PUMA BIOTECHNOLOGY, INC.
Form 10-K
March 29, 2012
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2011 December 31, 2011

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: 000-52811

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	None

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 x

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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 x 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	x

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter. **Not applicable.**

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date. **20,040,000 shares of Common Stock, par value $0.0001 per share, were outstanding as of March 23, 2012.**

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement for the 2012 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission no later than 120 days after the close of the registrant s fiscal year ended December 31, 2011, are incorporated by reference in Part III hereof.

Table of Contents

TABLE OF CONTENTS

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These forward-looking statements include, but are not limited to, statements about:

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

These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, ongoing, expect, believe, intend and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Annual Report, including Part II, the section entitled Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations. These forward-looking statements involve risks and uncertainties, including the risks discussed in Item 1A of this Annual Report, 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

The Company was originally incorporated in the State of Delaware in April 2007 under the name Innovative Acquisitions Corp. Innovative Acquisitions Corp. was a shell company registered under the Exchange Act with no specific business plan or purpose until it acquired Puma Biotechnology, Inc., a privately-held Delaware corporation, or Puma, through a reverse merger transaction, or the Merger, on October 4, 2011. Puma, a development-stage company, was formed in September 2010 to focus primarily on acquiring and developing pharmaceutical technologies. As a result of the Merger, Puma became our wholly-owned subsidiary. Immediately following the Merger, Puma merged with and into us, leaving us as the surviving corporation. As a result of this subsequent Merger, or the Short-Form Merger, we changed our name to Puma Biotechnology, Inc. and adopted the business of Puma. The Merger was accounted for as a reverse acquisition with Puma as the

Table of Contents

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.

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., and all references to Puma refer to Puma Biotechnology, Inc., a privately-held Delaware corporation formed on September 15, 2010, prior to giving effect to the Merger and the Short-Form Merger.

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

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients and gastric cancer patients;
- PB272 (neratinib (intravenous)), which we are developing for the treatment of advanced cancer patients; and
- PB357, which we believe can serve as a backup compound to PB272, and which we plan to evaluate for further development in 2012.

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

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

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

- commence Phase II clinical trials evaluating the use of neratinib in combination with chemotherapy and other anti-cancer drugs as a second or third-line treatment for HER2 positive breast cancer;
- initiate Phase II clinical trials to evaluate the use of neratinib for the treatment of HER2 positive gastric cancer; and
- continue to evaluate the application of neratinib in the treatment of other forms of HER resistant cancers where there may be unmet medical needs.

Our President and Chief Executive Officer, or CEO, Alan Auerbach has extensive experience in identifying and developing drug candidates for use in the treatment of cancer. He was the founder and CEO of Cougar

Table of Contents

Biotechnology, Inc., or Cougar, where he was responsible for in-licensing and developing abiraterone acetate for the treatment of advanced prostate cancer. Mr. Auerbach progressed abiraterone acetate into two Phase III clinical trials before Cougar was purchased by Johnson & Johnson in 2009.

Our executive offices are located at 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024. Our telephone number is (424) 248-6500 and our internet address is *www.pumabiotechnology.com*.

Our Strategy

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

Advance PB272 (neratinib (oral)), our lead drug candidate, toward regulatory approval and commercialization. We are primarily focused on developing neratinib for the treatment of patients with HER2 positive metastatic breast cancer. We plan to modify the previous clinical development strategy that Pfizer employed by focusing our planned Phase II and Phase III clinical trials on the use of neratinib as a second- or third-line treatment option, which we believe may be underserved by current treatment alternatives and where clinical trials have shown substantial levels of activity.

Expand our product pipeline by pursuing additional applications of neratinib. We believe there are additional applications for neratinib in HER2 positive gastric cancer, which we also believe may be underserved by current treatment alternatives, and tumor types where HER2 is over-expressed, and we intend to further evaluate the safety and efficacy of neratinib for treating these cancers.

Focus on developing innovative cancer therapies. We focus on oncology drug candidates in order to capture efficiencies and economies of scale. We believe that drug development for cancer markets is particularly attractive because relatively small clinical trials can provide meaningful information regarding patient response and safety. Furthermore, we believe that our capabilities are well suited to the oncology market and represent distinct competitive advantages.

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

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

Table of Contents

Product Development Pipeline

Breast Cancer Overview

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

Trastuzumab is a monoclonal antibody that binds to the HER2 protein and thereby causes the cells to cease reproducing. Trastuzumab given in combination with chemotherapy is the current standard of care for HER2 positive metastatic breast cancer. Unfortunately, most patients with HER2 positive breast cancer eventually develop resistance to this treatment, resulting in disease progression. For these reasons, there is a need for alternatives to block HER2 signaling in patients who fail trastuzumab. 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.

PB272 (neratinib (oral)) Breast Cancer

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

Advantages of Neratinib

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

Clinical Trials of Neratinib in Patients with Metastatic Breast Cancer

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

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

Table of Contents

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

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

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

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. In 2011, the preliminary Phase II results of this trial were presented at the San Antonio Breast Cancer Symposium. The results of the study showed that the combination of PB272 and temsirolimus had acceptable tolerability. The efficacy results from the trial showed that for the 15 patients with HER2 positive disease, 9 patients, or 60%, experienced a partial response and 1 patient, or 7%, experienced stable disease for greater than 6 months, which translates to a clinical benefit rate of 67%. Patients who experienced a partial response to the combination of neratinib plus temsirolimus demonstrated a maximum change in the size of their target lesions of between 33% and 83%. None of the 5 patients with triple negative breast cancer demonstrated a partial response or stable disease for greater than 6 months. We expect additional data from this trial to be presented in 2012. The National Surgical Adjuvant Breast and Bowel Project, or NSABP is also running a separate Phase I study of neratinib given in combination with the anticancer drug paclitaxel and the anticancer drug trastuzumab in patients who have failed multiple prior regimens. We anticipate that data from this trial will be presented in 2012.

