PUMA BIOTECHNOLOGY, INC.
Form 424B1
February 11, 2014
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Filed Pursuant to Rule 424(b)(1)
Registration Nos. 333-193641 and 333-193870

PROSPECTUS

979,592 Shares

Puma Biotechnology, Inc.

Common Stock

We are selling 979,592 shares of our common stock.

Our shares trade on the New York Stock Exchange under the symbol PBYI. On February 10, 2014, the last sale price of the shares as reported on the New York Stock Exchange was $125.27 per share.

Investing in the common stock involves risks that are described in the Risk Factors section beginning on page 10 of this prospectus.

	Per Share	Total
Public offering price	$122.50	$120,000,020
Underwriting discount (1)	$7.35	$7,200,001
Proceeds, before expenses, to us	$115.15	$112,800,019

(1) See Underwriting for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses. The underwriters may also exercise their option to purchase up to an additional 146,938 shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about February 14, 2014.

BofA Merrill Lynch **Citigroup** **Leerink Partners**

Cowen and Company **UBS Investment Bank**

The date of this prospectus is February 10, 2014.

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

This prospectus includes estimates, statistics and other industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and publicly available information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. This prospectus also includes data based on our own internal estimates. We caution you not to give undue weight to such projections, assumptions and estimates.

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PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere or incorporated by reference in this prospectus. This summary is not complete and does not contain all of the information that should be considered before investing in our common stock. Before making an investment decision, investors should carefully read the entire prospectus, including the information incorporated by reference in this prospectus, paying particular attention to the risks referred to under the headings Cautionary Statements Regarding Forward-Looking Statements, Risk Factors and our financial statements and the notes to those financial statements. As used in this prospectus, unless the context requires otherwise, the terms Company, we, our and us refer to Puma Biotechnology, Inc., a Delaware corporation formed on April 27, 2007 and formerly known as Innovative Acquisitions Corp., together with its wholly-owned subsidiary, Puma Biotechnology Ltd, and the term Former Puma refers to Puma Biotechnology, Inc., a private Delaware corporation that merged with and into us in October 2011.

Our Company

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

We currently license the rights to three drug candidates:

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

PB272 (neratinib (intravenous)), which we are developing for the treatment of advanced cancer patients; and

PB357, which we believe can serve as a backup compound to PB272, and which we are evaluating for further development.

We are initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor, or EGFR, type 2, or HER2, positive breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. Studies show that approximately 20% to 25% of breast cancer tumors have an over-expression of the HER2 protein. Women with breast cancer that over-expresses HER2, referred to as HER2-positive breast cancer, are at greater risk for disease progression and death than women whose tumors do not over-express HER2. We believe that there are approximately 36,000 patients in the United States and 34,000 patients in the European Union, or EU, with newly diagnosed HER2-positive breast cancer, representing an estimated total market opportunity between $1 billion and $2 billion. Therapeutic strategies, such as the use of Herceptin (trastuzumab), Perjeta (pertuzumab), and Kadcyla (T-DM1), produced by Genentech, and Tykerb (lapatinib), produced by GlaxoSmithKline, given either alone or in combination with chemotherapy, have been developed to improve the treatment of this cancer by binding HER2. There are also a number of trials ongoing that involve various combinations of these drugs (for example, Perjeta plus Kadcyla). Based on pre-clinical and clinical studies to date, we believe that neratinib may offer an advantage over existing treatments by more potently inhibiting HER2 at a different site and using a different mechanism than these other drugs.

Currently, the first-line therapy approved by the U.S. Food and Drug Administration, or FDA, for treatment of HER2-positive metastatic breast cancer is the combination of Perjeta plus Herceptin and taxane

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chemotherapy. The drug Tykerb, given in combination with the chemotherapy drug capecitabine, is also FDA approved for the treatment of HER2-positive metastatic breast cancer that has failed prior treatment. In a Phase III clinical trial, patients with HER2-positive metastatic breast cancer who received the combination of Tykerb plus capecitabine demonstrated a median progression free survival, or PFS, of 27.1 weeks and a response rate of 23.7%.

