

PUMA BIOTECHNOLOGY, INC.  
Form 424B3  
October 24, 2012

Filed pursuant to Rule 424(b)(3)  
File Number 333-178308

**PROSPECTUS SUPPLEMENT NO. 6**

**(To Prospectus Dated April 16, 2012)**

**Puma Biotechnology, Inc.**

**16,000,000**

**Shares of Common Stock**

This prospectus supplement no. 6 further supplements and updates the prospectus dated April 16, 2012, as supplemented by prospectus supplement no. 1 dated April 19, 2012, prospectus supplement no. 2 dated April 30, 2012, prospectus supplement no. 3 dated May 25, 2012, prospectus supplement no. 4 dated June 26, 2012 and prospectus supplement no. 5 dated August 14, 2012, relating to the offering of up to 16,000,000 shares of our common stock that were privately issued to selling stockholders in connection with a merger transaction and a private placement.

This prospectus supplement incorporates into our prospectus the information contained in our attached Current Report on Form 8-K, which was filed with the Securities and Exchange Commission on October 24, 2012.

You should read this prospectus supplement together with the prospectus and all other supplements and amendments thereto. This prospectus supplement is qualified by reference to the prospectus and the other prospectus supplements except to the extent that the information in the prospectus supplement supersedes the information contained in the prospectus or the other prospectus supplements.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, and all other supplements and amendments thereto.

On October 19, 2012, our common stock began trading on the New York Stock Exchange (the NYSE ) under the symbol PBYI. On October 23, 2012, the closing price of our common stock on the NYSE was \$22.60 per share.

**You should carefully consider matters discussed in the Risk Factors attached as Exhibit 99.4 to the Current Report on Form 8-K attached to this prospectus supplement.**

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

The date of this prospectus supplement is October 24, 2012.

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 8-K**

**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 18, 2012**

**PUMA BIOTECHNOLOGY, INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction**

**of incorporation)**

**000-52811**  
**(Commission**

**File Number)**  
**10880 Wilshire Boulevard, Suite 2150**

**77-0683487**  
**(IRS Employer**

**Identification No.)**

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**Los Angeles, California 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:

- .. 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.**

*Underwriting Agreement*

On October 18, 2012, Puma Biotechnology, Inc. (the Company) entered into an underwriting agreement (the Underwriting Agreement) with Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC, as representatives of the several underwriters named therein (collectively, the Underwriters), providing for the offer and sale in a firm commitment underwritten public offering (the Offering) of 7,500,000 shares of the Company's common stock, par value \$0.0001 per share (the Common Stock), at a price of \$16.00 per share (the Public Offering Price), less the underwriting discount. On October 19, 2012, the representatives of the Underwriters exercised the overallotment option granted to the Underwriters in the Underwriting Agreement to purchase an additional 1,125,000 shares of Common Stock from the Company at the Public Offering Price, less the underwriting discount.

The transactions contemplated by the Underwriting Agreement were consummated on October 24, 2012. The net proceeds received by the Company from the sale of 8,625,000 shares of Common Stock were approximately \$129.1 million after deducting the underwriting discount and estimated offering expenses payable by the Company.

The foregoing description of the Underwriting Agreement is qualified in its entirety by reference to the Underwriting Agreement, a copy of which is attached hereto as Exhibit 1.1 and incorporated herein by reference.

Copies of the press releases issued by the Company in connection with the Offering are attached hereto as Exhibits 99.1, 99.2 and 99.3 and incorporated by reference herein.

*Indemnification Agreements*

On October 18, 2012, the Company entered into indemnification agreements (the Indemnification Agreements) with each of the Company's executive officers and directors. The Company's current executive officers are Alan H. Auerbach, President and Chief Executive Officer, Charles R. Eyler, Senior Vice President, Finance and Administration and Treasurer, Richard P. Bryce, Senior Vice President, Clinical Research and Development, and Richard Phillips, Ph.D., Senior Vice President, Regulatory Affairs, Quality Assurance and Pharmacovigilance. The Company's current directors are Alan H. Auerbach, Thomas R. Malley and Jay M. Moyes.

Under the Indemnification Agreements, the Company has agreed to, among other things, indemnify these individuals against certain liabilities that may arise in connection with their status or service as one of the Company's executive officers or directors or in their capacity at other specified entities at which they may serve at the Company's request and to advance their expenses incurred as a result of any proceeding for which they may be entitled to indemnification. The Indemnification Agreements are intended to provide indemnification rights to the fullest extent permitted by the General Corporation Law of the State of Delaware and are in addition to any other rights these individuals may have under the Company's organizational documents or applicable law.

The foregoing description of the Indemnification Agreements is qualified in its entirety by reference to the form of Indemnification Agreement, a copy of which is attached hereto as Exhibit 10.1 and incorporated by reference herein.

**Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing**

On October 19, 2012, the Company's Common Stock became listed and began trading on the New York Stock Exchange under the symbol PBVI. Prior to this time, shares of the Company's Common Stock were quoted for trading on the OTC Bulletin Board and OTCQB Market.

**Item 8.01 Other Events.**

In connection with the registration statement relating to the Offering, the Company provided additional information about the Company and updated its risk factors and business description. The updated risk factors and business description are attached hereto as Exhibits 99.4 and 99.5, respectively, and incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

- 1.1 Underwriting Agreement, dated October 18, 2012, among Puma Biotechnology, Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC, as representatives of the underwriters named therein
- 10.1 Form of Indemnification Agreement (incorporated by reference to Exhibit 10.17 of the Company's Amendment No. 1 to the Registration Statement on Form S-1 filed on October 15, 2012)
- 99.1 Press Release dated October 18, 2012
- 99.2 Press Release dated October 22, 2012
- 99.3 Press Release dated October 24, 2012
- 99.4 Risk Factors
- 99.5 Business Description

**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: October 24, 2012

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

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
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99.1	Press Release dated October 18, 2012
99.2	Press Release dated October 22, 2012
99.3	Press Release dated October 24, 2012
99.4	Risk Factors
99.5	Business Description

PUMA BIOTECHNOLOGY, INC.