In 2010, Pfizer, in collaboration with the 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, 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. We anticipate that this trial will be modified in 2012 to include a third treatment arm where patients will receive the combination of neratinib plus trastuzumab plus paclitaxel prior to having surgery to remove their tumors. We anticipate that enrollment in all three arms of this trial will continue in 2012.

Table of Contents

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

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

PB272 (neratinib (intravenous))

We also plan to develop neratinib as an intravenously administered agent. In pre-clinical studies the intravenous version of neratinib resulted in higher exposure levels of neratinib in pre-clinical models. We believe that this may result in higher blood levels of neratinib in patients, which may translate into better efficacy. We plan to file the Investigational New Drug application, or IND, for the intravenous formulation of neratinib in 2012.

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 2012.

Plan of Development

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

We also plan to conduct a Phase II clinical trial of neratinib in HER2 positive metastatic gastric cancer patients during 2012.

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.

Table of Contents

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

Competition

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

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

Intellectual Property and License Agreements

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

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

If we obtain marketing approval for neratinib or other drug candidates in the U.S. or in certain jurisdictions outside the U.S., we may be eligible for regulatory protection, such as five years of new chemical entity

Table of Contents

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

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

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

License Agreements

In August 2011, Puma entered into an agreement pursuant to which Pfizer agreed to grant to 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 license, it would not become effective until 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, 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, at our expense, 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

Table of Contents

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 to certain reductions and offsets in some circumstances. Our 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 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 New Drug Application, or 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

Table of Contents

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. The Company 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 Internal 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 it must monitor the study until it is completed. 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, the Company, 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. If a Phase III clinical trial is the subject of discussion at an end of Phase II meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or SPA. The purpose of which is to reach an agreement with the FDA on the design of the Phase III clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. 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 unless public health concerns unrecognized at the time of the protocol assessment are evident, and may not be changed except under a few specific circumstances.

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

Table of Contents

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 shelflife.

Assuming successful completion of the required clinical testing, the results of pre-clinical studies and of clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. An NDA must be accompanied by a significant user fee, which is waived for the first NDA submitted by a qualifying small business.

The testing and approval process requires substantial time, effort and financial resources. The agency reviews the application and may deem it to be inadequate to support the registration, and companies 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 usually will inspect the facility or the facilities at which the drug 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 an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA s satisfaction, the FDA will issue an approval 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.

The FDA may deny approval of an NDA by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. 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. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Alternatively, approval may occur with Risk Evaluation and Mitigation Strategies, or REMS, which limit the labeling, distribution or promotion of a drug product. Once issued, 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, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

Expedited Review and Approval. The FDA has various programs, including Fast Track, priority review and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a

Table of Contents

drug designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases, and to fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials.

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

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

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

Data and market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a

Table of Contents

certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to all of the pre-clinical studies, adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Foreign Regulation

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

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

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

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

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

Table of Contents

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 8 years of data exclusivity and 10 years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first 8 years of the 10 year marketing exclusivity period), we obtain an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product s first marketing authorization in the EU and prevents generics from relying on the marketing authorization holder s pharmacological, toxicological and clinical data for a period of 8 years. After 8 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 2 years later (or a total of 10 years after the first marketing authorization in the EU of the innovator product), or 3 years later (or a total of 11 years after the first marketing authorization in the EU of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the 8 year data exclusivity period. In Japan our products may be eligible for eight years of data exclusivity. There can be no assurance that we will qualify for such regulatory exclusivity, or that such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies.

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

Pricing and Reimbursement

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third-party payors, such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and the out-of-pocket obligations of member patients for such products. We may need to conduct pharmacoeconomic studies to demonstrate the cost effectiveness of our products for formulary coverage and reimbursement. Even with such studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

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

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

an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;

Table of Contents

a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period, or the donut hole; and

a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

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

Sales and Marketing

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

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

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

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

Table of Contents

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

Manufacturing

We do not currently have our own manufacturing facilities. We intend to continue to use our financial resources to accelerate development of our drug candidates rather than diverting resources to establish our own 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. We do not have any long-term agreements or commitments for these services. Likewise, we do not have any long-term agreements or commitments with vendors to supply the underlying component materials of our drug candidates, some of which are available from only a single supplier. While our drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. We intend to continue those relationships to maintain our supply of the drug candidates. We began this process following the closing of the Merger, though we cannot assure you that we will be successful in maintaining all or any of those relationships.

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

Other Laws and Regulatory Processes

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the United States, including laws relating to the oversight activities of the Securities and Exchange Commission, or SEC, and, if any of our capital stock becomes listed on a national securities exchange, we will be subject to the regulations of such exchange on which our shares are traded. 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

Table of Contents

disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights or acquisitions may be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation that might result from future legislation or administrative action cannot accurately be predicted.

Research and Development Expenses

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

Employees

As of December 31, 2011, we have 18 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 23 additional full-time employees devoted to clinical activities, seven 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 clinical research organizations and third parties to perform our clinical studies and manufacturing.

Available Information

Our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge via our website (*www.pumabiotechnology.com*) as soon as reasonably practicable after they are filed with, or furnished, to the SEC.