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

We commenced our Phase III clinical trial of neratinib (oral) for breast cancer patients who have previously failed two or more prior HER2-directed treatments in the second quarter of 2013. The Phase III trial is a randomized trial of PB272 plus Xeloda versus Tykerb plus Xeloda in patients with third-line HER2-positive metastatic breast cancer. The trial is expected to enroll approximately 600 patients who will be randomized (1:1) to receive either PB272 plus Xeloda or Tykerb plus Xeloda. The trial will be conducted at approximately 150 sites in North America, Europe and Asia-Pacific. The co-primary endpoints of the trial are progression free survival and overall survival. We plan to use the progression free survival data from the trial as the basis for submission of a New Drug Application, or NDA, to the FDA for accelerated approval of PB272 for this indication. We also plan to use the progression free survival data from this trial to support a MAA to the EMA for conditional approval for PB272 in the same indication.

We believe that there are between 5,000 and 6,000 patients in the United States with third line or later HER2-positive metastatic breast cancer that could benefit from treatment with neratinib, if approved. In 2013, worldwide sales of Tykerb for this indication were approximately $325 million.

We also have ongoing Phase II and Phase III clinical trials exploring the safety and efficacy of neratinib (oral):

- in combination with temsirolimus in patients with HER2-positive metastatic breast cancer who have failed multiple prior treatments;
- for the treatment of patients with HER2-positive metastatic breast cancer with brain metastases;
- for the treatment of HER2-positive neoadjuvant breast cancer;
- for the adjuvant treatment of HER2-positive breast cancer in patients who have completed adjuvant treatment with Herceptin;
- for the treatment of patients with first line HER2-positive metastatic breast cancer who have not previously received treatment in the metastatic setting;
- for the treatment of HER2 mutated non-small cell lung cancer;
- for the treatment of patients with HER2-negative breast cancer that has a HER2 mutation; and
- for the treatment of patients with solid tumors who have an activating HER2 mutation.

We expect to provide preliminary results for each of these clinical trials in 2014.

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

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

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

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

Recent Developments

Basket Trial for HER2 Mutation-Positive Solid Tumors

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

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In October 2013, we announced that we had initiated a Phase II clinical trial of neratinib as a single agent in patients with solid tumors who have an activating HER2 mutation (basket trial). The Phase II basket trial is an open-label, multicenter, multinational study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating HER2 mutations. The study initially included 6 cohorts (baskets) of patients, each of which will include one of the following cancers: (1) bladder/urinary tract cancer; (2) colorectal cancer; (3) endometrial cancer; (4) gastric/esophageal cancer; (5) ovarian cancer; and (6) all other solid tumors (including prostate, melanoma and pancreatic cancer). Each basket will initially consist of 7 patients. If a certain predetermined objective response rate is seen in the initial cohort of 7 patients, the basket will be expanded to include a larger number of patients. Additionally, we expect to add two additional baskets to the basket trial this year to enroll patients with EGFR mutated brain tumors and patients with HER3 mutations.

Top Line Data from I-SPY 2 Trial

In December 2013, we announced top line results from the Phase II clinical trial of neratinib for the neoadjuvant treatment of breast cancer, referred to as the I-SPY 2 TRIAL. The I-SPY 2 TRIAL, or Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2, is a randomized Phase II clinical trial for women with newly diagnosed Stage 2 or higher (tumor size at least 2.5 cm) breast cancer that addresses whether adding investigational drugs to standard chemotherapy in the neoadjuvant setting is better than standard chemotherapy. The primary endpoint is pathological complete response, or pCR, in the breast and the lymph nodes at the time of surgery. The goal of the trial is to match investigational regimens with patient subsets on the basis of molecular characteristics, referred to as biomarker signatures, that benefit from the regimen.

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

There were 115 patients assigned to neratinib in the trial, including 65 patients who were HER2-positive. For the patients in the trial who were HER2-positive, including those who were either hormone receptor-positive or negative, treatment with the neratinib-containing regimen also resulted in a higher pCR rate compared to the control arm. The Bayesian probability of superiority for the neratinib-containing regimen is 95.3%, which is analogous to a p-value of 0.047. In addition, the Bayesian predictive probability of showing statistical superiority in a 300-patient Phase III randomized trial of paclitaxel plus neratinib versus paclitaxel plus trastuzumab is 72.5%. Based on the results from the I-SPY 2 TRIAL, neratinib is now eligible for the upcoming I-SPY 3 Phase III trial. We intend to provide additional detail regarding the results of the I-SPY 2 TRIAL for PB272 at a future scientific meeting.

