferred tax assets as of December 31, 2013 and 2012 are as follows (in thousands):

	Federal	State	Total
Deferred tax assets—2013:			
Net operating loss carry forwards	$ 35,641	$ 6,116	$ 41,757
Business credit carryforwards	3,513	1,539	5,052
Organization costs	200	34	234
Compensation	9,791	1,681	11,472
Depreciation	42	7	49
Other	73	12	85
	49,260	9,389	58,649
Deferred tax liabilities	—	—	—
Total deferred tax assets	49,260	9,389	58,649
Valuation allowance	(49,260)	(9,389)	(58,649)
Net deferred tax assets	$ —	$ —	$ —

	Federal	State	Total
Deferred tax assets—2012:			
Net operating loss carry forwards	$ 19,020	$ 3,263	$ 22,283
Organization costs	230	40	270
Compensation	9,080	1,558	10,638
Other	64	11	75
	28,394	4,872	33,266
Deferred tax liabilities— depreciation	(2)	—	(2)
Total deferred tax assets	28,392	4,872	33,264
Valuation allowance	(28,392)	(4,872)	(33,264)
Net deferred tax assets	$ —	$ —	$ —

As the ultimate realization of the potential benefits of the Company's deferred tax assets is considered unlikely by management, the Company has offset the deferred tax assets attributable to those potential benefits through valuation allowances. Accordingly, the Company did not recognize any benefit from income taxes in the accompanying consolidated statements of operations to offset its pre-tax losses. The valuation allowance increased $25.3 million in 2013 and $29.2 million in 2012. At December 31, 2013, the Company had federal and state net operating loss carryforwards of approximately $104.8 million each, which will begin to expire in 2031. At December 31, 2013, the Company also has federal and state research and development credit carryforwards of approximately $4.4 million and $2.9 million, respectively. Pursuant to the Internal Revenue Code, Sections 382 and 383, use of the Company's net operating loss and credit carryforwards could be limited if a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not yet performed an assessment on the potential limitation on net operating loss and credit carryforwards.

As a result of certain realization requirements of ASC 718, the table of deferred tax assets and liabilities shown above does not include certain deferred tax assets as of December 31, 2013 and 2012 that arose directly from (or the use of which was postponed by) tax deductions related to equity compensation in excess of compensation recognized for financial reporting. Those deferred tax assets include federal and net operating

losses. Equity will be increased by approximately $8.1 million if and when such deferred tax assets are ultimately realized. The Company uses ASC 740 ordering when determining when excess tax benefits have been realized.

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

	2013	2012	2011
Tax computed at the federal statutory rate	$(18,584)	$(25,280)	$(3,479)
State taxes	(3,948)	(4,279)	(594)
Permanent items	(806)	346	24
Change in valuation allowance	23,338	29,213	4,049
Total provision	$ —	$ —	$ —

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits at December 31:

(in thousands)	2013	2012
Unrecognized tax benefits—January 1	$ —	$—
Gross increases—tax positions in prior period	205	—
Gross decreases—tax positions in prior period	—	—
Gross increases—tax positions in current period	1,058	—
Settlement	—	—
Lapse of statute of limitations	—	—
Unrecognized tax benefits—December 31	$1,263	$—

The unrecognized tax benefits that, if recognized, would affect the effective tax rate is zero at December 31, 2013. The Company does not have tax positions for which it is reasonable possible that the total amounts of unrecognized tax benefit will significantly increase or decrease within 12 months of the reporting date.

Note 9—Commitments and Contingencies:

Office Leases:

On December 7, 2011, the Company, entered into a non-cancelable operating lease for office space. The initial term of the lease is for seven years and commenced on December 10, 2011. The base rent was approximately $44,400 per month during the first year and will increase each year during the initial term, up to approximately $53,000 per month during the seventh year. The lease has an expiration date of December 9, 2018. In addition, the Company has an option to extend the lease for an additional five-year term. The lease is subject to additional charges for common area maintenance and other costs. Concurrent with the execution of the lease, the Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $1,000,000. The stand-by letter of credit is collateralized by a high-yield savings account in the amount of approximately $1,053,000, which is classified as restricted cash on the accompanying Consolidated Balance Sheets. Rent expense for the years ended December 31, 2013, 2012, and 2011, was approximately $872,500, $526,900 and $41,125, respectively.

On June 7, 2012, the Company entered into a long-term lease agreement for office space in South San Francisco, California. The initial term of the lease is seven years and commenced on November 1, 2012. The base rent was approximately $20,250 per month during the first year and will increase over the course of the initial term, up to approximately $30,820 per month during the seventh year. In addition, the Company has an option to extend the lease for an additional five-year term, which would commence upon the expiration of the

initial term. In the event the Company elects to extend the lease, the minimum monthly rent payable for the additional term will be the then-current fair market rent calculated in accordance with the terms of the lease. The Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $150,000. The stand-by letter of credit is collateralized by a high-yield savings account in the amount of approximately $159,000, which is classified as restricted cash on the accompanying Consolidated Balance Sheets.

