PUMA BIOTECHNOLOGY, INC.
Form 8-K/A
December 16, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K/A

(Amendment No. 2)

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

Date of Report (date of earliest event reported): October 4, 2011

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-52811**	**77-0683487**

(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10940 Wilshire Blvd, Suite 600, Los Angeles, CA 90024

(Address of principal executive offices) (Zip Code)

(424) 248-6500

(Registrant s telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

The disclosures set forth in Item 2.01 hereof are hereby incorporated by reference into this Item 1.01.

Item 2.01. Completion of Acquisition or Disposition of Assets.

Pursuant to an Agreement and Plan of Merger dated September 29, 2011, or the Merger Agreement, by and among Innovative Acquisitions Corp., which is referred to herein as the Company, IAC Merger Corporation, a Delaware corporation and wholly-owned subsidiary of the Company, or Merger Sub, and Puma Biotechnology, Inc., a Delaware corporation, which is referred to hereinafter as Puma, Merger Sub merged with and into Puma, with Puma remaining as the surviving entity and a wholly-owned operating subsidiary of the Company. This transaction is referred to throughout this report as the Merger. The Merger was effective as of October 4, 2011, upon the filing of a certificate of merger with the Secretary of State of the State of Delaware.

At the effective time of the Merger, or the Effective Time, the legal existence of Merger Sub ceased and all of the 18,666,733 shares of Puma common stock, par value $0.0001 per share, that were outstanding immediately prior to the Effective Time were cancelled, with one share of Puma common stock issued to the Company. Simultaneously, the Company issued to the former holders of Puma common stock, in consideration of their capital stock of Puma, an aggregate of 18,666,733 shares of the Company s common stock, par value $0.0001 per share. In addition, Puma had certain warrants outstanding that reflected the right to acquire additional shares of Puma common stock in the event Puma issued additional securities for consideration below a specified level. In connection with the Merger, the Company assumed these warrants and these warrants became the right to acquire shares of Company common stock on the same terms and conditions.

Following the closing of the Merger, pursuant to the terms of a Redemption Agreement dated October 4, 2011, or the Redemption Agreement, by and among the Company and its then-current stockholders, the Company completed the closing of a redemption of an aggregate 3,000,000 shares of common stock, or the Redemption, from its former stockholders in consideration of an aggregate of $40,000, plus professional costs related to the transaction, not to exceed $40,000. The 3,000,000 shares constituted all of the issued and outstanding shares of the Company s capital stock, on a fully-diluted basis, immediately prior to the Merger.

As a condition to the Merger, the Company entered into an Indemnity Agreement dated September 29, 2011 with its former officers and directors, pursuant to which the Company 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 and certain related transactions. A copy of the Indemnity Agreement is filed herewith as Exhibit 10.3, and is incorporated hereby by reference.

Upon completion of the Merger and the Redemption, the former stockholders of Puma held 100% of the outstanding shares of capital stock of the Company. Accordingly, the Merger represents a change in control of the Company. As of the date of this report, there are 18,706,733 shares of the Company s common stock and no shares of the Company s preferred stock outstanding.

The Merger will be accounted for as a capital transaction. Upon effectiveness of the Merger, Puma s business plan became the business plan of the Company. Upon completion of the Merger, all management of the Company resigned and the management of Puma became the management of the Company.

The foregoing description of the Merger Agreement, the Redemption Agreement and the transactions contemplated thereby do not purport to be complete and are qualified in their entireties by reference to the Merger Agreement and the Redemption Agreement, copies of which are filed as Exhibits 2.1 and 10.2, respectively, hereto and are hereby incorporated by reference herein.

Following the Merger on October 4, 2011, the Company s board of directors approved a transaction pursuant to which Puma merged with and into the Company, leaving the Company as the surviving corporation. This transaction is referred to throughout this report as the Short-Form Merger. In connection with the Short-Form Merger, the Company relinquished its corporate name and assumed in its place the name Puma Biotechnology, Inc. The Short-Form Merger and name change became effective on October 4, 2011, upon the filing of a Certificate of Ownership and Merger with the Secretary of State of the State of Delaware. The Certificate of Ownership and Merger is filed as Exhibit 3.2 hereto, and is incorporated herein by reference.

DESCRIPTION OF THE BUSINESS OF PUMA BIOTECHNOLOGY, INC.

Overview

We were originally incorporated in the State of Delaware in April 2007 under the name Innovative Acquisitions Corp. Innovative Acquisitions Corp., or Innovative Acquisitions, was a shell company registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act, with no specific business plan or purpose until it acquired Puma Biotechnology, Inc., or Puma, a Delaware corporation, through a merger transaction on October 4, 2011. Puma was a development stage company formed in September 2010 focused primarily on acquiring and developing pharmaceutical technologies. As a result of the Merger, Puma became the wholly-owned subsidiary of Innovative Acquisitions and subsequently merged with and into Innovative Acquisitions. As a result of the subsequent merger, Innovative Acquisitions changed its name to Puma Biotechnology, Inc. and adopted the business of the former Puma entity. As used herein, the words the Company, Puma, we, us, and refer to the current Delaware corporation operating the business acquired from Puma.

Puma is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. We focus on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then 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, gastric cancer patients and melanoma 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 HER2 positive metastatic breast cancer. Studies show that approximately 20% to 25% of breast cancer tumors have an over-expression of the human epidermal growth factor receptor type 2, or 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 of 22.3 weeks for patients that had

previously been treated with trastuzumab and an objective response rate of 56% and median progression free survival of 39.6 weeks for patients that 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.

As of October 4, 2011, we have licensed the exclusive worldwide rights to our current drug candidates from Pfizer Inc., 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 HER4 mutated melanoma; 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 founder and chief executive officer, Alan Auerbach, has extensive experience in identifying and developing drug candidates for use in the treatment of cancer. Prior to founding Puma, he was the founder and chief executive officer of Cougar Biotechnology, Inc. While at Cougar, Mr. Auerbach was responsible for in-licensing and developing abiraterone acetate for the treatment of advanced prostrate cancer, which he progressed into two Phase III clinical trials before Cougar was purchased by Johnson & Johnson in 2009.

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 overexpression 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 overexpress 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 using 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.

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), 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 employed by Pfizer, 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 HER4 mutated melanoma, 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.

Product Development Pipeline

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, gastric cancer and melanoma. 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 that have failed first-line therapy, including treatment with trastuzumab. Currently, the treatment of metastatic breast cancer that has 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 Results for Neratinib in Patients with Metastatic Breast Cancer

Trials of Neratinib as a Single Agent. In 2009, Pfizer presented data at the 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. The 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. The efficacy results from the trial showed that the objective response rate was 24% for patients who had received prior trastuzumab treatment and was 56% for patients with no prior trastuzumab treatment. Furthermore, the median progression free survival was shown to be 22.3 weeks for the patients who had received prior trastuzumab and 39.6 weeks for the patients who had not received prior trastuzumab.

Trials of Neratinib in Combination with other Anti-Cancer Drugs. 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 progression free survival of 63.1 weeks.

Pfizer also presented data from a second Phase II trial at the 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 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 that had received prior treatment with lapatinib, the overall response rate was 50%. The combination of vinorelbine and neratinib was generally well tolerated.

A third Phase II study of neratinib administered in combination with the anti-cancer drug capecitabine in patients with metastatic HER2 positive metastatic breast cancer, is currently ongoing. We anticipate initial results from this trial in late 2011 or early 2012.

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. In June 2011, Pfizer announced the results of the Phase I portion of this trial at the American Society of Clinical Oncology Meeting. The Phase I results showed that for the six patients treated at the maximum tolerated dose, four (67%) patients had a confirmed partial response and one (17%) patient had stable disease that lasted for greater than six months. Enrollment in this trial is continuing and the trial is currently ongoing. We expect additional data from this trial to be presented in 2012.