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Patent Claims for Treating Cancer with T790M Mutation Upheld

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

Additional Clinical Information

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

At the 2012 CTRC-AACR San Antonio Breast Cancer Symposium, preclinical data from cell lines that represented patients with HER2 negative breast cancer that had a mutation in HER2 were presented. The data showed that neratinib demonstrated strong antitumor activity in these cell lines compared to lapatinib.

Risks Affecting Us

Our business is subject to numerous risks, as more fully described in the section of this prospectus entitled Risk Factors, including the following:

- We currently have no product revenues and no products approved for marketing, and will need to raise additional capital to operate our business.
- We have a limited operating history and are not profitable and may never become profitable.
- We are heavily dependent on the success of neratinib (oral), our lead drug candidate, which is still under clinical development, and we cannot be certain that neratinib (oral) will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.
- Clinical trials are very expensive, time-consuming and difficult to design and implement.
- The results of our clinical trials may not support our drug candidate claims.

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We depend significantly on intellectual property licensed from Pfizer and the termination of this license would significantly harm our business and future prospects.

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

Corporate Information

We were incorporated on April 27, 2007 in Delaware under the name Innovative Acquisitions Corp. Until October 4, 2011, we were a shell company with nominal assets and no operations. On September 29, 2011, we entered into an Agreement and Plan of Merger with IAC Merger Corporation, a Delaware corporation and our wholly-owned subsidiary, or Merger Sub, and Former Puma. On October 4, 2011, Merger Sub merged with and into Former Puma, and Former Puma, as the surviving entity, became our wholly-owned subsidiary. In this prospectus, we refer to the merger between Merger Sub and Former Puma as the Merger. In November 2012, we established and incorporated Puma Biotechnology Ltd, a wholly owned subsidiary, for the sole purpose of serving as our legal representative in the United Kingdom and the European Union in connection with our clinical trial activity in those countries.

Our principal executive offices are located at 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024. Our telephone number is (424) 248-6500. Our website is *www.pumabiotechnology.com*. Information contained on our website is not incorporated by reference into, and should not be considered a part of, this prospectus.

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THE OFFERING

Common Stock Offered by Us	979,592 shares
Common Stock Outstanding After this Offering	29,668,896 shares
Option to Purchase Additional Shares	The underwriters have a 30-day option to purchase up to an additional 146,938 shares of our common stock at the public offering price less the underwriting discounts and commissions.
Use of Proceeds	We intend to use the net proceeds of this offering for the overall development of our drug candidates, including, but not limited to, research and development and clinical trial expenditures, and for general corporate and working capital purposes. See Use of Proceeds.
Public Offering Price	$122.50
Risk Factors	You should read the Risk Factors section beginning on page 10 of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.
New York Stock Exchange Symbol	PBYI

Unless otherwise noted, the number of shares of our common stock outstanding prior to and after this offering is based on 28,689,304 shares outstanding as of September 30, 2013, and excludes:

- 2,373,309 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2013 at a weighted average exercise price of $14.76 per share;
- 1,143,465 shares of common stock reserved for future issuance under our incentive award plan; and
- 2,116,250 shares of our common stock issuable upon the exercise of a warrant held by Alan Auerbach, our President and Chief Executive Officer, at $16.00 per share.

Unless otherwise indicated, the information in this prospectus assumes no exercise by the underwriters of their option to purchase additional shares of common stock from us.

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SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. The statement of operations data for the period from September 15, 2010 (inception) to December 31, 2010 and the years ended December 31, 2011 and 2012 is derived from our audited financial statements incorporated by reference in this prospectus. The statement of operations data for the nine months ended September 30, 2012 and 2013 and for the period from September 15, 2010 (inception) to September 30, 2013 and the balance sheet data as of September 30, 2013 have been derived from our unaudited financial statements incorporated by reference in this prospectus. You should read this data together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our audited financial statements and related notes incorporated by reference in this prospectus. Our historical results are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results to be expected for a full fiscal year.