(a Delaware corporation)

7,500,000 Shares of Common Stock

UNDERWRITING AGREEMENT

Dated: October 18, 2012



*Execution Version*

PUMA BIOTECHNOLOGY, INC.

(a Delaware corporation)

7,500,000 Shares of Common Stock

**UNDERWRITING AGREEMENT**

October 18, 2012

Merrill Lynch, Pierce, Fenner & Smith

Incorporated

Leerink Swann LLC

as Representatives of the several Underwriters

c/o Merrill Lynch, Pierce, Fenner & Smith

Incorporated

One Bryant Park

New York, New York 10036

c/o Leerink Swann LLC

One Federal Street, 37th Floor

Boston, Massachusetts 02110

Ladies and Gentlemen:

Puma Biotechnology, Inc., a Delaware corporation (the *Company*), confirms its agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated ( *Merrill Lynch* ), Leerink Swann LLC ( *Leerink* ) and each of the other Underwriters named in Schedule A hereto (collectively, the *Underwriters*, which term shall also include any underwriter substituted as hereinafter provided in Section 10 hereof), for whom Merrill Lynch and Leerink are acting as representatives (in such capacity, the *Representatives*), with respect to (i) the sale by the Company and the purchase by the Underwriters, acting severally and not jointly, of the respective numbers of shares of Common Stock, par value \$0.0001 per share, of the Company ( *Common Stock* ) set forth in Schedule A hereto and (ii) the grant by the Company to the Underwriters, acting severally and not jointly, of the option described in Section 2(b) hereof to purchase all or any part of 1,125,000 additional shares of Common Stock. The aforesaid 7,500,000 shares of Common Stock (the *Initial Securities* ) to be purchased by the Underwriters and all or any part of the 1,125,000 shares of Common Stock subject to the option described in Section 2(b) hereof (the *Option Securities* ) are herein called, collectively, the *Securities*.

The Company understands that the Underwriters propose to make a public offering of the Securities as soon as the Representatives deem advisable after this Agreement has been executed and delivered.

The Company has filed with the Securities and Exchange Commission (the *Commission* ) a registration statement on Form S-1 (No. 333-184187), including the related preliminary prospectus or prospectuses, covering the registration of the sale of the Securities under the Securities Act of 1933, as amended (the *1933 Act* ). Promptly after execution and delivery of this Agreement, the Company will

prepare and file a prospectus in accordance with the provisions of Rule 430A ( Rule 430A ) of the rules and regulations of the Commission under the 1933 Act (the 1933 Act Regulations ) and Rule 424(b) ( Rule 424(b) ) of the 1933 Act Regulations. The information included in such prospectus that was omitted from such registration statement at the time it became effective but that is deemed to be part of such registration statement at the time it became effective pursuant to Rule 430A(b) is herein called the Rule 430A Information. Such registration statement, including the amendments thereto, the exhibits thereto and any schedules thereto, at the time it became effective, and including the Rule 430A Information, is herein called the Registration Statement. Any registration statement filed pursuant to Rule 462(b) of the 1933 Act Regulations is herein called the Rule 462(b) Registration Statement and, after such filing, the term Registration Statement shall include the Rule 462(b) Registration Statement. Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a preliminary prospectus. The final prospectus, in the form first furnished to the Underwriters for use in connection with the offering of the Securities, is herein called the Prospectus. For purposes of this Agreement, all references to the Registration Statement, any preliminary prospectus, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval system or any successor system ( EDGAR ).

As used in this Agreement:

**Applicable Time** means 6:30 P.M., New York City time, on October 18, 2012 or such other time as agreed by the Company and the Representatives.

**General Disclosure Package** means any Issuer General Use Free Writing Prospectuses issued at or prior to the Applicable Time, the most recent preliminary prospectus that is distributed to investors prior to the Applicable Time and the information included on Schedule B-1 hereto, all considered together.

**Issuer Free Writing Prospectus** means any issuer free writing prospectus, as defined in Rule 433 of the 1933 Act Regulations ( Rule 433 ), including without limitation any free writing prospectus (as defined in Rule 405 of the 1933 Act Regulations ( Rule 405 )) relating to the Securities that is (i) required to be filed with the Commission by the Company, (ii) a road show that is a written communication within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Securities or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g).

**Issuer General Use Free Writing Prospectus** means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a *bona fide* electronic road show, as defined in Rule 433), as evidenced by its being specified in Schedule B-2 hereto.

**Issuer Limited Use Free Writing Prospectus** means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

**Testing-the-Waters Communication** means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the 1933 Act.

Written Testing-the-Waters Communication means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the 1933 Act.

SECTION 1. Representations and Warranties.

(a) *Representations and Warranties by the Company.* The Company represents and warrants to each Underwriter as of the date hereof, the Applicable Time, the Closing Time (as defined below) and any Date of Delivery (as defined below), and agrees with each Underwriter, as follows:

(i) Registration Statement and Prospectuses. Each of the Registration Statement and any amendment thereto has become effective under the 1933 Act. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated. The Company has complied with each request (if any) from the Commission for additional information.

Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, complied in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus, the Prospectus and any amendment or supplement thereto, at the time each was filed with the Commission, complied in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus delivered to the Underwriters for use in connection with this offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(ii) Accurate Disclosure. Neither the Registration Statement nor any amendment thereto, at its effective time, at the Closing Time or at any Date of Delivery, contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Applicable Time, none of (A) the General Disclosure Package and (B) any individual Issuer Limited Use Free Writing Prospectus, when considered together with the General Disclosure Package, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. Neither the Prospectus nor any amendment or supplement thereto (including any prospectus wrapper), as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Time or at any Date of Delivery, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

The representations and warranties in this subsection shall not apply to statements in or omissions from the Registration Statement (or any amendment thereto), the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) made in reliance upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives expressly for use therein. For purposes of this Agreement, the only information so furnished shall be the information in the first paragraph under the heading

Underwriting Commissions and Discounts, the information in the second and third paragraphs under the heading Underwriting Price Stabilization and Short Positions and the information under the heading Underwriting Electronic Distribution in each case contained in the Prospectus (collectively, the Underwriter Information ).

(iii) Issuer Free Writing Prospectuses. No Issuer Free Writing Prospectus conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, and any preliminary or other prospectus deemed to be a part thereof that has not been superseded or modified.

(iv) Testing-the-Waters Materials. The Company (A) has not engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the 1933 Act or institutions that are accredited investors within the meaning of Rule 501 under the 1933 Act and (B) has not authorized anyone to engage in Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications.

(v) Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or another offering participant made a *bona fide* offer (within the meaning of Rule 164(h)(2) of the 1933 Act Regulations) of the Securities and at the date hereof, the Company was and is an ineligible issuer, as defined in Rule 405.

(vi) Emerging Growth Company Status. From the time of the initial filing of the Registration Statement with the Commission (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an emerging growth company, as defined in Section 2(a) of the Securities Act (an Emerging Growth Company).

(vii) Independent Accountants. The accountants who certified the financial statements and supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus are independent public accountants as required by the 1933 Act, the 1933 Act Regulations, the 1934 Act, the 1934 Act Regulations and the Public Accounting Oversight Board.

(viii) Financial Statements. The financial statements included in the Registration Statement, the General Disclosure Package and the Prospectus, together with the related schedules and notes, present fairly in all material respects the financial position of the Company at the dates indicated and the statement of operations, stockholders' equity and cash flows of the Company for the periods specified; said financial statements have been prepared in conformity with U.S. generally accepted accounting principles (GAAP) applied on a consistent basis throughout the periods involved, except as may be stated in the related notes thereto. The supporting schedules, if any, present fairly in all material respects in accordance with GAAP the information required to be stated therein. The selected financial data and the summary financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included or incorporated by reference in the Registration Statement, the General Disclosure Package or the Prospectus under the 1933 Act, the 1933 Act Regulations or the 1934 Act Regulations. The interactive data in eXtensible Business Reporting Language included in the Registration Statement, the General Disclosure Package and the Prospectus fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(ix) No Material Adverse Change in Business. Except as otherwise stated therein, since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, (A) there has been no material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company, whether or not arising in the ordinary course of business (a Material Adverse Effect ), (B) there have been no transactions entered into by the Company, other than those in the ordinary course of business, which are material with respect to the Company, and (C) there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of its capital stock.

(x) Good Standing of the Company. The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware and has corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and to enter into and perform its obligations under this Agreement; and the Company is duly qualified as a foreign corporation to transact business and is in good standing in each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure so to qualify or to be in good standing would not result in a Material Adverse Effect.

(xi) Good Standing of Subsidiaries. The Company has no subsidiaries.

(xii) Capitalization. The authorized, issued and outstanding shares of capital stock of the Company are as set forth in the Registration Statement, the General Disclosure Package and the Prospectus in the column entitled Actual under the caption Capitalization (except for subsequent issuances, if any, pursuant to this Agreement, pursuant to reservations, agreements or employee benefit plans referred to in the Registration Statement, the General Disclosure Package and the Prospectus or pursuant to the exercise of convertible securities or options referred to in the Registration Statement, the General Disclosure Package and the Prospectus). The outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable. None of the outstanding shares of capital stock of the Company were issued in violation of the preemptive or other similar rights of any securityholder of the Company.

(xiii) Authorization of Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(xiv) Authorization and Description of Securities. The Securities to be purchased by the Underwriters from the Company have been duly authorized for issuance and sale to the Underwriters pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement against payment of the consideration set forth herein, will be validly issued and fully paid and non-assessable; and the issuance of the Securities is not subject to the preemptive or other similar rights of any securityholder of the Company. The Common Stock conforms in all material respects to all statements relating thereto contained in the Registration Statement, the General Disclosure Package and the Prospectus and such description conforms in all material respects to the rights set forth in the instruments defining the same. No holder of Securities will be subject to personal liability by reason of being such a holder.

(xv) Registration Rights. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, there are no persons with registration rights or other similar rights to have any securities registered for sale pursuant to the Registration Statement or otherwise registered for sale or sold by the Company under the 1933 Act pursuant to this Agreement.

(xvi) Absence of Violations, Defaults and Conflicts. The Company is not (A) in violation of its charter, by-laws or similar organizational document, (B) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease or other agreement or instrument to which the Company is a party or by which it or any of them may be bound or to which any of the properties or assets of the Company is subject (collectively, Agreements and Instruments ), except for such defaults that would not, individually or in the aggregate, result in a Material Adverse Effect, or (C) in violation of any law, statute, rule, regulation, judgment, order, writ or decree of any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency having jurisdiction over the Company or any of its subsidiaries or any of their respective properties, assets or operations (each, a Governmental Entity ), except for such violations that would not, individually or in the aggregate, result in a Material Adverse Effect. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the General Disclosure Package and the Prospectus (including the issuance and sale of the Securities and the use of the proceeds from the sale of the Securities as described therein under the caption Use of Proceeds ) and compliance by the Company with its obligations hereunder have been duly authorized by all necessary corporate action and do not and will not, whether with or without the giving of notice or passage of time or both, conflict with or constitute a breach of, or default or Repayment Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or any subsidiary pursuant to, the Agreements and Instruments (except for such conflicts, breaches, defaults or Repayment Events or liens, charges or encumbrances that would not, individually or in the aggregate, result in a Material Adverse Effect), nor will such action result in any violation of the provisions of the charter or by-laws of the Company or any law, statute, rule, regulation, judgment, order, writ or decree of any Governmental Entity. As used herein, a Repayment Event means any event or condition which gives the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company.