On November 28, 2012, the Company entered into an amendment to the lease for its office space in Los Angeles, California. This amendment added approximately 3,500 rentable square feet to the existing lease of approximately 13,250 square feet. Pursuant to the amendment, the Company's monthly rent increased by approximately $12,145 per month following the execution of the amendment and will be increased to approximately $14,080 per month at the end of the lease term.

On December 1, 2013, the Company entered into a second amendment to the lease for its office space in Los Angeles, California. This amendment added approximately 5,949 rentable square feet to the existing lease of approximately 16,750 square feet. Pursuant to the amendment, the Company's monthly rent increased by approximately $10,400 per month following the execution of the amendment and will be increased to approximately $25,100 per month at the end of the lease term.

Future minimum lease payments for each of the years subsequent to December 31, 2013, are as follows (in thousands):

Year Ending December 31,	Amount
2014	$1,117
2015	1,313
2016	1,376
2017	1,417
2018	1,459
Thereafter	308
Total	$6,990

License Agreement:

In August 2011, the Company entered into an agreement pursuant to which Pfizer, Inc., or the Licensor, agreed to grant it a worldwide license for the development, manufacture and commercialization of PB272 neratinib (oral), PB272 neratinib (intravenous) and PB357, and certain related compounds. The license is exclusive with respect to certain patent rights owned by or licensed to the Licensor. Under the agreement, the Company is obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and to use commercially reasonable efforts to complete clinical trials and to achieve certain milestones as provided in a development plan. From the closing date of the agreement through December 31, 2011, the Licensor continued to conduct the existing clinical trials on behalf of the Company at the Licensor's sole expense. At the Company's request, the Licensor has agreed to continue to perform certain services in support of the existing clinical trials at the Company's expense. These services will continue through the completion of the transitioned clinical trials. The license agreement "capped" the out of pocket expense the Company would be responsible for completing the then existing clinical trials. All agreed upon costs incurred by the Company above the "cost cap" would be reimbursed by the Licensor. The Company exceeded the "cost cap" during the fourth quarter for 2012. In accordance with the license agreement, the Company billed the Licensor for agreed upon costs above the "cost cap" and will continue to do so until the various clinical trials are closed.

As consideration for the license, the Company is required to make substantial payments upon the achievement of certain milestones totaling approximately $187.5 million if all such milestones are achieved. Should the Company commercialize any of the compounds licensed from the Licensor or any products containing any of these compounds, the Company will be obligated to pay to the Licensor annual royalties

between approximately 10% and 20% of net sales of all such products, subject to certain reductions and offsets in some circumstances. The Company's royalty obligation continues, on a product-by-product and country-by-country basis, until the later of (i) the last to expire licensed patent covering the applicable licensed product in such country, or (ii) the earlier of generic competition for such licensed product reaching a certain level in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that the Company sublicenses the rights granted to the Company under the license agreement with the Licensor to a third party, the same milestone and royalty payments are required. The Company can terminate the license agreement at will at any time after April 4, 2013, or for safety concerns, in each case upon specified advance notice.

Clinical Research Organization Contracts:

The Company engages with clinical research organizations, or CROs, for the management of its ongoing clinical trials. The Company may cancel these agreements with a 30 to 45 day written notice to the CRO. The Company would be obligated to pay for services rendered up to that point. The CRO contracts held by the Company as of December 31, 2013, are summarized as follows (in thousands):

Indication	Total Contract Amount Remaining as of December 31, 2013	Months Remaining on Contract
HER2 Mutation Positive Solid Tumor (5201)	$ 3,560	32
HER2 Mutuant Non-Small Cell Lung Cancer (4201)	5,060	28
HER2 Overexpressed/Amplified Breast Cancer (Licensor Legacy Clinical Trials)	18,389	15
HER2 Plus Metastatic Breast Cancer (1301)	46,477	43
Metastatic HER2-Amplified or Triple-Negative Breast Cancer (10-005)	1,399	36
	$74,885	

Note 10—Subsequent Event:

Financing:

On February 14, 2014, the Company completed an underwritten offering of 1,126,530 shares of the Company's common stock (including an additional 146,938 shares of Company common stock issued and sold pursuant to the underwriters' option to purchase additional shares), par value $0.0001 per share, at a price of $122.50 per share, less the underwriting discount. The net proceeds received by the Company were approximately $129.3 million after deducting the underwriting discount and estimated offering expenses payable by the Company.