Table of Contents

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 Relating to our Business

We currently have no product revenues or 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 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 is approved by the FDA for sale in the United States or by other regulatory authorities for sale outside the United States. Moreover, each of these drug candidates is in the early stages of development and will require significant time and capital before we can even apply for approval from the FDA. Therefore, for the foreseeable future we do not expect to achieve any product revenues and will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants, and potentially future offerings of our securities. Currently, we believe that our cash on hand is sufficient to fund our operations for the next 12 months. However, changes may occur that would consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional drug candidates and changes in regulation. We will need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in 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 Puma on October 4, 2011. 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 commence 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.

Table of Contents

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

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

- we may not be able to demonstrate that neratinib (oral) is safe and effective as a treatment for our targeted indications to the satisfaction of the FDA;
- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the clinical research organization, or CRO, that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA may not find the data from pre-clinical studies and clinical studies sufficient to demonstrate that the clinical and other benefits of neratinib (oral) outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our pre-clinical studies and clinical studies or may require that we conduct additional studies;
- the FDA may not accept data generated at our clinical study sites;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application;
- the advisory committee may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy as a condition of approval;

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

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

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

As of December 31, 2011, we had 18 employees, including our President and Chief Executive Officer, our Senior Vice President, Finance and Administration and Treasurer, and our Senior Vice President, Regulatory Affairs, Quality Assurance and Pharmacovigilance. Our future success depends on our ability to identify, attract,

Table of Contents

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. During the next year, we intend to hire up to 23 additional full-time employees devoted to clinical activities, seven additional full-time employees for the regulatory and quality assurance function, and three additional full-time employees devoted to general and administrative activities. 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.

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

Each of our drug candidates is still in development and will require extensive clinical testing before we are prepared to submit an NDA for regulatory approval. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for any of our drug candidates or whether any such NDA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials of our drug candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- failure to obtain regulatory and IRB 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 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.

Table of Contents

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

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

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

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

Physicians and patients may not accept and use our drugs.

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

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

cost-effectiveness of our product relative to competing products;

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

effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

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

We depend upon independent investigators and collaborators, such as CROs, universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with

Table of Contents

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. We currently have no agreements for the clinical or commercial-scale manufacture of our drug candidates. We intend to enter into agreements with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our clinical trials. While our drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. We intend to continue those relationships to maintain our supply of the drug candidates; however, we cannot assure you that we will be able to continue those relationships on commercially reasonable terms, if at all. If we are unable to continue those relationships, 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 will rely on one or more third-party contractors to manufacture the commercial supply of our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP regulations and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay (i) our clinical trials, (ii) the approval, if any, of our drug candidates by the FDA or (iii) the commercialization of our drug candidates; or result in higher costs or deprive us of potential product revenues.

Table of Contents

We are subject to uncertainty relating to reimbursement policies which, if not favorable to our drug candidates, could hinder or prevent our products commercial success.

Our ability to commercialize our drug candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish appropriate coverage and reimbursement levels for our drug candidates and related treatments. As a threshold for coverage and reimbursement, third-party payors generally require that drug products be approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not be able to obtain third-party coverage or reimbursement for our products in whole or in part.

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.

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

In March 2010, PPACA became law in the United States. PPACA substantially changed and will continue to change the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA, of greatest importance to the pharmaceutical industry are the following:

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

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

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

Table of Contents

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

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

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

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

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

a licensure framework for follow-on biologic products; and

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

A number of states have challenged the constitutionality of certain provisions of the PPACA, and many of these challenges are still pending final adjudication in several jurisdictions, including the U.S. Supreme Court. Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or in its entirety.

We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict all of the ways in which future federal or state legislative or administrative changes relating to healthcare reform will affect our business. Nevertheless, we anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Thus, we expect to experience pricing pressures in connection with the sale of neratinib (oral), neratinib (intravenous), PB357, and any other products that we may develop, due to the trend toward managed health care, 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 health care fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

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

24

Table of Contents

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 of a good or service for which payment may be made under a federal health care program, such as Medicare and Medicaid. 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 health care 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 health care programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

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

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

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

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

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

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have oncology compounds that have already been approved or are in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in the following:

developing drugs;

undertaking pre-clinical testing and clinical trials;

Table of Contents

obtaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from the following:

government and health administration authorities;

private health maintenance organizations and health insurers; and

other health care payors.

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

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

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

Our success and future growth depends to a significant degree on the skills and continued services of our management team, in particular Alan H. Auerbach, our President and CEO. 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.

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.

26

Table of Contents

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaborators or customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our collaboration partners or customers may experience reductions in revenues, profitability and/or cash flow that could lead them to modify, delay or cancel orders for our products once commercialized. If collaboration partners or customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. This, in turn, could adversely affect our financial condition and liquidity. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, prior to the effectiveness of certain provisions of the PPACA, a substantial number of people may become uninsured or underinsured. To the extent economic challenges result in fewer individuals pursuing or being able to afford our products once commercialized, our business, results of operations, financial condition and cash flows could be adversely affected.

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

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

Risks Related to Our Intellectual Property

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 neratinib (oral), neratinib (intravenous) and PB357 in the United States and certain other specified countries or to perform our other diligence obligations under the license agreement 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.

Table of Contents

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

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

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

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

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

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

Table of Contents

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 third-party intellectual property rights in our field are 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 United States 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.

Table of Contents

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

There is currently no market for our common stock and there can be no assurance that any market will ever develop. You may therefore be unable to re-sell shares of our common stock at times and prices that you believe are appropriate.