Discontinued Studies. Pfizer had previously been sponsoring two additional clinical trials of neratinib. The first trial, referred to as the NEfERTT trial, is 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, is 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 is being 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. PB 357 is structurally similar to PB272. Pfizer had completed single dose Phase I trials of PB357. We are evaluating PB357 and considering options relative to its development in 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 when given 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 and in patients with HER4 mutated melanoma 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.

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, or the EU, is conducted in accordance with applicable EU standards, such as the EU Clinical Trials Directive (Directive 2001/20/EC of April 4, 2001), or the EU Clinical Trials Directive, and the national laws of the Member States of the EU implementing its provisions.

Intellectual Property

As of October 4, 2011, we hold a worldwide exclusive license under our license agreement with Pfizer to 4 granted U.S. patents and 9 pending U.S. patent applications, as well as foreign counterparts thereof and other patent applications and patents claiming priority therefrom.

In the United States, we have a license to an issued patent for the composition of matter of neratinib, our lead compound, which currently will expire in 2025. 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 2030. 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 of the United States covering additional therapeutic uses and polymorphs of neratinib from these existing applications. In addition, we will pursue patent protection for any new discoveries or inventions made in the course of our development of neratinib.

If we obtain marketing approval for neratinib or other drug candidates in the United States or in certain jurisdictions outside of the United States, we may be eligible for regulatory protection, such as five years of new chemical entity exclusivity and as mentioned below, up to five years of patent term extension potentially available in the United States under the Hatch-Waxman Act, 8 to 11 years of data and marketing exclusivity potentially available for new drugs in the European Union, up to five years of patent extension in Europe (Supplemental Protection Certificate), and eight years of data exclusivity 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 will 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 will in the future rely on trade secret

protection and confidentiality agreements to protect our interests. To this end, we plan to 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.

Pfizer License

In August 2011, we entered into an agreement pursuant to which Pfizer agreed to grant us a worldwide license for the development, manufacture and commercialization of neratinib (oral), neratinib (intravenous) and PB357, and certain related compounds. Pursuant to the terms of the license, it did not become effective until we closed a capital raising transaction in which we raised at least $25 million. Upon the closing of the financing that preceded the Merger, we satisfied this condition. As a result, we only recently received the rights to the products licensed in the Pfizer agreement. The license is exclusive with respect to certain patent rights owned or licensed to Pfizer. Under the license agreement, Pfizer is obligated to transfer to Puma 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 agreed 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 to 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 further out-of-pocket costs of completing 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 substantial payments upon the achievement of certain milestones totaling $187.5 million, if all such milestones are achieved. Should we commercialize any of the compounds licensed from Pfizer or any products containing any of these compounds, we will be obligated to pay to Pfizer incremental annual royalties between approximately 10% and 20% of net sales of all such products, subject 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 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 by such other party of a material obligation 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.

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 being manufactured by third-party contractors. We intend to continue those relationships to maintain our supply of the drug candidates. We expect to begin 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 the 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.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. We do, however, have worldwide commercialization rights for our drug candidates. In order to commercialize any of our drug candidates if and when they are approved for sale in the United States or elsewhere, we will need to develop the necessary marketing, sales and distribution capabilities.

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 us 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.

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 Applications, 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 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 the 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 independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the study protocol and informed consent information for study subjects for any clinical trial before it commences at that center, and 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 1 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 2 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 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. Phase 3 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 1, Phase 2 or Phase 3 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 4 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 2, 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 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they

believe will support approval of the new drug. If a Phase 3 clinical trial is the subject of discussion at an end of Phase 2 meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, the purpose of which is to reach an agreement with the FDA on the design of the Phase 3 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 methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf-life.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the 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 an additional pivotal Phase 3 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 4 clinical trials, and surveillance programs to monitor the safety effects of approved products which 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 6 months as compared to a standard review time of 10 months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases, and that 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. Often times, 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 applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, or the USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

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

The Community MA, which is 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 which is 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, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, 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 make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor s generic product. For example, if any of our products receive marketing approval in the EEA, we expect they will benefit from 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 also 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 studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

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

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

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

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

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

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

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 can 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 can 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 is an increasing number of state laws that require manufacturers to provide 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.

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

Employees

As of the date of this report, we employed two employees, each of whom is full-time. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. We anticipate hiring up to 45 additional full-time employees devoted to research and development activities and up to 6 additional full-time employees for general and administrative activities over the next few years. In addition, we intend to use clinical research organizations and third parties to perform our clinical studies and manufacturing.

Properties

Our principal executive offices are located at 10940 Wilshire Boulevard, Suite 600, Los Angeles, California 90024, and are leased on a month-to-month basis. In order to accommodate additional employees and our increased operations, we intend to lease new space in the Los Angeles area and relocate our principal executive offices on or before December 1, 2011. Our telephone number is (310) 443-4150. We have no policies with respect to investments in real estate or interests in real estate, real estate mortgages, or securities of or interests in persons primarily engaged in real estate activities.

Legal Proceedings

We are not currently involved in any material legal proceedings.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, targets, likely, will, would, could, and similar expressions negative of those expressions or phrases identify forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. The sections in this report entitled Description of the Business of Puma Biotechnology, Inc., Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations as well as other sections in this report, discuss some of the factors that could contribute to these differences.

Other unknown or unpredictable factors also could harm our results. Consequently, actual results or developments anticipated by us may not be realized or, even if substantially realized, may not have the expected consequences to, or effects on, us. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements. Except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this report.

RISK FACTORS

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this Current Report on Form 8-K, you should carefully consider the factors discussed below when considering an investment in our common stock. If any of the events contemplated by the following discussion of risks should occur, our business, results of operations and financial condition could suffer significantly. As a result, you could lose some or all of your investment in our common stock. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Risks Related to Our Business

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

To date, we have generated no product revenues. Until, and unless, we receive approval from the 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. 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 September 2010 and, prior to entering into our license agreement with Pfizer in August 2011, our 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 the regulatory approval processes;
- formulating and manufacturing products;
- initiating and conducting sales and marketing activities; and
- implementing additional internal systems and infrastructure.

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

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

We currently have no products that are approved for commercial sale and 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, which regulations 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 its clinical studies may not meet the level of statistical or clinical significance required by the FDA for marketing approval;

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

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

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

the FDA may disagree with our interpretation of data from our pre-clinical studies and clinical studies or may require that we conduct additional studies;

the FDA may not accept data generated at our clinical study sites;

if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions;

the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;

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

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

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

We currently have only two employees, our President and Chief Executive Officer and our Senior Vice President, Finance and Treasurer. Our future success depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled scientific, technical, marketing, managerial and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite their collective efforts. We currently intend to hire up to 45 additional full-time employees devoted to research and development and 6 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 are 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.

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 depend 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 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 being 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 our clinical trials, the approval, if any, of our drug candidates by the FDA or the commercialization of our drug candidates or result in higher costs or deprive us of potential product revenues.

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

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

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

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

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

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

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new 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;

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

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

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

a licensure framework for follow-on biologic products; and

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

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. 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 its entirety.

We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict all of the ways in which future federal or state legislative or administrative changes relating to healthcare reform will affect our business. Nevertheless, we anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Thus, we expect to experience pricing pressures in connection with the sale of neratinib (oral), neratinib (intravenous), PB357 and any other products that we may develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payors and healthcare providers to use generic drugs that contain the active 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, financial condition and prospects.