(xvii) Absence of Labor Dispute. No labor dispute with the employees of the Company exists or, to the knowledge of the Company, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers, customers or contractors, which, in either case, would result in a Material Adverse Effect.

(xviii) Absence of Proceedings. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, there is no action, suit, proceeding, inquiry or investigation before or brought by any Governmental Entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would result in a Material Adverse Effect, or which would reasonably be expected to materially and adversely affect the consummation of the transactions contemplated in this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company is a party or of which any of their respective properties or assets is the subject which are not described in the Registration Statement, the General Disclosure Package and the Prospectus, including ordinary routine litigation incidental to the business, would not reasonably be expected to result in a Material Adverse Effect.

(xix) Accuracy of Exhibits. There are no contracts or documents which are required to be described in the Registration Statement, the General Disclosure Package or the Prospectus or to be filed as exhibits to the Registration Statement which have not been so described and filed as required.

(xx) Absence of Further Requirements. No filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any Governmental Entity is necessary or required for the performance by the Company of its obligations hereunder, in connection with the offering, issuance or sale of the Securities hereunder or the consummation of the transactions contemplated by this Agreement, except such as have been already obtained or as may be required under the 1933 Act, the 1933 Act Regulations, the rules of the New York Stock Exchange, the NYSE MKT, state securities laws or the rules of Financial Industry Regulatory Authority, Inc. ( FINRA ).

(xxi) Regulatory Matters: Possession of Licenses and Permits. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, and except as would not, individually or in the aggregate, result in a Material Adverse Effect: (i) the Company has not received any FDA Form 483 notice of adverse finding, warning letter or other written correspondence or notice from the U.S. Food and Drug Administration ( FDA ) or any other Governmental Entity alleging or asserting noncompliance with any Applicable Laws (as defined in clause (ii) below) or Authorizations (as defined in clause (iii) below); (ii) the Company is and has been in compliance with statutes, laws, ordinances, rules and regulations applicable to the Company for the ownership, testing, development, manufacture, packaging, processing, use, labeling, promotion, storage, import, export or disposal of any product manufactured or distributed by the Company, including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., similar laws of other Governmental Entities and the regulations promulgated pursuant to such laws (collectively, Applicable Laws ); (iii) the Company possesses all licenses, certificates, approvals, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws and/or for the ownership of its properties or the conduct of its business as described in the Registration Statement, the General Disclosure Package and the Prospectus (collectively, Authorizations ) and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iv) the Company has not received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product, operation or activity is in violation of any Applicable Laws or Authorizations or has any knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, to the best of the Company s knowledge, has there been any noncompliance with or violation of any Applicable Laws by the Company that could reasonably be expected to require the issuance of any such written notice or result in an investigation, corrective action, or enforcement action by FDA or similar Governmental Entity; (v) the Company has not received written notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such Governmental Entity has threatened or is considering such action; and (vi) the Company has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete,

correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission). Neither the Company nor, to the Company's knowledge, any of its directors, officers, employees or agents has been convicted of any crime under the federal Food, Drug and Cosmetic Act or comparable laws of other Governmental Entities or has been the subject of an FDA debarment proceeding. The Company has not been nor is it now subject to FDA's Application Integrity Policy. To the Company's knowledge, neither the Company, nor any of its directors, officers, employees or agents, has made, or caused the making of, any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other Governmental Entity.

(xxii) Studies and Tests. The preclinical and clinical studies and tests conducted by, or to the knowledge of the Company, or on behalf of the Company and its subsidiaries have been and, if still pending, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to all Applicable Laws and Authorizations; the descriptions of the results of such preclinical and clinical studies and tests contained in the Registration Statement, the General Disclosure Package and the Prospectus are accurate and complete in all material respects and fairly present the data derived from such preclinical and clinical studies and tests; except to the extent disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company is not aware of any preclinical or clinical studies or tests, the results of which the Company believes reasonably call into question the research, preclinical or clinical study or test results described or referred to in the Registration Statement, the General Disclosure Package and the Prospectus when viewed in the context in which such results are described; and the Company has not received any written notices or correspondence from any Governmental Entity requiring the termination, suspension or material modification of any preclinical or clinical study or test conducted by or on behalf of the Company or its subsidiaries, as applicable.

(xxiii) Title to Property. The Company has good and marketable title to all real property owned by it and good title to all other properties owned by it, in each case, free and clear of all mortgages, pledges, liens, security interests, claims, restrictions or encumbrances of any kind except such as (A) are described in the Registration Statement, the General Disclosure Package and the Prospectus or (B) do not, individually or in the aggregate, materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company; and all of the leases and subleases material to the business of the Company, and under which the Company holds properties described in the Registration Statement, the General Disclosure Package or the Prospectus, are in full force and effect, and the Company has no notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company to the continued possession of the leased or subleased premises under any such lease or sublease.