(in thousands except share and per share data)	Period from September 15, 2010 (date of inception) to December 31, 2010	Year ended December 31, 2011	Year ended December 31, 2012	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Period from September 15, 2010 (date of inception) to September 30, 2013
Operating expenses:						
General and administrative	$ 7	$ 9,331	$ 24,814	$ 11,149	$ 6,804	$ 40,956
Research and development		826	49,636	41,354	32,040	82,502
Totals	7	10,157	74,450	52,503	38,844	123,458
Loss from operations	(7)	(10,157)	(74,450)	(52,503)	(38,844)	(123,458)
Other income (expenses):						
Interest income		4	98	63	128	230
Other income (expense)		(80)			3	(77)
Totals		(76)	98	63	131	153
Net loss	$ (7)	$ (10,233)	$ (74,352)	$ (52,440)	$ (38,713)	$ (123,305)
Net loss per common share basic and diluted	$ (0.002)	$ (1.321)	$ (3.422)	$ (2.617)	$ (1.350)	
Weighted-average common shares outstanding basic and diluted	4,000,000	7,746,529	21,725,986	20,040,000	28,678,439	

(1) Please see Note 2 to our audited financial statements for the year ended December 31, 2012 and Note 2 to our unaudited financial statements for the nine months ended September 30, 2013 incorporated by reference in this prospectus for an explanation of the method used to calculate basic and diluted net loss per share of common stock.

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Balance sheet data (in thousands)	As of September 30, 2013 Actual	As Adjusted (1)
Cash and cash equivalents	$ 51,261	$ 163,683
Marketable securities	44,377	44,377
Total Assets	115,109	227,531
Total Liabilities	20,349	20,349
Deficit accumulated during the development stage	(123,305)	(123,305)
Total stockholders equity	94,760	207,182

(1) Reflects the sale by us of 979,592 shares of our common stock in this offering at the public offering price of $122.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

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

Risks Related to our Business

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

To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities overseas for one or more of our drug candidates, we cannot market or sell our products and will not have product revenues. Currently, our only drug candidates are neratinib (oral), neratinib (intravenous) and PB357, and none of these products has been approved by the FDA for sale in the United States or by other regulatory authorities for sale outside the United States. Moreover, each of these drug candidates is in clinical development and will require significant time and capital before we can even apply for approval from the FDA. Therefore, for the foreseeable future, we do not expect to achieve any product revenues and will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants, and potentially, future offerings of our securities. We believe that our cash on hand is sufficient to fund our operations into the first half of 2015. However, changes may occur that would consume our available capital faster than anticipated, including changes in and progress of our development activities, acquisitions of additional drug candidates and changes in regulation. In such situations, we may need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in timely raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of any drug candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on our stockholders.

We have a limited operating history and are not profitable and may never become profitable.

We were formed in April 2007 and were a shell company with no specific business plan or purpose until we acquired Former Puma on October 4, 2011. Former Puma was a development stage company formed in September 2010 and, prior to entering into the license agreement with Pfizer in August 2011, its operations were limited to identifying compounds for in-licensing. As a result, we have a history of operating losses and no meaningful operations upon which to evaluate our business. We expect to incur substantial losses and negative operating cash flow for the foreseeable future as we continue development of our drug candidates, which we do not expect will be commercially available for a number of years, if at all. Even if we succeed in developing and commercializing one or more drug candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. The successful development and commercialization of any drug candidates will require us to perform a variety of functions, including:

- undertaking pre-clinical development and clinical trials;
- hiring additional personnel;
- participating in regulatory approval processes;
- formulating and manufacturing products;

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initiating and conducting sales and marketing activities; and

implementing additional internal systems and infrastructure.

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

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

We currently have no products that are approved for commercial sale, and we may never be able to develop marketable drug products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead drug candidate, neratinib (oral). Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of neratinib (oral). We cannot be certain that neratinib (oral) will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, l