Our common stock is not listed on a national securities exchange, an over-the-counter market or any other exchange. Therefore, there is no trading market, active or otherwise, for our common stock and our common stock may never be included for trading on any stock exchange, automated quotation system or any over-the-counter market. Accordingly, our common stock is highly illiquid and you will likely experience difficulty in re-selling such shares at times and prices that you may desire.

Our common stock may not be eligible for listing or quotation on any securities exchange.

We do not currently meet the initial quantitative listing standards of any national securities exchange. We cannot assure you that we will be able to meet the initial listing standards of any national securities exchange, or, if we do meet such initial listing standards, that we will be able to maintain any such listing. Further, the national securities exchanges have adopted so-called seasoning rules that require that we meet certain requirements, including prescribed periods of time trading over-the-counter and minimum filings of periodic reports with the SEC, before we are eligible to apply for listing on such national securities exchanges. We have contacted an authorized market maker for an over-the-counter quotation system for sponsorship of our common stock, but we cannot guarantee that our common stock will be listed and quoted for sale. Even if our common stock is quoted for sale on an over-the-counter quotation system, buyers may be insufficient in numbers to allow for a robust market and it may prove impossible to sell your shares. In addition, an investor may find it difficult to obtain accurate quotations as to the market value of our common stock. In addition, if we fail to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect its liquidity. This would also make it more difficult for us to raise additional capital.

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

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

The designation of our common stock as a penny stock would limit the liquidity of our common stock.

Our common stock may be deemed a penny stock (as that term is defined under Rule 3a51-1 of the Exchange Act) in any market that may develop in the future. Generally, a penny stock is a common stock that

Table of Contents

is not listed on a securities exchange and trades for less than $5.00 a share. Prices often are not available to buyers and sellers and the market may be very limited. Penny stocks in start-up companies are among the riskiest equity investments. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stocks and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser s written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. Because of the penny stock rules, there may be less trading activity in penny stocks in any market that develops for our common stock in the future and stockholders are likely to have difficulty selling their shares.

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 significant dilutive effect to stockholders and a material decrease in our 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 any of our outstanding warrants, holders of our common stock may experience immediate dilution and the market price of our common stock may be adversely affected.

In connection with the Merger, we assumed the warrants issued by Puma in a private placement to certain investors that provides such investors with anti-dilution protection in regard to certain issuances. The warrants are exercisable only if we sell securities at a price below $3.75 per share on or prior to the date on which shares of our common stock are first quoted in an over-the-counter market or listed for quotation on any national securities exchange or trading system. The warrants automatically terminate ten days after our common stock is quoted on an over-the-counter market or listed for quotation on a national securities exchange or trading system if we have not previously sold securities for less than $3.75 per share. Otherwise, the warrants have a ten-year term and an exercise price of $0.01 per share. If triggered, each warrant becomes exercisable for the number of shares of our common stock as would equal the difference between (i) the number of shares purchased by the warrant holder in Puma s private placement and (ii) the number of shares that could have been purchased by such holder in the private placement at a purchase price equal to the lowest price associated with any subsequent issuance of our common stock.

In connection with the Merger, we assumed a warrant issued to Mr. Auerbach by the former Puma entity. This warrant is exercisable only in the event that we conduct an additional offering of our securities resulting in gross cash proceeds to us of at least $15 million, excluding certain types of financings that occur within a specified time period after the closing of the Merger. This warrant has a ten-year term, an exercise price equal to the price paid per share in such additional offering, and is exercisable for the number of shares of our common stock as would be necessary for Mr. Auerbach to maintain, as calculated under the terms of the warrant, ownership of 20% of our outstanding shares of common stock after such additional offering.

If any of our outstanding warrants are 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 will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We will also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the

Table of Contents

Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC or any stock exchange or inter-dealer quotations system on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities 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 required to comply with Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors. 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.

Because the Merger was a reverse merger, we may not be able to attract the attention of major brokerage firms.

Additional risks may exist as a result of our becoming a public reporting company through a reverse merger. Certain SEC rules are more restrictive when applied to reverse merger companies, such as the ability of stockholders to re-sell their shares of common stock pursuant to Rule 144. In addition, securities analysts of major brokerage firms may not provide coverage of our capital stock or business. Because we became a public reporting operating company through a reverse merger, there is no incentive to brokerage firms to recommend the purchase of our common stock. We cannot assure you that brokerage firms will want to provide analyst coverage of our capital stock or business in the future.

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 filed, at our expense, a registration statement, which was declared effective by the SEC on February 14, 2012, registering the resale of 16,000,000 shares of our common stock. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for investors in our common stock to sell shares of our common stock at times and prices that such investors feel are appropriate. Furthermore, we expect that, because there are a large number of shares registered pursuant to the resale registration statement, the selling

Table of Contents

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.

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 13,254 square feet of office space in the building located at 10880 Wilshire Boulevard for use as our corporate headquarters. Our lease commenced in December 2011 and terminates in December 2018, 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 pending legal proceedings and are not aware of any threatened or contemplated legal proceedings against us.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

Table of Contents

Part II

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

Market for Common Stock

There is not currently, and there has never been, any market for any of our securities. Our securities are not currently eligible for trading on any national securities exchange or NASDAQ. We have arranged for a registered broker-dealer to apply to have our common stock quoted on the OTC Bulletin Board and the OTCQB Market; however, there is no guarantee that our common stock will be quoted on such markets or any other over-the-counter market.

Record Holders

As of March 16, 2012, we had approximately 167 holders of record of our common stock.

Dividends

We have not paid or declared any dividends on our common stock and we do not anticipate paying dividends on our common stock in the foreseeable future.