(xxiv) Intellectual Property. To the Company's knowledge, the Company owns or possesses, or has obtained valid and enforceable licenses for, the valid right to use all patents, trademarks, trademark registrations, service marks, service mark registrations, trade names, copyrights, databases, Internet domain names, trade secrets and other intellectual property (collectively, Intellectual Property) necessary to carry on its business as currently conducted, and as proposed to be conducted, in each case as described in the Registration Statement, the General Disclosure Package and the Prospectus (collectively, Relevant Intellectual Property), except where the failure to own, license or have such rights would not, individually or in the aggregate, have Material Adverse Effect, and the Company has not received any written notice of any claim to the contrary with respect to the foregoing. Each of the agreements described in the



Registration Statement, the General Disclosure Package and the Prospectus, that include licenses or transfers of the Relevant Intellectual Property (each an Intellectual Property Agreement ) is valid, binding upon and enforceable against the Company in accordance with its terms. The Company has complied in all material respects with, and are not in material breach of, and have not received any asserted or threatened claim of material breach of, any Intellectual Property Agreement, and the Company has no knowledge of any material breach or anticipated material breach by any other person to any Intellectual Property Agreement. To the Company's knowledge, the Company's business as now conducted and as proposed to be conducted, in each case as described in the Registration Statement, the General Disclosure Package and the Prospectus, does not infringe or conflict with the Intellectual Property rights of any person or entity. The Company has not received any claim alleging infringement, misappropriation or other violation by the Company of any Intellectual Property of any person or entity, and the Company is unaware of any facts that could form a reasonable basis for any such claim upon commercialization of the drug candidates described in the Registration Statement, the General Disclosure Package and the Prospectus. To the Company's knowledge, no person or entity infringes, misappropriates or otherwise violates any Intellectual Property owned by or licensed to the Company ( Company Intellectual Property ) in any material respect. The Company has taken all steps reasonably necessary to protect, maintain and safeguard its rights in all Company Intellectual Property, including the execution of appropriate nondisclosure and confidentiality agreements when disclosing trade secrets or confidential information. The granted and issued registered Company Intellectual Property is currently in force and has been properly maintained and has not been adjudged by a court or tribunal of competent jurisdiction as invalid or unenforceable, in whole or in part, and except as otherwise disclosed in the Registration Statement, the General Disclosure Package and the Prospectus and, except as would not, individually or in the aggregate, have a Material Adverse Effect, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Company Intellectual Property. The Company (and to the Company's knowledge, the Company's licensors) have followed in all material respects all relevant laws, rules, procedures and requirements in the filing, prosecution and maintenance of pending government registered Company Intellectual Property in the relevant jurisdiction to which such government registered Company Intellectual Property is pending.

(xxv) Environmental Laws. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus or would not, individually or in the aggregate, result in a Material Adverse Effect, (A) the Company is not in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mold (collectively, Hazardous Materials ) or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, Environmental Laws ), (B) the Company has all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (C) there are no pending or, to the knowledge of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company and (D) to the knowledge of the Company there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or Governmental Entity, against or affecting the Company relating to Hazardous Materials or any Environmental Laws.

(xxvi) Accounting Controls and Disclosure Controls. The Company maintains effective internal control over financial reporting (as defined under Rule 13-a15 and 15d-15 under the rules and regulations of the Commission under the 1934 Act (the "1934 Act Regulations")) and a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (E) the interactive data in eXtensible Business Reporting Language included in the Registration Statement, the General Disclosure Package and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (1) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company maintains an effective system of disclosure controls and procedures (as defined in Rule 13a-15 and Rule 15d-15 under the 1934 Act Regulations) that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the 1934 Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, and is accumulated and communicated to the Company's management, including its principal executive officer or officers and principal financial officer or officers, as appropriate, to allow timely decisions regarding disclosure.

(xxvii) Compliance with the Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "Sarbanes-Oxley Act") with which the Company is required to comply, including Section 402 related to loans and Sections 302 and 906 related to certifications.

(xxviii) Payment of Taxes. All United States federal income tax returns of the Company required by law to be filed have been filed, except insofar as the failure to file such returns would not result in a Material Adverse Effect, and all taxes shown by such returns or otherwise assessed, which are due and payable, have been paid, except taxes and assessments against which appeals have been or will be promptly taken and as to which adequate reserves have been provided. The Company has filed all other tax returns that are required to have been filed by it pursuant to applicable foreign, state, local or other law except insofar as the failure to file such returns would not result in a Material Adverse Effect, and has paid all taxes due pursuant to such returns or pursuant to any assessment received by the Company, except for such taxes, if any, as are being contested in good faith and as to which adequate reserves have been established by the Company. The charges, accruals and reserves on the books of the Company in respect of any income and corporation tax liability for any years not finally determined are adequate to meet any assessments or re-assessments for additional income tax for any years not finally determined, except to the extent of any inadequacy that would not result in a Material Adverse Effect.

(xxix) Insurance. The Company carries or is entitled to the benefits of insurance, with financially sound and reputable insurers, in such amounts and covering such risks as is generally maintained by similar-sized companies of established repute engaged in the same or similar business, and all such insurance is in full force and effect. The Company has no reason to believe that it will not be able (A) to renew its existing insurance coverage as and when such policies expire or (B) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Effect. The Company has not been denied any insurance coverage which it has sought or for which it has applied.

(xxx) Investment Company Act. The Company is not required, and upon the issuance and sale of the Securities as herein contemplated and the application of the net proceeds therefrom as described in the Registration Statement, the General Disclosure Package and the Prospectus will not be required, to register as an investment company under the Investment Company Act of 1940, as amended (the 1940 Act ).

(xxxii) Absence of Manipulation. Neither the Company nor any affiliate of the Company has taken, nor will the Company or any affiliate take, directly or indirectly, any action which is designed, or would be expected, to cause or result in, or which constitutes, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities or to result in a violation of Regulation M under the 1934 Act; provided that no representation is made in this subsection with respect to actions of the Underwriters.