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

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

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, 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 a False Claims Act action. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

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

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

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 already approved or 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:

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

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

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

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

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

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

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

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

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

We may be adversely affected by the current economic environment.

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

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

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.

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 these fields 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. Providing invalidity, in the United States, in particular, is difficult 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 product.

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 USPTO to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our filed foreign patent applications. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Additionally, any uncertainties resulting from the initiation and continuation of any litigation may have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit, the third party s patent is ultimately invalid or unenforceable, or we are ultimately found to have not infringed;

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a third party s patent;

- we may be ordered by a court to stop making, selling or licensing our products or technologies without a license from a patent holder, and such license may not be available on commercially acceptable terms, if at all, or may require us to pay substantial royalties or grant cross-licenses to our patents; and

we may have to redesign our products so that they do not infringe upon others patent rights, which may not be possible or could require substantial investment and/or time.

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

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

Risks Related to Owning our Common Stock

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 or over-the-counter trading system. 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 are adopting so-called seasoning rules that will 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 intend to contact an authorized market maker for an over-the-counter quotation system for sponsorship of our common stock, but we cannot guarantee that such sponsorship will be approved and our common stock 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 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.

We have no independent audit committee. Our full board of directors functions as our audit committee and only one of our directors is considered independent. This may hinder our board of directors effectiveness in fulfilling the functions of the audit committee.

We are not required to have an audit committee and have not established one. Our full board of directors functions as our audit committee and is comprised of two directors, only one whom is considered to be independent in accordance with the requirements of Rule 10A-3 under the Exchange Act. An independent audit committee plays a crucial role in the corporate governance process, assessing a company s processes relating to its risks and control environment, overseeing financial reporting and evaluating internal and independent audit processes. The lack of an independent audit committee may prevent our board of directors from being independent from management in its judgments and decisions and its ability to pursue the

committee s responsibilities without undue influence. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified, independent directors, the management of our business could be compromised.

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.

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 substantial expenses in connection with the preparation and filing of the registration statement required by our registration rights agreement and responding to SEC comments in connection with its review of the registration statement. We will also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules implemented by the 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 will be 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.

The shares of common stock issued in the Merger are restricted securities and, as such, may not be sold except in limited circumstances.

None of the shares of common stock issued in the Merger have been registered under the Securities Act of 1933, as amended, or the Securities Act, or registered or qualified under any state securities laws. The shares of common stock issued in the Merger were sold and/or issued pursuant to exemptions contained in and under those laws. Accordingly, such shares of common stock are restricted securities as defined in Rule 144 under the Securities Act and must, therefore, be held indefinitely unless registered under applicable federal and state securities laws, or an exemption is available from the registration requirements of those laws. The certificates representing the shares of common stock issued in the Merger reflect their restricted status.

We have agreed to register the shares of common stock issued in the Merger. There can be no assurance, however, that the SEC will declare the registration statement effective, thereby enabling the shares of common stock issued in the Merger to be freely tradable. In addition, Rule 144 under the Securities Act, which permits the resale, subject to various terms and conditions, of limited amounts of restricted securities after they have been held for six months will not immediately apply to our common stock because we were at one time designated as a shell company under SEC regulations. Pursuant to Rule 144(i), securities issued by a current or former shell company that otherwise meet the holding period and other requirements of Rule 144 nevertheless cannot be sold in reliance on Rule 144 until one year after the date on which the issuer filed current Form 10 information (as defined in Rule 144(i)) with the SEC reflecting that it ceased being a shell company, and provided that at the time of a proposed sale pursuant to Rule 144, the issuer has satisfied certain reporting requirements under the Exchange Act. We believe this requirement to file Form 10 information has been satisfied by the filing of this report on Form 8-K. Because, as a former shell company, the reporting requirements of Rule 144(i) will apply regardless of holding period, the restrictive legends on certificates for the shares of common stock issued in the Merger cannot be removed except in connection with an actual sale that is subject to an effective registration statement under, or an applicable exemption from the registration requirements of, the Securities Act.

If we are unable to register in a timely manner the shares of common stock issued to investors in the Merger, then the ability to re-sell shares of our common stock so issued will be delayed.

We have agreed, at our expense, to prepare a registration statement, and to cause our Company to file a registration statement with the SEC registering the resale of 14,666,733 shares of our common stock issued in connection with the Merger. There are many reasons, including some over which we have little or no control, which could keep the registration statement from being declared effective by the SEC, including delays resulting from the SEC review process and comments raised by the SEC during that process. Accordingly, in the event that the registration

statement is not declared effective within these timeframes, the shares of common stock proposed to be covered by such registration statement will not be eligible for resale until the registration statement is effective or an exemption from registration, such as Rule 144, becomes available. If the registration statement is not filed within 60 days of the closing of the Merger, then we may be subject to certain liquidated damages pursuant to the registration rights agreement we entered into with the holders of 14,666,733 shares of our common stock issued in connection with the Merger.

Because the Merger was a reverse merger, the registration statement we file with respect to the shares of common stock received by investors in the Merger might be subject to heightened scrutiny by the SEC, and 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, and the SEC may subject the registration statement we file with respect to the shares of common stock received by investors in the Merger to heightened scrutiny. 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. We have agreed, at our expense, to prepare a registration statement, and to cause our Company to file a registration statement with the SEC registering the resale of 14,666,733 shares of our common stock issued in connection with the Merger. Once effective, the registration statement will permit the resale of these shares at any time. 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 you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there will be a large number of shares registered pursuant to a registration statement, selling stockholders 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 an offering pursuant to a 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.

MANAGEMENT S DISCUSSION AND ANALYSIS

OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations of Puma Biotechnology, Inc. should be read in conjunction with the financial statements and the notes to those statements included in this Current Report on Form 8-K. This discussion includes forward-looking statements that involve risk and uncertainties. As a result of many factors, such as those set forth above under Risk Factors, actual results may differ materially from those anticipated in these forward-looking statements.

Overview

Since inception, our efforts and resources have been focused primarily on acquiring and developing our pharmaceutical technologies and recruiting personnel. We are a development stage company and have no product sales to date and we will not receive any product sales until we receive approval from the FDA or equivalent foreign regulatory bodies to begin selling our drug candidates. Developing such products, however, is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety issues during the course of developing our drug candidates, we do not expect to complete the development of a drug candidate for several years, if at all. Currently, we expect a large portion of our development expenses to relate to our lead drug candidate, neratinib (oral). As we proceed with the clinical development of neratinib (oral) and as we further develop neratinib (intravenous) and PB357, our second and third drug candidates, respectively, our research and development expenses will further increase. To the extent we are successful in acquiring additional drug candidates for our development pipeline, our need to finance further research and development will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our drug candidates, but also on our ability to finance the development of the products.

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 Biotechnology, Inc., a Delaware corporation, through a merger transaction. Puma was a development stage company formed in September 2010 focused primarily on acquiring and developing pharmaceutical technologies. As a result of the Merger, Puma become our wholly-owned subsidiary and subsequently merged with and into us. Upon effectiveness of the Merger, our prior business plan was abandoned and we adopted the business plan of Puma. The transaction was accounted for as a reverse acquisition with Puma as the acquiring party and us as the acquired party. Accordingly, when we refer to our business and financial information relating to periods prior to the merger, we are referring to the business and financial information of Puma, unless otherwise indicated.

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 $40,000 paid to our former stockholders will be recorded as an other expense item and included in our net loss for the period ending December 31, 2011.

Results of Operations

The following discussion summarizes the key factors our management believes are necessary for an understanding of our financial statements.

Period Ended December 31, 2010

General and administrative expenses

For the period from September 15, 2010 (date of inception) to December 31, 2010, general and administrative expense was $6,931. We commenced operations on September 15, 2010 and our expenses for the period ending December 31, 2010 represent legal fees associated with our incorporation.