Note 11 – Quarterly Financial Data:

Quarterly financial data (in thousands except share data):
(unaudited)

	Three Months Ended			
	March 31,	June 30,	September 30,	December 31,
2013				
Revenues	$ —	$ —	$ —	$ —
Net loss	(11,780)	(12,650)	(14,283)	(15,946)
Net loss applicable to common stock	(11,780)	(12,650)	(14,283)	(15,946)
Net loss per share—basic and diluted	(0.41)	(0.44)	(0.50)	(0.55)
Weighted-average common shares outstanding—basic and diluted	28,676,666	28,676,666	28,682,055	28,750,382
2012				
Revenues	$ —	$ —	$ —	$ —
Net loss	(11,826)	(14,754)	(25,859)	(21,913)
Net loss applicable to common stock	(11,826)	(14,754)	(25,859)	(21,913)
Net loss per share—basic and diluted	(0.59)	(0.74)	(1.29)	(0.83)
Weighted-average common shares outstanding—basic and diluted	20,040,000	20,040,000	20,040,000	26,511,141

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER,
AS ADOPTED PURSUANT TO SECTION 302

I, Alan H. Auerbach, certify that:

1. I have reviewed this Annual Report on Form 10-K of Puma Biotechnology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Alan H. Auerbach

Alan H. Auerbach
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 3, 2014

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER,
AS ADOPTED PURSUANT TO SECTION 302

I, Charles R. Eyler, certify that:

1. I have reviewed this Annual Report on Form 10-K of Puma Biotechnology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Charles R. Eyler

Charles R. Eyler
Senior Vice President, Finance and Administration and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

Date: March 3, 2014

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Alan H. Auerbach, President and Chief Executive Officer of Puma Biotechnology, Inc. (the "Company"), certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The accompanying Annual Report on Form 10-K of the Company for the annual period ended December 31, 2013 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Alan H. Auerbach

Alan H. Auerbach
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 3, 2014

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Charles R. Eyler, Senior Vice President, Finance and Administration and Treasurer of Puma Biotechnology, Inc. (the "Company"), certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The accompanying Annual Report on Form 10-K of the Company for the annual period ended December 31, 2013 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Charles R. Eyler

Charles R. Eyler
Senior Vice President, Finance and Administration and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

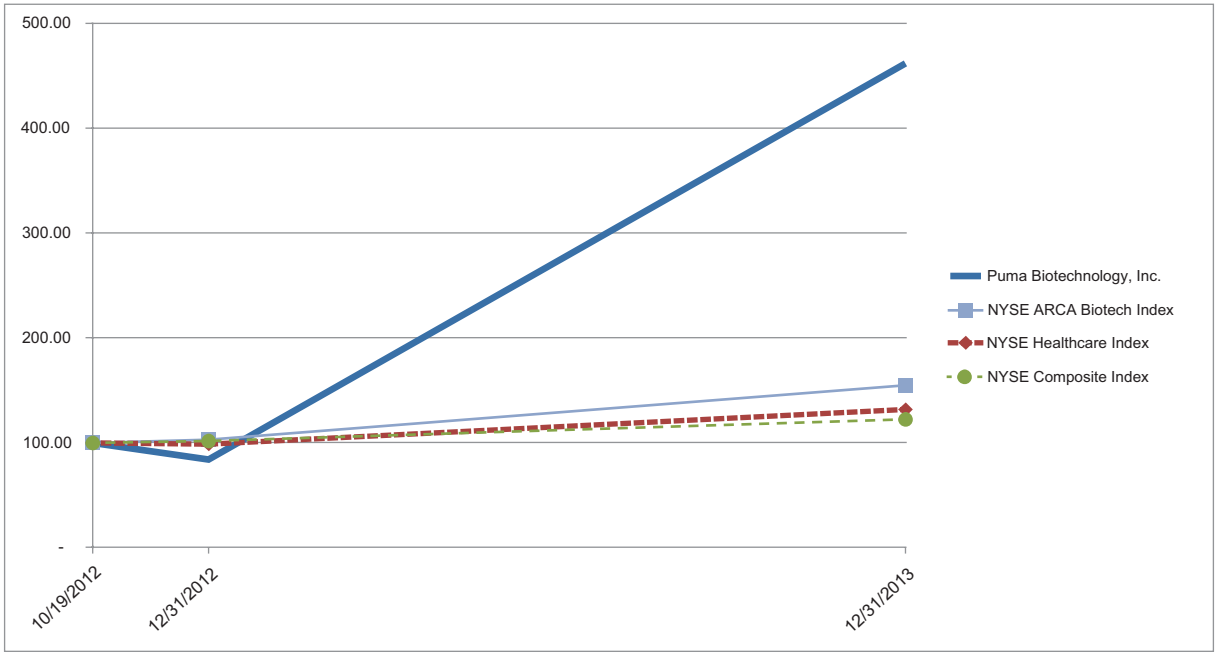
Date: March 3, 2014

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Puma Biotechnology, Inc. (PBYI)*
Stock Price Performance Graph