(xxxiii) Rated Debt. The Company has no debt securities or preferred stock that is rated by any nationally recognized statistical rating agency (as that term is defined by the Commission for purposes of Rule 436(g)(2) under the 1933 Act).

(xxxiiii) Foreign Corrupt Practices Act. Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the FCPA ), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any foreign official (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(xxxv) Money Laundering Laws. The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the Money Laundering Laws ); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xxxv) OFAC. Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or representative of the Company is an individual or entity ( Person ) currently the subject or target of any sanctions administered or enforced by the United States Government, including, without limitation, the U.S. Department of the Treasury's Office of Foreign Assets Control ( OFAC ), the United Nations Security Council ( UNSC ), the European Union, Her Majesty's Treasury ( HMT ), or other relevant sanctions authority (collectively, Sanctions ), nor is the Company located, organized or resident in a country or territory that is the subject of Sanctions; and the Company will not directly or indirectly use the proceeds of the sale of the Securities, or lend, contribute or otherwise make available such proceeds to any of its joint venture partners or other Person, to fund any activities of or business with any Person, or in any country or territory, that, at the time of such funding, is the subject of Sanctions or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

(xxxvi) Lending Relationship. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of any Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Securities to repay any outstanding debt owed to any affiliate of any Underwriter.

(xxxvii) Statistical and Market-Related Data. Any statistical and market-related data included in the Registration Statement, the General Disclosure Package or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate in all material respects and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

(b) Officer's Certificates. Any certificate signed by any officer of the Company delivered to the Representatives or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

## SECTION 2. Sale and Delivery to Underwriters; Closing.

(a) Initial Securities. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company agrees to sell to each Underwriter, severally and not jointly, and each Underwriter, severally and not jointly, agrees to purchase from the Company, at the price per share set forth in Schedule A, that number of Initial Securities set forth in Schedule A opposite the name of such Underwriter, plus any additional number of Initial Securities which such Underwriter may become obligated to purchase pursuant to the provisions of Section 10 hereof, subject, in each case, to such adjustments among the Underwriters as the Representatives in their sole discretion shall make to eliminate any sales or purchases of fractional shares.

(b) Option Securities. In addition, on the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company hereby grant(s) an option to the Underwriters, severally and not jointly, to purchase up to an additional 1,125,000 shares of Common Stock, at the price per share set forth in Schedule A, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities. The option hereby granted may be exercised for 30 days after the date hereof and may be exercised in whole or in part at any time from time to time only for the purpose of covering overallocments made in connection with the offering and distribution of the Initial Securities upon notice by the Representatives to the Company setting forth the number of Option Securities as to which the

several Underwriters are then exercising the option and the time and date of payment and delivery for such Option Securities. Any such time and date of delivery (a Date of Delivery ) shall be determined by the Representatives, but shall not be later than seven full business days after the exercise of said option or, unless otherwise agreed upon by the Representatives and the Company, earlier than two full business days after the exercise of said option, nor in any event prior to the Closing Time. If the option is exercised as to all or any portion of the Option Securities, each of the Underwriters, acting severally and not jointly, will purchase that proportion of the total number of Option Securities then being purchased which the number of Initial Securities set forth in Schedule A opposite the name of such Underwriter bears to the total number of Initial Securities, subject, in each case, to such adjustments as the Representatives in their sole discretion shall make to eliminate any sales or purchases of fractional shares.

(c) *Payment.* Payment of the purchase price for, and delivery of certificates for, the Initial Securities shall be made at the offices of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Chrysler Center, 666 Third Avenue, New York, New York, 10017 or at such other place as shall be agreed upon by the Representatives and the Company, at 9:00 A.M. (New York City time) on the third (fourth, if the pricing occurs after 4:30 P.M. (New York City time) on any given day) business day after the date hereof (unless postponed in accordance with the provisions of Section 10), or such other time not later than ten business days after such date as shall be agreed upon by the Representatives and the Company (such time and date of payment and delivery being herein called Closing Time ).

In addition, in the event that any or all of the Option Securities are purchased by the Underwriters, payment of the purchase price for, and delivery of certificates for, such Option Securities shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representatives and the Company, on each Date of Delivery as specified in the notice from the Representatives to the Company.

Payment shall be made to the Company by wire transfer of immediately available funds to a bank account designated by the Company against delivery to the Representatives for the respective accounts of the Underwriters of certificates for the Securities to be purchased by them. It is understood that each Underwriter has authorized the Representatives, for its account, to accept delivery of, receipt for, and make payment of the purchase price for, the Initial Securities and the Option Securities, if any, which it has agreed to purchase. The Representatives, individually and not as representatives of the Underwriters, may (but shall not be obligated to) make payment of the purchase price for the Initial Securities or the Option Securities, if any, to be purchased by any Underwriter whose funds have not been received by the Closing Time or the relevant Date of Delivery, as the case may be, but such payment shall not relieve such Underwriter from its obligations hereunder.

SECTION 3. Covenants of the Company. The Company covenants with each Underwriter as follows:

(a) *Compliance with Securities Regulations and Commission Requests.* The Company, subject to Section 3(b), will comply with the requirements of Rule 430A, and will notify the Representatives promptly, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed, (ii) of the receipt of any comments from the Commission, (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or for additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any preliminary prospectus or the Prospectus, or of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d)

or 8(e) of the 1933 Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the 1933 Act in connection with the offering of the Securities. The Company will effect all filings required under Rule 424(b), in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and will take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company will make every reasonable effort to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof at the earliest possible moment.