Recent Sales of Unregistered Securities; Repurchases of Securities

Other than the sales of unregistered securities that we reported in Quarterly Reports on Form 10-Q or Current Report on Form 8-K during fiscal year 2011, we did not make any sales of unregistered securities during 2011.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

ISSUER PURCHASES OF EQUITY SECURITIES(1)

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) that May Yet Be Purchased Under the Plans or Program
Month #1 (October 1 to 31, 2011)	3,000,000	$ 0.013		
Month #2 (November 1 to 30, 2011)				
Month #3 (December 1 to 31, 2011)				
Total	3,000,000	$ 0.013		

(1) Following the closing of the Merger with Puma, pursuant to the terms of a Redemption Agreement dated October 4, 2011, or the Redemption Agreement, between us and our stockholders immediately prior to the Merger, we completed the repurchase of an aggregate 3,000,000 shares of common stock from our former stockholders for consideration of an aggregate of $40,000. The 3,000,000 shares constituted all of the issued and outstanding shares of our common stock, on a fully-diluted basis, immediately prior to the Merger. Upon completion of the Merger and the redemption, the former stockholders of Puma held 100% of the outstanding shares of our common stock.

ITEM 6. SELECTED FINANCIAL DATA

As a smaller reporting company, we are not required to provide the information required by this Item.

Table of Contents

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes that appear elsewhere in this Annual Report. The following discussion includes forward-looking statements that reflect our plans, estimates and beliefs and involve risks and uncertainties. As a result of many factors, such as those set forth under Risk Factors in Item 1A of this Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.

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 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.

Currently, a large portion of our expenses have been related to execution of our license agreement, hiring of staff and the build out of our corporate infrastructure. As we proceed with clinical development of PB272 (neratinib (oral)), and as we further develop PB272 (neratinib (intravenous)), and PB357, our second and third product candidates, respectively, our research and development expenses will increase significantly. To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance research and development will increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance product development. Our major sources of working capital have been proceeds from private sales of our common stock.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs and fees paid to consultants. We expense our R&D costs as they are incurred.

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 Puma in the Merger. As a result of this transaction, Puma become our wholly-owned subsidiary and subsequently merged with and into us. Upon completion of the Merger, Puma merged with and into us, leaving us as the surviving corporation, and we adopted Puma s business plan and changed our name to Puma Biotechnology, Inc.

The Merger was accounted for as a reverse acquisition whereby 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 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 Puma, the historical operations of 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.

Table of Contents

Results of Operations

Years Ended December 31, 2011 and 2010

General and administrative expenses:

For the year ended December 31, 2011, general and administrative, or G&A, expenses were approximately $9,319,600 compared to $6,900 for 2010. During 2011, the majority of our G&A expenses were associated with acquiring our drug candidates, executing two private equity placements, executing a reverse merger and beginning to build out our corporate infrastructure. During the fourth quarter of 2011, we began hiring staff and recorded approximately $481,300 of payroll and payroll-related expenses. We incurred approximately $858,900 in professional fees associated with the licensing of three drug compounds, executing the reverse merger, and filing various forms with the SEC in 2011. The Company also incurred approximately $52,000 in travel expense related to licensing our drug compounds and executing the two private placements. During 2011, we incurred approximately $47,000 in accounting fees associated with our 2010 audit, filing of a short-year tax return, and review of our SEC filings. Rent expense for 2011 was approximately $41,000 compared to $0 of rent expense for 2010. We anticipate our rent expense for 2012 to be approximately $500,000. Also included in 2011, was $32,700 of expenses related to an investor relations consultant. Additionally, we incurred approximately $32,200 in expenses associated with the implementation of a financial reporting system. We incurred approximately $31,000 of printing expense, mainly associated with our SEC filings and print material for our equity placements. During 2011, approximately $29,500 of stock-based compensation issued to employees was included in G&A expenses. Also included in stock-based compensation was $7,585,600 related to the issuance of an anti-dilutive warrant issued to our CEO (see note 7 of the accompanying financial statements). The remaining expenses of approximately $128,400 are associated with the commencement of operations and include such items as business insurance, office supplies, telecommunication cost and banking fees. We expect our G&A expenses, excluding stock-based compensation, to increase significantly for fiscal year 2012 as our cost for 2011 reflects only four months of activity.

Research and development expenses:

For the year ended December 31, 2011, research and development, or R&D, expenses were approximately $826,400 compared to $0 for the prior year. Approximately $696,000 of the total expenses incurred were related to payroll associated with the hiring of 14 employees. Our payroll cost will continue to grow, as the current plan is to hire an additional 30 employees in 2012. We also incurred approximately $38,000 in recruiting expense during 2011 and expect this cost to increase as we hire additional employees. We also incurred approximately $43,000 in consulting expense during 2011. During 2011, approximately $37,500 of stock-based compensation was included in R&D expenses. The remaining expenses of approximately $11,900 were related to travel expenses and office supplies. During 2012, we expect to spend approximately $20 million to $25 million in R&D expenses as we begin to actively manage the existing clinical trials and potentially commence additional clinical trials.

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

Table of Contents

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

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

Liquidity and Capital Resources

Operating Activities

We reported a net loss of approximately $10.2 million and negative cash flow from operating activities of approximately $1.8 million for the year ended December 31, 2011. Our net loss from Puma s date of inception, September 15, 2010, to December 31, 2011, amounted to approximately $10.2 million, while negative cash flow from operating activities amounted to approximately $1.8 million.