Period Ended June 30, 2011

General and administrative expenses

For the three and six months ended June 30, 2011, we incurred general and administrative expense of approximately $34,300 and $38,200, respectively. For the six months ended June 30, 2011, we expended approximately $22,550 for travel, $6,000 for legal fees, $6,500 for rent and $3,150 on miscellaneous expenses. The travel and legal fees were associated with acquiring the licensing agreement with Pfizer.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Liquidity and Capital Resources

Management believes that we will continue to incur losses for the foreseeable future. Therefore we will either need additional equity or debt financing, or we will need to generate revenue from the licensing of our products or by entering into strategic alliances to sustain our operations until we can achieve profitability and positive cash flows from operating activities, if ever.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing. Such additional funds may not become available on acceptable terms, if at all, and we cannot assure you that any additional funding we do obtain will be sufficient to meet our needs in the long term. Through June 2011, we were funded through capital contributions of approximately $49,800 by our founder and chief executive officer. On September 2, 2011, our founder and Chief Executive Officer advanced us $150,000 to fund our operations until we were able to complete an equity placement. The advance was converted to an unsecured, non-interest bearing convertible note on September 9, 2011 that would mature in one year. On October 6, 2011, our Chief Executive Officer converted the note, in accordance with its terms, into 40,000 shares of our common stock.

Immediately prior to the closing of the Merger, Puma sold 14,666,733 shares of common stock to various investors at a purchase price of $3.75 per share, for aggregate gross proceeds of approximately $55 million. We believe that the net proceeds from this offering will be sufficient to meet our capital needs for at least the next 12 months.

We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give 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 on acceptable terms, or at all, we may be forced to curtail our desired development. In addition we could be forced to delay or discontinue product development, 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.

Plan of Operation

Our plan of operation for the years ending December 31, 2011 and 2012 is to continue implementing our business strategy, including the clinical development of our three drug candidates, focusing primarily on the development of neratinib for the treatment of breast cancer. We also intend to expand our drug candidate portfolio by acquiring additional drug technologies for development. We expect our principal expenditures during the next 12 months to include:

- operating expenses, including expanded research and development and general and administrative expenses; and
- product development expenses, including the costs incurred with respect to applications to conduct clinical trials in the United States for our three products and the costs of ongoing and planned clinical trials.

As part of our planned expansion, we anticipate hiring up to 45 additional full-time employees devoted to research and development activities and up to 6 additional full-time employees for general and administrative activities. In addition, we intend to use clinical research organizations and third parties to perform our clinical studies and manufacturing. At our current and desired pace of clinical development of our three drug candidates, during the remaining months of 2011 through 2012, we expect to spend approximately $27 million on clinical development and research and development activities, approximately $6.3 million on general and administrative expenses and approximately $0.5 million on facilities rent. Additionally, we expect to spend approximately $250,000 on capital expenditures. We cannot assure you these amounts will be sufficient to fund our operations over the course of the next two years and we may need to expend significantly greater amounts to accomplish our goals in clinical development.

Research and Development Projects

Neratinib (Oral). We plan to conduct additional clinical trials of neratinib in patients with HER2 positive metastatic breast cancer over the next 12 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 (oral) in patients with HER2 positive metastatic breast cancer with brain metastases. We will also continue the ongoing trial of neratinib when given in combination with the anti-cancer drug temsirolimus in patients with HER2 positive metastatic breast cancer.

We also plan to conduct Phase II clinical trials of neratinib (oral) in HER2 positive metastatic gastric cancer patients and in patients with HER4 mutated melanoma during 2012.

Pfizer had previously been sponsoring two ongoing late stage clinical trials of neratinib (oral), the NEfERTT trial and the ExteNET trial. On October 5, 2011, we announced that enrollment in the ExteNET trial is being 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.

We expect that it will take at least four years to complete development and obtain FDA approval of neratinib (oral) for any indication, and we may never obtain such approval. Currently, we anticipate that we will need to expend approximately an additional $20 to $25 million in development costs through fiscal 2012 and at least an aggregate of approximately $80 to $100 million before we receive FDA approval for neratinib for treatment of breast cancer.

Neratinib (Intravenous). We also intend 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 IND for the intravenous formulation of neratinib in 2012.

We expect that it will take an additional seven to nine years to complete development and obtain FDA approval of neratinib (intravenous), if ever. Currently, we anticipate that we will need to expend approximately an additional $2 to $7 million in development costs through fiscal 2012 and at least an aggregate of approximately $80 to $100 million until we receive FDA approval for neratinib (intravenous) should we choose to continue development.

PB357. PB357 is an orally administered agent that is an irreversible TKI that blocks signal transduction through the EGFRs, HER1, HER2 and HER4. PB 357 is structurally similar to neratinib and has completed Phase I single dose pharmacokinetic studies. We plan to consider our strategic options for PB357 during 2012.

License Agreement Obligations

In August 2011, we entered into an agreement with Pfizer pursuant to which Pfizer granted us a worldwide license for neratinib (oral), neratinib (intravenous) and PB357. This license became effective on October 4, 2011. As consideration for these rights, the license agreement requires that we make aggregate milestone payments of up to $187.5 million, payable upon the achievement of certain milestones. Additionally, should we commercialize any of the compounds 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 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 any of these compounds to a third party, the same milestone and royalty payments are required.

Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of expenses for the periods presented. Judgments must also be made about the disclosure of contingent liabilities. Accordingly, actual results could differ significantly from those estimates. We believe the following discussion addresses the accounting policies that are necessary to understand and evaluate our reported financial results.

Income Taxes

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

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FASB ASC 740, we 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. FASB 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 June 30, 2011 and December 31, 2010, the Company does not have a liability for unrecognized tax uncertainties.

Our policy is to record interest and penalties on uncertain tax positions as income tax expense. As of June 30, 2011 and December 31, 2010, we had no accrued interest or penalties related to uncertain tax positions.

Net loss per 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 FASB ASC 260, *Earnings Per Share*. There were no dilutive shares outstanding at June 30, 2011 or December 31, 2010.

Recently Issued Accounting Pronouncements

FASB issued the following accounting amendments:

In April 2010, the FASB issued amendments related to the revenue recognition method for milestone payments in research and development agreements. Under these amendments, entities can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The amendments are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010, which means such amendments will take effect beginning with the fiscal year starting on January 1, 2011. The adoption of this standard has not had a material impact on our financial position, cash flow or results of operations.

In October 2009, the FASB issued authoritative guidance for arrangements with multiple deliveries. The guidance will allow companies to allocate consideration from contractual arrangements in multiple deliverables arrangements in a manner that better reflects the economics of the transaction. The new guidance requires expanded qualitative and quantitative disclosures and is effective for fiscal years beginning on or after June 15, 2010. The adoption of this standard has not had a material impact on our financial position, cash flow or results of operations.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

In connection with the closing of the merger, PKF Certified Public Accountants, a Professional Corporation, or PKF, which was the independent registered public accounting firm for Puma prior to the merger, became the independent registered public accounting firm for us, and MaloneBailey, LLP was dismissed as our independent registered public accounting firm. The decision to appoint PKF and dismiss MaloneBailey, LLP was recommended, and subsequently approved, by our board of directors.

The reports of MaloneBailey, LLP on our financial statements for the period ended December 31, 2010 did not contain an adverse opinion or a disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope or accounting principles.

In connection with the audit of our financial statements for the year ended December 31, 2010 and through MaloneBailey, LLP s dismissal, there were no disagreements with MaloneBailey, LLP on any matters of accounting principles or practices, financial statement disclosures, or auditing scope or procedures, which if not resolved to MaloneBailey, LLP s satisfaction would have caused MaloneBailey, LLP to make reference to the matter in their report.