(b) *Continued Compliance with Securities Laws.* The Company will comply with the 1933 Act and the 1933 Act Regulations so as to permit the completion of the distribution of the Securities as contemplated in this Agreement and in the Registration Statement, the General Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172 of the 1933 Act Regulations ( Rule 172 ), would be) required by the 1933 Act to be delivered in connection with sales of the Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) amend or supplement the General Disclosure Package or the Prospectus in order that the General Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the General Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the 1933 Act or the 1933 Act Regulations, the Company will promptly (A) give the Representatives notice of such event, (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the General Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representatives with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representatives or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company has given the Representatives notice of any filings made pursuant to the 1934 Act or 1934 Act Regulations within 48 hours prior to the Applicable Time; the Company will give the Representatives notice of its intention to make any such filing from the Applicable Time to the Closing Time and will furnish the Representatives with copies of any such documents a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representatives or counsel for the Underwriters shall reasonably object.

(c) *Delivery of Registration Statements.* The Company has furnished or will deliver to the Representatives and counsel for the Underwriters, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and signed copies of all consents and certificates of experts, and will also deliver to the Representatives, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(d) *Delivery of Prospectuses.* The Company has delivered to each Underwriter, without charge, as many copies of each preliminary prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the 1933 Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(e) *Blue Sky Qualifications.* The Company will use its best efforts, in cooperation with the Underwriters, to qualify the Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representatives may designate and to maintain such qualifications in effect so long as required to complete the distribution of the Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

(f) *Rule 158.* The Company will timely file such reports pursuant to the 1934 Act as are necessary in order to make generally available to its securityholders as soon as practicable an earnings statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, the last paragraph of Section 11(a) of the 1933 Act.

(g) *Use of Proceeds.* The Company will use the net proceeds received by it from the sale of the Securities in the manner specified in the Registration Statement, the General Disclosure Package and the Prospectus under Use of Proceeds.

(h) *Listing.* The Company will use its best efforts to effect and maintain the listing of the Common Stock (including the Securities) on the New York Stock Exchange.

(i) *Restriction on Sale of Securities.* During a period of 90 days from the date of the Prospectus, the Company will not, without the prior written consent of the Representatives, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or file any registration statement under the 1933 Act with respect to any of the foregoing or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock, whether any such swap or transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise. The foregoing sentence shall not apply to (A) the Securities to be sold hereunder, (B) any shares of Common Stock issued by the Company upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, the General Disclosure Package and the Prospectus, or (C) any shares of Common Stock issued or options to purchase Common Stock granted pursuant to existing employee benefit plans of the Company referred to in the Registration Statement, the General Disclosure Package and the Prospectus.

(j) If the Representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up agreement described in Section 5(i) hereof for an officer or director of the Company and provide the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit D hereto through a major news service at least two business days before the effective date of the release or waiver.

(k) *Reporting Requirements.* The Company, during the period when a Prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, will file all documents required to be filed with the Commission pursuant to the 1934 Act within the time periods required by the 1934 Act and 1934 Act Regulations.

(l) *Issuer Free Writing Prospectuses.* The Company agrees that it will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a free writing prospectus required to be filed by the Company with the Commission under Rule 433.

(m) *Underwriter Free Writing Prospectuses.* Each Underwriter severally agrees with the Company and each other Underwriter that such Underwriter has not made, and will not make, any offer relating to the Securities that would constitute a free writing prospectus required to be filed with the Commission under Rule 433.

(n) *Emerging Growth Company Status.* The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Securities within the meaning of the Securities Act and (ii) completion of the 90-day restricted period referred to in Section 3(i).

#### SECTION 4. Payment of Expenses.

(a) *Expenses.* The Company will pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, printing and filing of the Registration Statement (including financial statements and exhibits) as originally filed and each amendment thereto, (ii) the preparation, printing and delivery to the Underwriters of copies of each preliminary prospectus, each Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto and any costs associated with electronic delivery of any of the foregoing by the Underwriters to investors, (iii) the preparation, issuance and delivery of the certificates for the Securities to the Underwriters, including any stock or other transfer taxes and any stamp or other duties payable upon the sale, issuance or delivery of the Securities to the Underwriters, (iv) the fees and disbursements of the Company's counsel, accountants and other advisors, (v) the qualification of the Securities under securities laws in accordance with the provisions of Section 3(e) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters up to \$15,000 in connection therewith and in connection with the preparation of the Blue Sky Survey and any supplement thereto, (vi) the fees and expenses of any transfer agent or registrar for the Securities, (vii) the costs and expenses of the Company relating to investor presentations on any road show undertaken in connection with the marketing of the Securities, including without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and one-half of the cost of chartered aircraft and other transportation chartered in connection with the road show, (viii) the filing fees incident to, and the reasonable fees and disbursements of counsel to the Underwriters in connection with, the review by FINRA of the terms of the sale of the Securities, (ix) the fees and expenses incurred in connection with the listing of the Securities on the New York Stock Exchange and (x) the costs and expenses (including, without limitation, any damages or other amounts payable in connection with legal or contractual liability) associated with the reforming of any contracts for sale of the Securities made by the Underwriters caused by a breach of the representation contained in the third sentence of Section 1(a)(ii). Except as provided in this Section 4, Section 6 and Section 7, the Underwriters shall pay their own expenses, including the fees and disbursements of their counsel.



(b) *Termination of Agreement.* If this Agreement is terminated by the Representatives in accordance with the provisions of Section 5, Section 9(a)(i) or (iii) or Section 10 hereof, the Company shall reimburse the Underwriters (or, in the case of a termination in accordance with Section 10, solely the non-defaulting Underwriters) for all of their accountable out-of-pocket expenses, including the reasonable fees and disbursements of counsel for the Underwriters incurred by them in connection with the offering of the Securities.

