PUMA BIOTECHNOLOGY, INC.
Form FWP
October 20, 2016

Filed Pursuant to Rule 433
Issuer Free Writing Prospectus dated October 19, 2016
Relating to Preliminary Prospectus Supplement dated October 18, 2016
Registration Statement No. 333-201603

Puma Biotechnology, Inc.

FREE WRITING PROSPECTUS

This free writing prospectus relates to the proposed public offering of common stock of Puma Biotechnology, Inc. (the Company) and should be read together with the preliminary prospectus supplement dated October 18, 2016 and the accompanying prospectus dated January 20, 2015 filed with the Securities and Exchange Commission (SEC) before making a decision in connection with an investment in shares of the Company s common stock.

In our preliminary prospectus supplement we reference our plan to commence an expanded access program/clinical trial for neratinib for the extended adjuvant treatment of patients with early stage HER2-overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab-based therapy. Patients in this trial will be given prophylactic loperamide and budesonide in order to prevent and reduce the neratinib-related diarrhea. In addition, we received a question from an investor regarding whether this trial would be treated as an expanded access program, to which we responded in an email as follows:

Yes the EAP will be run as an expanded access program. The other example given below is for clinical trials where for example you started a Phase II or Phase III trial 3 or 4 years ago and you still have patients on study and you don t want the expenses of CROs etc. for a full trial. That is not relevant to this situation. The EAP will be run as an expanded access program under the guidance that you show below.

The guidance referenced by the investor appears in questions 26 and 27 of the FDA s Expanded Access to Investigational Drugs for Treatment Use Questions and Answers, Guidance for Industry, which are repeated below:

Q26: Can FDA consider an IND or protocol submission to be an expanded access submission and identify and review it as such, even though the applicant does not identify it as an expanded access submission?

A26: Yes. For example, FDA intends to evaluate whether proposals for studies described as open-label safety studies should be considered treatment INDs or protocols. The goal of an open-label safety study is to better characterize the safety of a drug late in its development. However, in practice, many studies that are described as open-label safety studies have characteristics that appear to be more consistent with treatment INDs or protocols. If an IND or protocol describes an open-label study that provides for broad expanded access to an investigational drug in the later stages of development, but lacks planned, systematic data collection and a design adequate to meaningfully evaluate a safety issue, FDA will generally consider the submission to be a treatment IND or protocol. In the event that a protocol is not submitted as an expanded access protocol, but is designated as such by FDA, the review division will notify the sponsor of the designation.

Q27: What is the difference between an expanded access protocol and a continuation or open-label safety protocol?

A27: A continuation protocol describes a trial in which patients are allowed to remain on an investigational drug or cross over to an investigational drug from placebo or active control following conclusion of the randomized phase of a trial. An open-label safety study is an uncontrolled trial (i.e., there is no comparison or control group). The primary

purpose of both continuation and open-label safety protocols, in contrast to expanded access protocols, is to obtain safety data on the investigational drug. The conduct of continuation and open-label safety protocols differs from that of expanded access protocols in that (1) participation in open-label safety and continuation protocols is usually limited to specific, named institutions/centers; (2) participating investigators in continuation or open-label safety protocols are already identified and trained to collect needed safety data; and (3) in the case of a continuation trial, participants are typically limited to those in the original randomized, controlled trial.

The Company has filed a registration statement (including a prospectus) and a preliminary prospectus supplement with the SEC for the offering to which this communication relates. Before you invest, you should read the preliminary prospectus supplement and prospectus contained in the registration statement and other documents the Company has filed with the SEC for more complete information about the Company and this offering. You may get these documents for free by visiting EDGAR on the SEC web site at www.sec.gov. Alternatively, the Company, any underwriter or any dealer participating in the offering will arrange to send you the preliminary prospectus supplement and the accompanying prospectus, if you request them by contacting Citigroup Global Markets Inc., c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717, or by phone at (800) 831-9146, or J.P. Morgan Securities LLC, Attention: Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717, or by phone at (866) 803-9204.