In connection with our audited financial statements through MaloneBailey, LLP s dismissal, there have been no reportable events with the Company as set forth in Item 304(a)(1)(v) of Regulation S-K.

We requested that MaloneBailey, LLP furnish us with a letter addressed to the SEC stating whether it agrees with the above statements. A copy of the letter, dated October 10, 2011, is filed herewith as Exhibit 16.1.

Quantitative and Qualitative Disclosures about Market Risk

Our primary exposure to market risk is related to changes in interest rates. As of October 6, 2011, we had cash, cash equivalents and short-term investments of approximately $52,167,900, consisting of money market funds, U.S. treasuries, certificates of deposit and cash equivalents. This exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Our short-term investments are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10 percent change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our short-term investments until maturity, and therefore we would not expect our operations results or cash flows to be affected by any significant degree by the effect of a change in market interest rates on our investments. We carry our investments based on publicly available information. We do not currently have any hard to value investment securities or securities for which a market is not readily available or active.

We are not subject to significant credit risk as this risk does not have the potential to materially impact the value of our assets and liabilities.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth the number of shares of our common stock beneficially owned as of October 6, 2011 by (i) each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock, (ii) each of our directors and executive officers and (iii) all officers and directors as a group. Unless otherwise indicated in the table, the persons and entities named in the table have sole voting and sole investment power with respect to the shares set forth opposite the stockholder s name, subject to community property laws, where applicable. Unless otherwise noted below, the address of each stockholder below is c/o Puma Biotechnology, Inc., 10940 Wilshire Boulevard, Suite 600, Los Angeles, California 90024.

NAME	TITLE	SHARES OF COMMON STOCK BENEFICIALLY OWNED (#) (1)	PERCENTAGE OF COMMON STOCK BENEFICIALLY OWNED (%) (1)
Alan H. Auerbach	President, Chief Executive Officer and Director	4,040,000	21.60%
Charles R. Eyler	Senior Vice President, Finance and Treasurer		
Thomas R. Malley	Director		
Adage Capital Partners L.P. (2)		3,200,000	17.11%
Brookside Capital Partners Fund, L.P. (3)		1,666,667	8.91%
Entities affiliated with Fidelity Management & Research Company (4)		1,666,667	8.91%
Foresite Capital II-A, LLC (5)		1,386,666	7.41%
Entities affiliated with Hambrecht & Quist Capital Management, LLC (6)		1,106,667	5.92%
Frank Zavrl (7)		1,066,666	5.70%
OrbiMed Private Investments IV, LP (8)		992,000	5.30%
All executive officers and directors as a group (3 individuals)		4,040,000	21.60%

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

(2) Adage Capital Partners GP, LLC, or ACPGP, is the general partner of Adage Capital Partners L.P., or the Adage Fund. Adage Capital Advisors, LLC, or ACA, is the

managing member of ACPGP. Each of Robert Atchinson and Phillip Gross is a managing member of ACA. The Adage Fund, ACPGP, ACA, Robert Athchinson and Phillip Gross each have shared voting power and shared dispositive power with respect to the shares. The address for the Adage Fund is 200 Clarendon Street, 52nd, Boston, MA 02116.

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

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

(5) Foresite Capital II-A Management, LLC is the sole managing member of Foresite Capital II-A, LLC, or Foresite. The sole manager of Foresite Capital II-A Management, LLC is James B. Tananbaum, and as such, James B. Tananbaum may be deemed to have sole voting and investment power of the securities held by Foresite. James B. Tananbaum disclaims beneficial ownership of these securities except to the extent of its pecuniary interest therein. The address for Foresite is c/o Foresite Capital Management, P.O. Box 405, Esparto, CA 95627.

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

(7) The address for Frank Zavrl is 87 Salem Street, Andover, MA 01810.

(8) OrbiMed Capital GP IV, LLC is the sole general partner of OrbiMed Private Investments IV, LP, or OrbiMed, and OrbiMed Advisors LLC, a registered investment adviser under the Investment Advisers Act of 1940, is the sole managing member of OrbiMed Capital GP IV, LLC. Samuel D. Isaly, a natural person, owns a controlling interest in OrbiMed Advisors LLC, and may be deemed to be the beneficial owner of the securities held by OrbiMed. Samuel D. Isaly disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein. The address for OrbiMed is 767 Third Avenue, 30th Floor, New York, NY 10017.

MANAGEMENT AND DIRECTORS

At the effective time of the Merger, our board of directors was reconstituted by the appointment of Alan H. Auerbach and Thomas R. Malley as directors, and the resignations of Robert Johnson, Kapil Mujal and Faraaz Siddiqi from their roles as directors. Our executive management team was also reconstituted by the appointment of Mr. Auerbach as our President and Chief Executive Officer and Charles R. Eyler as our Senior Vice President, Finance and Treasurer, and the resignations of Mr. Johnson from his position as our President and Mr. Siddiqi from his position as our Secretary. The following table sets forth the name and positions of each of our directors and executive officers after the Merger.

Name	Age	Positions
Alan H. Auerbach	42	President, Chief Executive Officer and Chairman of the Board
Charles R. Eyler	63	Senior Vice President, Finance and Treasurer
Thomas R. Malley	42	Director

Alan H. Auerbach. Mr. Auerbach has served as our Chairman of the Board and as our President and Chief Executive Officer since the closing of the Merger on October 4, 2011 and, prior to the Merger, served in such capacity at Puma since its inception. Prior to joining Puma, Mr. Auerbach founded Cougar Biotechnology, Inc. in May 2003 and served as its Chief Executive Officer, President and a member of its board of directors until July 2009 when Cougar was acquired by Johnson & Johnson. From July 2009 until January 2010, Mr. Auerbach served as the Co-Chairman of the Integration Steering Committee at Cougar (as part of Johnson & Johnson) that provided leadership and oversight for the development and global commercialization of Cougar s lead drug candidate, abiraterone acetate, for the treatment of advanced prostate cancer. Prior to founding Cougar, from June 1998 to April 2003, Mr. Auerbach was a Vice President, Senior Research Analyst at Wells Fargo Securities, where he was responsible for research coverage of small- and middle- capitalization biotechnology companies, with a focus on companies in the field of oncology. Mr. Auerbach currently serves as a director of Radius Health, Inc., a publicly-reporting pharmaceutical company focused on acquiring and developing new therapeutics for the treatment of osteoporosis and other women s health conditions. Mr. Auerbach received a B.S. in Biomedical Engineering from Boston University and an M.S. in Biomedical Engineering from the University of Southern California. Mr. Auerbach was selected as a director because of his business and professional experience, including but not limited to his leadership of Cougar in drug development, private and public financings and a successful sale of the business.

Charles R. Eyler. Mr. Eyler has served as our Senior Vice President, Finance and Treasurer since the closing of the Merger on October 4, 2011 and, prior to the Merger, served in such capacity at Puma since September 1, 2011. Prior to joining Puma, Mr. Eyler served as Vice President of Finance at Cougar Biotechnology, Inc. from August 2004 until July 2009 when Cougar was acquired by Johnson & Johnson. He also served as the Treasurer of Cougar from April 2006 to July 2009. From July 2009 until March 2010, Mr. Eyler served on the Cougar Integration Committee and oversaw the integration of Cougar s finance and IT functions with

those of Johnson & Johnson. Prior to joining Cougar, Mr. Eyler served as Chief Financial Officer and Chief Operating Officer of Hayes Medical Inc. from March 1999 to January 2004. Mr. Eyler received his B.S. from Drexel University and his M.B.A. from Saint Francis College.