The graph and table below compare the cumulative total return on Puma Biotechnology common stock from October 19, 2012, through December 31, 2013, with the cumulative total returns on (i) the NYSE ARCA Biotech Index, (ii) the NYSE Healthcare Index, and (iii) the NYSE Composite Index. The comparison assumes investment of $100 on October 19, 2012, in our common stock and in each index and, for each index, assumes reinvestment of all dividends.

The historical stock price performance included below is not necessarily indicative of future stock price performance.



Cumulative Total Return
Puma Biotechnology, Inc. Compared to the NYSE ARCA Biotech Index,
NYSE Healthcare Index and NYSE Composite Index

	10/19/2012	12/31/2012	12/31/2013
Puma Biotechnology, Inc.	$100	83.78	462.60
NYSE ARCA Biotech Index	$100	102.56	154.50
NYSE Healthcare Index	$100	98.64	127.86
NYSE Composite Index	$100	101.43	124.94

* Shares of Puma Biotechnology were quoted on the OTC Bulletin Board from April 20, 2012, through October 18, 2012. On October 19, 2012, shares of Puma common stock were listed and began trading on the New York Stock Exchange.

Company Leadership

Board of Directors

Alan H. Auerbach
Chairman, President and Chief Executive Officer
Puma Biotechnology, Inc.

Thomas R. Malley
President
Mossrock Capital, LLC

Jay M. Moyes
Chief Financial Officer (retired)
Myriad Genetics, Inc.

Troy E. Wilson, Ph.D., J.D.
President and Chief Executive Officer
Avidity NanoMedicines LLC
President and Chief Executive Officer
Wellspring Biosciences LLC

Corporate Officers

Alan H. Auerbach
Chairman, President and Chief Executive Officer

Richard P. Bryce, MBChB, MRCGP, MFPM
Senior Vice President, Clinical Research & Development

Charles R. Eyler
Senior Vice President, Finance and Administration, and Treasurer

Richard B. Phillips, Ph.D.
Senior Vice President, Regulatory Affairs, Quality Assurance and Pharmacovigilance

Stockholder Information

Corporate Headquarters

Puma Biotechnology, Inc.
10880 Wilshire Blvd., Suite 2150
Los Angeles, CA 90024
424-248-6500

Investor Relations

Securities analysts, investment professionals and stockholders should direct inquiries to Investor Relations at 424-248-6500 Ext. 2011 or ir@pumabiotechnology.com.

For further information about Puma, please visit our website at www.pumabiotechnology.com.

Common Stock

Puma's common stock is listed on the New York Stock Exchange under the trading symbol "PBYI."

Transfer Agent

Wells Fargo Shareowner Services SM
Mail:
P.O. Box 64854
St. Paul, MN 55164

Courier:
1110 Centre Pointe Curve, Suite 101
Mendota Heights, MN 55120-4100

Telephone:
800-468-9716
651-450-4064

Website:
www.shareowneronline.com

Annual Meeting

The 2014 Annual Meeting of Stockholders will be held at 1:00 p.m. PDT on Tuesday, June 10, 2014, at the Luxe Sunset Boulevard Hotel
11461 Sunset Boulevard
Los Angeles, CA 90049

Independent Registered Public Accounting Firm

PKF Certified Public Accountants, a Professional Corporation
2020 Camino del Rio North, Suite 500
San Diego, CA 92108

Forward-Looking Statements

This document contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding anticipated timing for the commencement and completion of various clinical trials and the announcement of data relative to these trials. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "expects," "plans," "believes," "intends," and similar words or phrases. Discussions containing these forward-looking statements may be found throughout this document, including the sections entitled "Item 1. Business" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013. All forward-looking statements included in this document involve risks and uncertainties that could cause the Company's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the fact that the Company has no product revenue and no products approved for marketing; the Company's dependence on PB272 (neratinib (oral)), which is its lead product candidate and is still under development and may never receive regulatory approval; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support the Company's drug candidate claims; even if approved, the risk that physicians and patients may not accept or use the Company's products; the Company's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates; the Company's dependence on licensed intellectual property; and the other risk factors disclosed in the periodic reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, which is included herein. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

Puma Biotechnology, Inc.
10880 Wilshire Blvd., Suite 2150
Los Angeles, CA 90024

www.pumabiotechnology.com