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

We anticipate that our cash on hand, including our cash equivalents as of December 31, 2011, will be sufficient to enable us to meet our anticipated expenditures for at least the next 18 months. We expect to continue incurring significant losses for the foreseeable future. Our continued operations will depend on whether we are able to raise additional funds through either strategic alliance with a third party concerning one or more of our product candidates or through additional equity or debt financing. Through December 31, 2011, a significant portion of our financing has primarily been through private placements of our equity securities. We will continue to fund operations from cash on hand 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.

Investing Activities

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

Table of Contents

Financing Activities

October 2011 Common Stock Offering. Immediately prior to the Merger, pursuant to 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. We assumed these warrants in the Merger and they are exercisable only if we sell securities at a price below $3.75 per share on or prior to the date on which shares of our common stock are first quoted in an over-the-counter market or listed for quotation on a national securities exchange or trading system if we have not previously sold securities for less than $3.75 per share. Otherwise, the warrants have a ten-year term and an exercise price of $0.01 per share.

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, in connection with Leerink Swann LLC, or Leerink, acting as Puma s placement agent in this private placement, we paid Leerink $2,338,215 as compensation for its services and $75,000 for reimbursable expenses.

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

Current and Future Financing Needs

We have incurred negative cash flows from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and development efforts. Given the current and desired pace of clinical development of our three product candidates, over the next 12 months we estimate that our research and development spending will be approximately $20 million to $25 million. We will need approximately $5 million to $6 million for general and administrative expenses over the next 12 months. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control.

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.

Contractual Obligations

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

Table of Contents

Off-Balance Sheet Arrangements

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

Critical Accounting Policies

Research and Development

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

Investment Securities

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

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

Warrants Issued with Private Placement:

In connection with the October 2011 Securities Purchase Agreement, the Company issued anti-dilutive warrants to 27 investors (see Note 6 of the accompanying financial statements). The fair value of warrants were estimated at the date of issuance using the Monte Carlo Simulation method. As the Company has no trading history, the Company calculated the expected volatility based on the historical volatilities of nine companies with similar attributes to the Company including industry, stage of life cycle, size and financial leverage. The risk-free rate was based on the U.S. Treasury yield curve covering the term of the warrants.

Table of Contents

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

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

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

Stock-based Compensation

As required, we adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, or ASC 718, *Compensation Stock Compensation*. ASC 718 requires the fair value of all stock-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Adoption of the fair value method required by ASC 718 will have a material impact on our results of operations, although it will have no impact on our cash flows or our overall financial position. Because of the variability in the assumptions used in the valuation of stock options granted and the variability in the quantity and other terms of stock-based awards we may issue in the future, our ability to predict future stock-based compensation expense is limited. Under ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The Company recognizes the valuation of each stock option grant over the service period of the grant, which normally commences with the grant date but can precede the grant date. Our 2011 financial statements reflect stock option grants issued to our employees where the service period commenced prior to their grant date of 2012. The amounts recognized in the financial statements related to employee stock-based compensation were approximately $67,000 and $0 for the years ended December 31, 2011 and 2010, respectively, and were included in general and administrative expenses and research and development expenses. Also included in stock-based compensation expense for 2011 was approximately $7.6 million related to the anti-dilutive warrant issued to our CEO on October 4, 2011, compared to $0 expense in 2010 (see note 7 of the accompanying financial statements).

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

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

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

Table of Contents

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

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

We will revalue the warrant each reporting period until such time as the grant date of the warrant is determined.

Recently Issued Accounting Standards

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

In May 2011, FASB issued Accounting Standards Update No. 2011-04, or ASU 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, which clarifies some existing concepts and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. ASU 2011-04 was effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-04 to have a material effect on its financial condition, profitability, and cash flows.

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to disclose the information required by this Item.

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.

41

Table of Contents

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 Securities Exchange Act of 1934, as amended, or 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, as appropriate, to allow timely decisions regarding required disclosure. 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, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of December 31, 2011. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance have concluded that these disclosure controls and procedures were effective as of December 31, 2011.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2011, 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 generally accepted accounting principles in the United States.

Under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2011. 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, our management concluded that as of December 31, 2011, our internal control over financial reporting was effective at the reasonable assurance level.

The Company s internal control over financial reporting was not subject to attestation by the Company s registered public accounting firm pursuant to the rules of the SEC that permit the Company, as a smaller reporting company, to provide only management s report in this annual report.

ITEM 9B. OTHER INFORMATION

Not applicable.

Table of Contents

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Incorporated by reference to our definitive Proxy Statement for the 2012 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2011.

ITEM 11. EXECUTIVE COMPENSATION

Incorporated by reference to our definitive Proxy Statement for the 2012 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2011.

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

Incorporated by reference to our definitive Proxy Statement for the 2012 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2011.

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

Incorporated by reference to our definitive Proxy Statement for the 2012 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2011.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Incorporated by reference to our definitive Proxy Statement for the 2012 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2011.

Part IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

Financial Statement Schedules.

(a) Documents Filed as Part of Report

(1) Financial Statements.

(2) Financial Statement Schedules.

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 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.

Table of Contents

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 29, 2012.

PUMA BIOTECHNOLOGY, INC.

