PUMA BIOTECHNOLOGY, INC.
Form 424B3
April 12, 2013
Table of Contents

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-178308

PROSPECTUS

Puma Biotechnology, Inc.

10,942,158 Shares

Common Stock

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

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

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

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

See Risk Factors beginning on page 5.

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

The date of this prospectus is April 11, 2013.

Table of Contents

Table of Contents

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

Discussions containing these forward-looking statements may be found throughout this prospectus. Forward-looking statements speak only as of the date the statements are made. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after

the date of this document. The risks discussed in this prospectus should be considered in evaluating our prospects and future financial performance.

Table of Contents

PROSPECTUS SUMMARY

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

Our Company

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

We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients and non-small cell lung cancer patients;
- PB272 (neratinib (intravenous)), which we are developing for the treatment of advanced cancer patients; and
- PB357, which we believe can serve as a backup compound to PB272, and which we are evaluating for further development.

We are initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive breast cancer, HER2 mutated non-small cell lung cancer, and HER2-negative breast cancer that has a HER2 mutation. Studies show that approximately 20% to 25% of breast cancer tumors have an over-expression of the HER2 protein. Women with breast cancer that over-expresses HER2, referred to as HER2-positive breast cancer, are at greater risk for disease progression and death than women whose tumors do not over-express HER2. Therapeutic strategies, such as the use of Herceptin (trastuzumab), Perjeta (pertuzumab), and Kadcyla (T-DM1), produced by Genentech, and Tykerb (lapatinib), produced by GlaxoSmithKline, given either alone or in combination with chemotherapy, have been developed to improve the treatment of this cancer by binding HER2. Based on pre-clinical and clinical studies to date, we believe that neratinib may offer an advantage over existing treatments by more potently inhibiting HER2 at a different site and using a different mechanism than these other drugs.

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

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

Table of Contents

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

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

- in combination with temsirolimus in patients with HER2-positive metastatic breast cancer who have failed multiple prior treatments;
- for the treatment of patients with HER2-positive metastatic breast cancer with brain metastases;
- for the treatment of HER2-positive neoadjuvant breast cancer;
- for the treatment of HER2 mutated non-small cell lung cancer; and
- in the treatment of patients with HER2-negative breast cancer that has a HER2 mutation.

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

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

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

Corporate Information

We were incorporated on April 27, 2007 in Delaware under the name Innovative Acquisitions Corp. Until October 4, 2011, we were a shell company with nominal assets and no operations. On September 29, 2011, we entered into an Agreement and Plan of Merger with IAC Merger Corporation, a Delaware corporation and our wholly-owned subsidiary, or Merger Sub, and Former Puma. On October 4, 2011, Merger Sub merged with and into Former Puma, and Former Puma, as the surviving entity, became our wholly-owned subsidiary. In this prospectus, we refer to the merger between Merger Sub and Former Puma as the Merger. Immediately following the Merger, we effected a short-form merger whereby Former Puma merged with and into us, leaving us as the surviving corporation. In connection with the short-form merger, we changed our name to Puma Biotechnology, Inc. and adopted the business of Former Puma.

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

3

Table of Contents

THE OFFERING

Common Stock Offered by the Selling Stockholders	Up to 10,942,158 shares
Common Stock Outstanding Prior to and After this Offering:	28,676,666 shares