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

Executive Compensation

Since our inception, we have not paid any cash or other compensation to our principal executive officer (Alan H. Auerbach) or our principal financial officer (Charles R. Eyler), who are our only executive officers and are hereinafter collectively referred to as our named executive officers. In addition, we have no plans in place for the payment of retirement benefits or benefits that will be paid primarily following retirement including, but not limited to, tax qualified deferred benefit plans, supplemental executive retirement plans, tax qualified deferred contribution plans and nonqualified deferred contribution plans. Similarly, we have no contracts, agreements, plans or arrangements, whether written or unwritten, that provide for payments to the named executive officers or any other persons following, or in connection with the resignation, retirement or other termination of a named executive officer, or a change in control of us or a change in a named executive officer s responsibilities following a change in control. We may pay compensation to our named executive officers in the future; however, the amounts and timing of the payments have not been determined.

Executive Compensation under the 2011 Incentive Award Plan

No options to purchase shares of our common stock were granted by us during the fiscal year ended December 31, 2010. Upon the Merger, we assumed Puma s 2011 Incentive Award Plan, or the Plan. There are 3,529,412 shares of our common stock reserved for issuance under the Plan. As of October 6, 2011, no awards had been issued under the Plan. While we may grant stock options and other incentive awards in the future, the amounts and timing of such grants have not been determined.

Compensation of Directors

None of our directors has received any compensation of any nature on account of services rendered in such capacity. We have not established a policy to provide compensation to our directors for their services in such capacity. Our board will consider developing such a policy in the future.

Employment Agreements with Executives

We have not entered into written employment agreements with Alan H. Auerbach, our President and Chief Executive Officer, or Charles R. Eyler, our Senior Vice President of Finance and Treasurer, but we may do so in the future.

Compensation Committee Interlocks and Insider Participation

We have not paid any compensation to our officers in the past and do not have a compensation committee or a committee performing similar functions. All compensation matters are determined by our board of directors. We plan to have a compensation committee when we elect additional independent persons to our board of directors.

Terms of Office

Our directors and officers have been appointed for a one-year term or until their respective successors are duly elected and qualified or until their earlier resignation or removal in accordance with our bylaws.

Certain Relationships & Transactions

Officers

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

Capital Contributions

Puma received $6,531 additional cash capital contributions from Mr. Auerbach during the year ended December 31, 2010, and received $49,829 cash capital contributions from Mr. Auerbach from September 15, 2010 (inception) to June 30, 2011. No additional shares of common stock were issued as a result of these capital contributions. On September 2, 2011, Mr. Auerbach advanced Puma $150,000 to fund its operations until such time as Puma could complete an equity placement. The advance was converted to an unsecured, non-interest bearing convertible note on September 9, 2011 that would mature in one year. On October 6, 2011, Mr. Auerbach converted the note, in accordance with its terms, into 40,000 shares of our common stock.

Redemption of Common Stock

The shares held by our former stockholders, Messrs. Johnson, Siddiqi and Munjal, were repurchased by us for any aggregate purchase price of $40,000.

Composition of Board

Pursuant to an agreement with the investors in Puma s private placement offering of 14,666,733 shares of Puma s common stock on October 4, 2011, from and after the closing of

the Merger until the next annual meeting of our stockholders, our board of directors may consist of up to a maximum of seven members. These members will consist of (a) our current directors, (b) at the election of the investors who purchased a majority of the shares sold in Puma s private placement, either one of two representatives designated by such investors (which designee shall be selected by Mr. Auerbach) or two of four representatives designated by such investors (which designees shall be selected by Mr. Auerbach), and (c) such other directors as designated by our board.

Lock-Up Agreement

In connection with the private placement of Puma s securities on October 4, 2011, Mr. Auerbach entered into a lock-up agreement with us pursuant to which he agreed not to sell, dispose of, contract to sell, sell any option or contract to purchase, or otherwise transfer or dispose of, directly or indirectly, without the written consent of the investors who purchased a majority of the shares sold in Puma s private placement, any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock until the later of (a) the date of the closing of an additional private placement of our common stock that results in the Company receiving gross proceeds of up to $10 million and (b) the date on which shares of our common stock are first listed for quotation on an over-the-counter market or listed for quotation on any national securities exchange or trading system. We have agreed that we will not amend or terminate the lock-up agreement for a period of 12 months without the prior written consent of a majority of the investors that purchased shares in Puma s most recent financing transaction.

Warrant

Also in connection with the private placement of Puma s securities on October 4, 2011, Puma issued a warrant to Mr. Auerbach. We assumed this warrant in connection with the Merger. 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.

Significant Employees

As of the date hereof, we have no significant employees, other than our named executive officers.

Family Relationships

There are no family relationships among our directors or executive officers.

Involvement in Certain Legal Proceedings

To our knowledge, there have been no events under any bankruptcy act, no criminal proceedings and no federal or state judicial or administrative orders, judgments or decrees or findings, no violations of any federal or state securities law, and no violations of any federal commodities law material to the evaluation of the ability and integrity of any director (existing or proposed) or executive officer (existing or proposed) of the Company during the past ten (10) years.

Policies and Procedures for Review, Approval or Ratification of Transactions with Related Persons

We do not have any special committee, policy or procedure related to the review, approval or ratification of transactions with related persons that are required to be disclosed pursuant to Item 404(a) of Regulation S-K, other than as required by the Delaware General Corporation Law.

Director Independence

Our securities are not listed on a national securities exchange or on any inter-dealer quotation system which has a requirement that a majority of directors be independent. We evaluate independence by the standards for director independence set forth in the NASDAQ Marketplace Rules.

Under these rules, a director is not considered to be independent if he or she also is an executive officer or employee of the corporation. As a result, Mr. Auerbach would not be considered independent because he serves as an executive officer of the Company. Our other director, Mr. Malley, would be considered independent under these rules.

Board of Directors Meetings

During the fiscal year ended December 31, 2010, our board of directors did not meet and we did not hold an annual meeting. Our board conducted all of its business and approved all corporate action during the fiscal year ended December 31, 2010 by the unanimous written consent of its members, in the absence of formal board meetings.

Committees of the Board of Directors

As our common stock is not presently listed for trading or quotation on a national securities exchange or NASDAQ, we are not presently required to have board committees.

Our board of directors performs the functions of the audit committee. We do not have a qualified financial expert at this time because we have not been able to hire a qualified candidate. Further, we believe that we have inadequate financial resources at this time to hire such an expert. We intend to continue to search for a qualified individual for hire.

Due to our small size and limited operations to date, we do not presently have a nominating committee, compensation committee or other committee performing similar functions. We have not adopted any procedures by which security holders may recommend nominees to our board, and we do not have a diversity policy.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and officers, and persons who beneficially own more than ten percent (10%) of our common stock, who are hereinafter collectively referred to as Reporting Persons, to file reports with the SEC of beneficial ownership and reports of changes in beneficial ownership of our common stock on Forms 3, 4 and 5. Reporting Persons are required by applicable SEC rules to furnish us with copies of all such forms filed with the SEC pursuant to Section 16(a) of the Exchange Act. To our knowledge, based solely on our review of the copies of the Forms 3, 4 and 5 received by us during the fiscal year ended December 31, 2010 and written representations that no other reports were required, we believe that all reports required to be filed by such persons with respect to the Company s fiscal year ended December 31, 2010 were timely filed.

Code of Ethics

On December 31, 2007, we adopted a formal code of ethics statement for senior officers and directors that is designed to deter wrongdoing and to promote ethical conduct and full, fair, accurate, timely and understandable reports that we file or submit to the SEC and others. A form of the Code of Ethics was filed with our Form 10-KSB filed with the SEC on March 31, 2008.