By: /s/ Alan H. Auerbach
Alan H. Auerbach
President & Chief Executive Officer

(Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alan H. Auerbach and Charles R. Eyler, and each or any one of them, each with the power of substitution, his or her attorney-in-fact, to sign any amendments to this report, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

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	President, Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2012
/s/ Charles R. Eyler Charles R. Eyler	Senior Vice President, Finance and Administration and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2012
/s/ Thomas R. Malley Thomas R. Malley	Director	March 29, 2012

Table of Contents

EXHIBIT INDEX

Exhibit		Incorporation by Reference		
No.	**Description**	**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	Form of Warrant to Purchase Shares of Common Stock of Puma Biotechnology, Inc., dated October 4, 2011, issued to investors in private placement	8-K	4.1	10/11/2011
4.3	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	Redemption Agreement, dated October 4, 2011, by and among Innovative Acquisitions Corp., Robert Johnson, Faraaz Siddiqi and Kapil Munjal	8-K	10.2	10/11/2011
10.3	Indemnity Agreement, dated as of September 29, 2011, by and among Innovative Acquisitions Corp., Puma Biotechnology, Inc., Robert Johnson, Faraaz Siddiqi and Kapil Munjal	8-K	10.1	10/4/2011
10.4	Puma Biotechnology, Inc. 2011 Incentive Award Plan, assumed in the Merger	8-K	10.4	10/11/2011
10.5+	Form of Stock Option Grant Notice and Stock Option Agreement, issued pursuant to the 2011 Incentive Award Plan			
10.6+	Form of Chief Executive Officer Stock Option Grant Notice and Stock Option Agreement, issued pursuant to the 2011 Incentive Award Plan			

Table of Contents

Exhibit No.	Description	Incorporation by Reference Form	Exhibit	Filing Date
10.7	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
10.8	Amendment No. 1 to Registration Rights Agreement	8-K	10.2	11/23/2011
10.9	Securities Purchase Agreement, dated October 4, 2011, by and among Puma, the investors listed on Schedule 1 attached hereto and the Company	8-K/A	10.6	12/16/2011
10.10	Letter Agreement, dated October 21, 2011, between the Company and Richard Phillips	8-K	10.1	10/27/2011
10.11	Letter Agreement, dated October 21, 2011, between the Company and Charles Eyler	8-K	10.2	10/27/2011
10.12	Form of Subscription Agreement	8-K	10.1	11/23/2011
10.13	Office Lease by and between Puma Biotechnology, Inc. and CA 10880 Wilshire Limited Partnership, executed on December 7, 2011	8-K	10.1	12/13/2011
10.14	Employment Agreement, dated January 19, 2012, by and between Puma Biotechnology, Inc. and Alan H. Auerbach	8-K	10.1	1/24/2012
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			

+ Filed herewith
* 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.
** In accordance with Rule 406(T) of Regulation S-T, the XBRL-related information in Exhibit 101 shall be deemed to be furnished and not filed and shall not be part of this Annual Report.

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A Development Stage Company)

Index To Financial Statements

Table of Contents

Report of Independent Registered Public Accounting Firm

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

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

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

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

/s/ PKF

San Diego, California
March 29, 2012

PKF
Certified Public Accountants

A Professional Corporation

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

BALANCE SHEETS

DECEMBER 31, 2011 AND 2010

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

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS

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

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF STOCKHOLDERS EQUITY

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

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

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CASH FLOWS

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

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

Note 1 Business and Basis of Presentation:

Business:

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

Basis of Presentation:

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

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

Note 2 Merger with Public Company:

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

At the effective time of the Merger, the Company s then issued and outstanding 18,666,733 shares of common stock were exchanged for 18,666,733 shares of common stock of IAC. At the effective time of the Merger, each share of the Company common stock that was outstanding immediately prior to the effective time was cancelled, with one share of the Company common stock issued to IAC. Concurrently, IAC redeemed all of

Table of Contents

its shares from its pre-Merger stockholders in exchange for an aggregate consideration of $40,000 paid by the Company. The Company paid $40,000 for IAC s professional fees associated with the Merger, directly to the service providers. Following the Merger and the redemption, the Company s prior stockholders owned the same percentage of IAC s common stock as they held of the Company s common stock prior to the Merger.

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

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

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

Note 3 Significant Accounting Policies:

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

Use of Estimates:

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

Cash and Cash Equivalents:

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

Investment Securities:

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

Assets Measured at Fair Value on a Recurring Basis:

ASC 820, *Fair Value Measurement* (ASC 820) provides a single definition of fair value and a common framework for measuring fair value as well as new disclosure requirements for fair value measurements used in

Table of Contents

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

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

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

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

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

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

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

Property and Equipment:

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

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been an impairment, by comparing the asset s carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. Should impairment exist, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through December 31, 2011.

Research and Development Expenses:

Research and development costs are charged to operations as incurred. Research and development expenses include costs associated with services provided by consultants who conduct research on behalf of the Company, contract organizations for manufacturing of clinical materials and clinical trials. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is

Table of Contents

recognized over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. The Company determines the total cost of a given study based on the terms of the related contract. The Company accrues for costs incurred as services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in that period. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

Concentration of Risk:

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

Stock-Based Compensation:

Stock option awards:

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

Warrants:

Warrants granted to employees are normally valued at the fair value of the instrument on the date of the grant (grant date) and are recognized in the statement of operations over the requisite service period. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Monte Carlo Simulation Method. As allowed by ASC 718 for companies with a short period of publicly traded stock history, the Company s estimate of expected volatility is based on the average volatilities of a sampling of nine companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value, the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair market value of the warrant at the time of issuance as stock based compensation as an equity transaction. The warrant is then revalued each reporting period up to the grant date when the final fair value of the warrant is established and recorded.

Income Taxes:

The Company follows ASC 740, *Income Taxes* (ASC 740), which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial

Table of Contents

statements or tax returns. Under this method, deferred tax assets and liabilities are based on the differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

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

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

Net Loss per Common Share:

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

Deferred Rent:

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

Reclassifications:

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

Recently Issued Accounting Pronouncements:

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

In May 2011, the FASB issued Accounting Standards Update (ASU) 2011-04, Fair Value Measurement (Topic 820): *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS,* which clarifies some existing concepts and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. ASU 2011-04 will be effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-04 to have a material effect on its financial condition, profitability, and cash flows.