Board Leadership Structure and Role on Risk Oversight

Alan H. Auerbach currently serves as our President and Chief Executive Officer, and Charles R. Eyler currently serves as our Senior Vice President, Finance and Treasurer. Our board of directors is comprised of Mr. Auerbach and Thomas R. Malley, with Mr. Auerbach serving as Chairman. At present, we have determined this leadership structure is appropriate due to our small size and limited operations and resources.

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

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

Legal Proceedings

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

Stockholder Communication with the Board of Directors

Stockholders may send communications to our board of directors by writing to Puma Biotechnology, Inc., 10940 Wilshire Boulevard, Suite 600, Los Angeles, California 90024, Attention: Board of Directors.

Other Information

We are required to file periodic reports, proxy statements and other information with the SEC. You may read and copy this information at the Public Reference Room of the SEC, 100 F. Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You may also obtain a copy of these reports by accessing the SEC s website at http://www.sec.gov. You may also send communications to our board of directors at: Puma Biotechnology, Inc., 10940 Wilshire Boulevard, Suite 600, Los Angeles, California 90024, Attention: Board of Directors.

Market Price of and Dividends on Our Common Equity and Related Stockholder Matters

There is not currently, and there has never been, any market for any of our securities. Our securities are not eligible for trading on any national securities exchange, the Nasdaq or other over-the-counter markets, including the Over-the-Counter Bulletin Board.

As of October 6, 2011, we had outstanding 18,706,733 shares of common stock and no outstanding shares of preferred stock.

Description of Securities

The following statements are qualified in their entirety by reference to the detailed provisions of our certificate of incorporation and bylaws.

Capital Structure

We currently have authorized capital stock of 110,000,000 shares, of which 100,000,000 are designated as common stock, par value $0.0001 per share, and 10,000,000 shares are designated as preferred stock, par value $0.0001 per share. As of October 6, 2011, 18,706,733 shares of our common stock and no shares of our preferred stock were issued and outstanding. As of October 6, 2011, there were 28 holders of record of our common stock.

Common Stock

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

Preferred Stock

On October 4, 2011, our board of directors and our stockholders approved by written consent an amendment to our certificate of incorporation to remove the class of our capital stock designated as preferred stock. We intend to prepare and file an information statement on Schedule 14C with the SEC to notify the stockholders of this action. Twenty days after we mail the information statement, we expect to file the amendment with the Secretary of State of the State of Delaware. When the amendment becomes effective, we will have authorized capital stock of 100,000,000 shares, all of which will be designated as common stock, par value $0.0001 per share. Prior to the effective date of the amendment to our certificate of incorporation, we have agreed not to issue any shares of our preferred stock.

Convertible Note

On September 2, 2011, Mr. Auerbach, the founder of Puma and our President and Chief Executive Officer, advanced Puma $150,000 to fund its operations. On September 9, 2011, Puma converted this advance into a non-interest bearing unsecured convertible promissory note due and payable upon demand on or after the one-year anniversary of the date of issuance, if not converted prior to the maturity date. On October 6, 2011, Mr. Auerbach converted the note, in accordance with its terms, into 40,000 shares of our common stock.

Warrants

On October 4, 2011, Puma issued 14,666,733 shares of its common stock to 27 investors in a private placement for aggregate consideration of approximately $55 million. Puma also issued a warrant to each investor in the private placement that provided such investor with anti-dilution protection in regard to certain issuances. We assumed these warrants in connection with the Merger. 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.

On October 4, 2011, Puma also issued a warrant to Mr. Auerbach. We assumed this warrant in connection with the Merger. 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.

Registration Rights Agreement

At the closing of Puma s private placement, Puma entered into a registration rights agreement with the investors in the private placement. We assumed the registration rights agreement in connection with the Merger. Pursuant to the registration rights agreement, we will file a shelf registration statement covering the resale of the shares of our common stock, including the common stock issuable upon exercise of our outstanding warrants, held by the investors in Puma s private placement. We are generally required to file the shelf registration statement within 60 days of the closing date of the Merger. We are also required to use reasonable best efforts to cause the shelf registration statement to become effective no later than 180 days after it was filed with the SEC. We are further required to use our best efforts to qualify the shares included in the shelf registration statement for listing on a national securities exchange or comparable trading system within 12 months of the date the registration statement is declared effective.

If the registration statement is not filed within the timeframe specified above, then we will be liable to each investor for liquidated damages, on a 30-day basis, equal to 1.0% of the aggregate purchase price paid by the investor for the registrable shares of our common stock then held by the investor. Additionally, if we do not, subject to certain exceptions, maintain the effectiveness of the registration statement until the second anniversary of the date the registration statement is initially declared effective or if we suspend the use of the registration statement in excess of permitted periods, then we will also be required to pay liquidated damages, on a 30-day basis, to each investor equal to 1.0% of the aggregate purchase price paid by the investor for the registrable shares of our common stock then held by the investor; provided, however, that the aggregate amount of liquidated damages payable by us to each investor as a result of our suspension or failure to maintain the effectiveness of the registration statement shall not exceed 10.0% of the aggregate purchase price paid by the investor in the private placement. The registration rights agreement also gives investors the right to participate as sellers in a firm commitment underwritten offering of the shares of our common stock held by Mr. Auerbach.

Dividend Policy

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

Securities Authorized for Issuance under Equity Compensation Plans

A total of 3,529,412 shares are reserved for issuance under our 2011 Equity Incentive Plan, or the Plan. As of October 6, 2011, no awards had been granted under the Plan.

Plan Category	Number of shares to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in the first column)
Equity compensation plans approved by security holders (1)			3,529,412
Equity compensation plans not approved by security holders			
Total			3,529,412

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

Administration

Our board of directors does not currently have a compensation committee and, in the absence of such a committee, the board will administer the Plan. Subject to the terms of the Plan, the board will have complete authority and discretion to determine the terms of awards under the Plan.

Eligible Recipients

Any officer or other employee of the Company or its affiliates, or an individual that the Company or an affiliate has engaged to become an officer or employee, or a consultant or advisor who provides services to the Company or its affiliates, including a non-employee director of the Board, is eligible to receive awards under the Plan.

Grants

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

Duration, Amendment, and Termination

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

Recent Sales of Unregistered Securities

The following summarizes all sales of unregistered securities by us and Puma within the past three years:

On September 15, 2010, in connection with Puma s incorporation, Puma issued an aggregate of 4,000,000 shares of its common stock to Alan H. Auerbach, our President and Chief Executive officer, for aggregate consideration of $400.

On October 4, 2011, Puma issued 14,666,733 shares of its common stock and anti-dilutive warrants to 27 investors in a private placement for aggregate consideration of approximately $55 million. Puma also issued an anti-dilutive warrant to its founder in connection with such private placement. For a description of the warrants, please see Description of Securities Warrants.

On October 4, 2011, we issued 18,666,733 shares of our common stock to Puma s stockholders and assumed Puma s outstanding warrants in exchange for all of the outstanding shares of Puma s common stock.

On October 6, 2011, we issued 40,000 shares of our common stock to Mr. Auerbach upon his conversion of an unsecured convertible promissory note issued to him in connection with his advance of $150,000 to Puma prior to the Merger.

The sales of the securities identified above were made pursuant to privately negotiated transactions that did not involve a public offering of securities and, accordingly, we believe that these transactions were exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof and the rules promulgated thereunder. Each of the above-referenced investors in Puma s stock represented to Puma in connection with their investment that they were accredited investors (as defined by Rule 501 under the Securities Act) and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The investors received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

Shares Eligible for Future Sale

As of October 6, 2011, we had outstanding 18,706,733 shares of common stock. All of these shares are restricted securities under Rule 144, in that they were issued in private transactions not involving a public offering.

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

Rule 144 is not available for the resale of securities initially issued by companies that are, or previously were, blank check companies like us, to their promoters or affiliates despite technical compliance with the requirements of Rule 144. Rule 144 also is not available for resale of securities issued by any shell companies (other than business combination-related shell companies) or any issuer that has been at any time previously a shell company. The SEC has provided an exception to this prohibition, however, if the following conditions are met:

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

As a result, none of our stockholders is currently able to sell shares of our common stock in reliance on Rule 144. Assuming we continue to meet the requirements set forth above, Rule 144 will become available to our stockholders one year after the date of this report. Our stockholders may currently resell their shares of our common stock only pursuant to a registration statement that has been declared effective under the Securities Act or pursuant to another exemption from registration.

Indemnification of Directors and Officers

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

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

Delaware Anti-Takeover Statute

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

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the interested stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers, and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is any person who, together with such person s affiliates and associates (i) owns 15% or more of a corporation s voting securities or (ii) is an affiliate or associate of a corporation and was the owner of 15% or more of the corporation s voting securities at any time within the three year period immediately preceding a business combination of the corporation governed by Section 203. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage takeover attempts that might result in a premium over the market price, once a market exists, for the shares of common stock held by our stockholders.

Item 3.02. Unregistered Sales of Equity Securities.

The disclosures set forth in Item 2.01 above are hereby incorporated by reference into this Item 3.02.

Item 4.01. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

The disclosures set forth under the heading Changes in and Disagreements with Accountants on Accounting and Financial Disclosure in Item 2.01 above are hereby incorporated by reference into this Item 4.01.

Item 5.01. Changes in Control of Registrant.

The disclosures set forth in Item 2.01 above are hereby incorporated by reference into this Item 5.01.

Item 5.02. Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.

At the Effective Time, our board of directors was reconstituted by the appointment of Alan H. Auerbach and Thomas R. Malley, with Mr. Auerbach serving as Chairman of the Board, and the resignations of Robert Johnson, Faraaz Siddiqi and Kapil Munjal from their roles as directors. Additionally, pursuant to an agreement with the investors in Puma s private placement offering of 14,666,733 shares of its common stock as referenced in Item 2.01 above, from and after the closing of the Merger until the next annual meeting of our stockholders, our board may consist of up to a maximum of seven members. These members will consist of (a) Messrs. Auerbach and Malley, (b) at the election of the investors holding a majority of the shares sold in Puma s private placement, either one of two representatives designated by such investors (which designee shall be selected by Mr. Auerbach) or two of four representatives designated by such investors (which designees shall be selected by Mr. Auerbach), and (c) such other directors as designated by the Board.

At the Effective Time, our executive management team was also reconstituted and Robert Johnson resigned from his position as the Company s President and Faraaz Siddiqi resigned from his position as Secretary. Upon the Effective Time, the following individuals (all of whom were officers of Puma prior to the Merger) took the positions set after their names: Alan H. Auerbach (President and Chief Executive Officer) and Charles R. Eyler (Senior Vice President, Finance and Treasurer). Biographical and other information regarding these individuals is provided under the caption Management and Directors in Item 2.01 above, which is incorporated by reference into this Item 5.02.

Item 5.03. Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On October 4, 2011, we filed a Certificate of Ownership and Merger with the Secretary of State of the State of Delaware pursuant to which Puma Biotechnology, Inc., our wholly-owned subsidiary pursuant to the Merger, merged with and into us with us remaining as the surviving corporation to the merger. In connection with the Short-Form Merger, and as set forth in the Certificate of Ownership and Merger, we changed our corporate name to Puma Biotechnology, Inc. The Certificate of Ownership and Merger is filed herewith as Exhibit 3.2.

On October 4, 2011, our board of directors and our stockholders approved by written consent an amendment to our Certificate of Incorporation to remove the class of our capital stock designated as preferred stock. We intend to prepare and file an information statement on Schedule 14C with the SEC to notify the stockholders of this action. Twenty days after we mail the information statement, we expect to file the amendment with the Secretary of State of the State of Delaware. When the amendment becomes effective, we will have authorized capital stock of 100,000,000 shares, all of which will be designated as common stock, par value $0.0001 per share.

Item 5.06. Change in Shell Company Status.

As described in Items 1.01 and 2.01 above, which are incorporated by reference into this Item 5.06, we ceased being a shell company (as defined in Rule 12b-2 under the Exchange Act) upon completion of the Merger.

Item 9.01. Financial Statements and Exhibits.

(a) As a result of its acquisition of Puma as described in Item 2.01, the registrant is filing herewith Puma s audited financial statements as of and for the fiscal year ended December 31, 2010 and its unaudited condensed financial statements as of and for the three and six months ended June 30, 2011 as Exhibit 99.1 to this current report.

(b) Unaudited pro forma condensed combined financial information as of and for the fiscal year ended December 31, 2010 and as of and for the six months ended June 30, 2011 is attached as Exhibit 99.2 to this current report.

(d) Exhibits.

Exhibit	Description
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 (2)
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 the State of Delaware on October 4, 2011 (1)
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 (1)
3.3	Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on April 27, 2007 (3)
3.4	Bylaws of Puma Biotechnology, Inc. (3)
4.1	Form of Warrant to Purchase Shares of Common Stock of Puma Biotechnology, Inc., dated October 4, 2011, issued to investors in private placement (1)
4.2	Warrant to Purchase Shares of Common Stock of Puma Biotechnology, Inc., dated October 4, 2011, issued to Alan H. Auerbach (1)
10.1*	License Agreement, dated August 18, 2011, by and between the Company, as successor to Puma Biotechnology, Inc., and Pfizer Inc.
10.2	Redemption Agreement, dated October 4, 2011, by and between Innovative Acquisitions Corp., Robert Johnson, Faraaz Siddiqi and Kapil Munjal (1)
10.3	Indemnity Agreement, dated as of September 29, 2011, between Innovative Acquisitions Corp., Puma Biotechnology, Inc., Robert Johnson, Faraaz Siddiqi and Kapil Munjal (2)
10.4	Puma Biotechnology, Inc. 2011 Incentive Award Plan, assumed in the Merger (1)

10.5	Registration Rights Agreement, dated October 4, 2011, by and among Puma, the persons listed on Exhibit A attached thereto and the Company
10.6	Securities Purchase Agreement, dated October 4, 2011, by and among Puma, the investors listed on Schedule I attached thereto and the Company
16.1	Letter from MaloneBailey, LLP as to the change in certifying accountant, dated as of October 10, 2011 (1)
99.1	Audited financial statements of Puma Biotechnology, Inc. as of and for the fiscal year ended December 31, 2010 and unaudited condensed financial statements of Puma Biotechnology, Inc. as of and for the three and six months ended June 30, 2011 (1)
99.2	Unaudited Pro Forma Condensed Combined Financial Statements as of and for the fiscal year ended December 31, 2010 and as of and for the six months ended June 30, 2011 (1)
99.3	Press Release dated October 5, 2011 (1)

* **Confidential Treatment Requested by Registrant. Redacted Portion Filed Separately with Commission.**

(1) Incorporated by reference to the Company s Current Report on Form 8-K filed with the Commission on October 11, 2011.

(2) Incorporated by reference to the Company s Current Report on Form 8-K filed with the Commission on October 4, 2011.

(3) Incorporated by reference to the Company s Registration Statement on Form 10-SB filed with the Commission on September 14, 2007.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: December 16, 2011

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

EXHIBIT INDEX

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