Table of Contents

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

Note 4 Property and Equipment:

Property and equipment at December 31 consisted of the following:

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

Note 5 Accrued Expenses:

Accrued expenses at December 31 consisted of the following:

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

Note 6 Private Placement and Other Offering:

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

In connection with the Securities Purchase Agreement, the Company entered into an agreement with Leerink Swann LLC (Leerink) whereby Leerink agreed to act as placement agent in connection with the placement of the common shares. In consideration for Leerink s services, the Company agreed to pay

Table of Contents

Leerink aggregate cash commissions equal to 6% of the gross cash proceeds from the equity placement not to exceed $3.6 million. The Company also agreed to pay Leerink up to $75,000 as a non-accountable reimbursement allowance. The Company paid Leerink $2,338,215 for services and $75,000 for reimbursable expenses for the private placement transaction. In addition, the Company agreed to reimburse an investor in the private placement for all of the reasonable fees and expenses associated with this agreement subject to a maximum aggregate amount of $125,000.

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

Note 7 Stockholder s Equity:

Common Stock:

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

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

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

Authorized Shares:

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

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

Warrants:

In connection with the October 2011 Securities Purchase Agreement, the Company issued anti-dilutive warrants to 27 investors (see Note 6). The fair value of warrants is estimated at the date of issuance using the Monte Carlo Simulation method. As the Company has no trading history, the Company calculated the expected

Table of Contents

volatility based on the historical volatilities of nine companies with similar attributes to the Company including industry, stage of life cycle, size and financial leverage. The risk-free rate was based on the U.S. Treasury yield curve covering the term of the warrants.

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

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

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

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

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

The Company determined that the warrant has an implied service requisite period that is prior to its grant date. The Company also determined that a market condition subsequent to the implied service period exists as the exercise or partial exercise of the warrant can only occur if there is a subsequent financing. The Company has recorded the fair market value as determined by the following assumptions using the Monte Carlo Simulation method, as stock-based compensation in its statement of operations:

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

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

Table of Contents

Stock-Based Compensation:

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

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

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

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

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

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

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

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

Note 8 Stockholder Note Payable:

On September 2, 2011, the Company s CEO and sole stockholder at the time advanced the Company $150,000 to fund its operations until such time as the Company could complete an equity placement. The advance was unsecured, non-interest bearing and due on demand. On September 9, 2011, the advance was converted to an unsecured convertible promissory note. The note was a non-interest bearing note that could be

Table of Contents

converted into the Company s common stock at the option of the stockholder. The note was due and payable upon demand of the stockholder on or after the one-year anniversary of the date, if not converted prior to the maturity date. The Company s CEO converted the note into 40,000 shares of the Company s common stock on October 6, 2011 at a price of $3.75 per share.

Note 9 Income Taxes:

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

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

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

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

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

	2011	2010
Tax computed at the federal statutory rate	$ (3,479,000)	$ (2,400)
State taxes	(593,800)	(400)
Permanent items	24,300	
Change in valuation allowance	4,048,500	2,800

Total provision	$	$

Table of Contents

Note 10 Commitments and Contingencies:

Leases:

On February 4, 2011, the Company executed a lease agreement effective March 1, 2011 for new office space that requires monthly payments of $1,657 and expires on April 30, 2012.

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 is 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 balance sheets. Rent expense for the years ended December 31, 2011 and 2010 was $41,125 and $0, respectively.

Future minimum lease payments for each of the years subsequent to December 31, 2011 are as follow:

Year Ending December 31,	Amount
2012	$ 273,033
2013	548,795
2014	565,258
2015	582,216
2016	599,683
Thereafter	1,253,877
Total	$ 3,822,862

License Agreement:

In August 2011, the Company entered into an agreement pursuant to which Pfizer, Inc., or Pfizer, agreed to grant it a worldwide license for the development, manufacture and commercialization of neratinib (oral), neratinib (intravenous) and PB357, and certain related compounds. The license is exclusive with respect to certain patent rights owned by or licensed to Pfizer. 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, Pfizer continued to conduct the existing clinical trials on behalf of the Company at Pfizer s sole expense. At the Company s request, Pfizer has agreed to continue to perform certain services in support of the existing clinical trials, at the Company s expense for the first quarter of 2012.

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 Pfizer or any products containing any of these compounds, the Company will be obligated to pay to Pfizer 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 Pfizer 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.

Table of Contents

Note 11 Subsequent Events:

Employment Contract:

On January 19, 2012, the Company entered into an employment agreement with Alan H. Auerbach, the Company s President and CEO. The employment agreement governs the terms of Mr. Auerbach s employment since September 15, 2010 and expires on September 1, 2014, unless earlier terminated, with automatic one-year renewal terms unless either the Company or Mr. Auerbach gives written notice of termination 60 days prior to the end of the term. The employment agreement provides that Mr. Auerbach will receive an annual base salary of $470,000, retroactively effective to September 1, 2011, and will be eligible to receive an annual discretionary bonus in an amount up to 50% of his base salary. Per the employment agreement, Mr. Auerbach was granted an option to purchase 200,000 shares of Company common stock, which will vest as to 1/3 of the shares underlying the option on January 19, 2013, and as to 1/36 of the shares underlying the option on each monthly anniversary thereafter, subject to Mr. Auerbach s continued employment through the vesting dates.