SECTION 5. Conditions of Underwriters Obligations. The obligations of the several Underwriters hereunder are subject to the accuracy of the representations and warranties of the Company contained herein or in certificates of any officer of the Company delivered pursuant to the provisions hereof, to the performance by the Company of its covenants and other obligations hereunder, and to the following further conditions:

(a) *Effectiveness of Registration Statement; Rule 430A Information.* The Registration Statement, including any Rule 462(b) Registration Statement, has become effective and, at the Closing Time, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated; and the Company has complied with each request (if any) from the Commission for additional information. A prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) without reliance on Rule 424(b)(8) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

(b) *Opinion of Counsel for Company.* At the Closing Time, the Representatives shall have received the favorable opinion and negative assurance letter, dated the Closing Time, of Latham & Watkins LLP, counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, together with signed or reproduced copies of such letters for each of the other Underwriters to the effect set forth in Exhibit A hereto.

(c) *Opinion of Intellectual Property Counsel for Company.* At the Closing Time, the Representatives shall have received the favorable opinion, dated the Closing Time, of Jones Day, intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, together with signed or reproduced copies of such letter for each of the other Underwriters to the effect set forth in Exhibit B hereto.

(d) *Opinion of Counsel for Underwriters.* At the Closing Time, the Representatives shall have received the favorable opinion, dated the Closing Time, of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel for the Underwriters, together with signed or reproduced copies of such letter for each of the other Underwriters with respect to the matters set forth in Exhibit A, clauses (v), (vi) (solely as to preemptive or other similar rights arising by operation of law or under the charter or by-laws of the Company), (viii), (x), (xiv) (solely as to the information in the Prospectus under Description of Capital Stock Common Stock ), the penultimate paragraph of Exhibit A hereto, and other related matters as the Representatives may require. In giving such opinion such counsel may rely, as to all matters governed by the laws of jurisdictions other than the law of the State of New York, the General Corporation Law of the State of Delaware and the federal securities laws of the United States, upon the opinions of counsel satisfactory to the Representatives. Such counsel may also state that, insofar as such opinion involves factual matters, they have relied, to the extent they deem proper, upon certificates of officers and other representatives of the Company and certificates of public officials.

(e) *Officers Certificate*. At the Closing Time, there shall not have been, since the date hereof or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company, whether or not arising in the ordinary course of business, and the Representatives shall have received a certificate of the Chief Executive Officer or the President of the Company and of the chief financial or chief accounting officer of the Company, dated the Closing Time, to the effect that (i) there has been no such material adverse change, (ii) the representations and warranties of the Company in this Agreement are true and correct with the same force and effect as though expressly made at and as of the Closing Time, (iii) the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied at or prior to the Closing Time, and (iv) no stop order suspending the effectiveness of the Registration Statement under the 1933 Act has been issued, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to their knowledge, contemplated.

(f) *Accountant's Comfort Letter*. At the time of the execution of this Agreement, the Representatives shall have received from PKF LLP a letter, dated such date, in form and substance satisfactory to the Representatives, together with signed or reproduced copies of such letter for each of the other Underwriters containing statements and information of the type ordinarily included in accountants' comfort letters to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the General Disclosure Package and the Prospectus.

(g) *Bring-down Comfort Letter*. At the Closing Time, the Representatives shall have received from PKF LLP a letter, dated as of the Closing Time, to the effect that they reaffirm the statements made in the letter furnished pursuant to subsection (f) of this Section, except that the specified date referred to shall be a date not more than three business days prior to the Closing Time.

(h) *Approval of Listing*. At the Closing Time, the Securities shall have been approved for listing on the New York Stock Exchange, subject only to official notice of issuance.

(i) *No Objection*. FINRA has confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Securities.

(j) *Lock-up Agreements*. At the date of this Agreement, the Representatives shall have received an agreement substantially in the form of Exhibit C hereto signed by the persons listed on Schedule C hereto.

(k) *Conditions to Purchase of Option Securities*. In the event that the Underwriters exercise their option provided in Section 2(b) hereof to purchase all or any portion of the Option Securities, the representations and warranties of the Company contained herein and the statements in any certificates furnished by the Company hereunder shall be true and correct as of each Date of Delivery and, at the relevant Date of Delivery, the Representatives shall have received:

(i) *Officers Certificate*. A certificate, dated such Date of Delivery, of the President or a Vice President of the Company and of the chief financial or chief accounting officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(e) hereof remains true and correct as of such Date of Delivery.

(ii) Opinion and Negative Assurance Letter of Counsel for Company. If requested by the Representatives, the favorable opinion and negative assurance letter of Latham & Watkins LLP, counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(b) hereof.

(iii) Opinion of Intellectual Property Counsel for Company. If requested by the Representatives, the favorable opinion of Jones Day, intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(c) hereof.

(iv) Opinion of Counsel for Underwriters. If requested by the Representatives, the favorable opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(d) hereof.

(v) Bring-down Comfort Letter. If requested by the Representatives, a letter from PKF LLP, in form and substance satisfactory to the Representatives and dated such Date of Delivery, substantially in the same form and substance as the letter furnished to the Representatives pursuant to Section 5(g) hereof, except that the specified date in the letter furnished pursuant to this paragraph shall be a date not more than three business days prior to such Date of Delivery.

(l) Additional Documents. At the Closing Time and at each Date of Delivery (if any) counsel for the Underwriters shall have been furnished with such documents and opinions as they may reasonably require for the purpose of enabling them to pass upon the issuance and sale of the Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters.

(m) Termination of Agreement. If any condition specified in this Section shall not have been fulfilled when and as required to be fulfilled, this Agreement, or, in the case of any condition to the purchase of Option Securities on a Date of Delivery which is after the Closing Time, the obligations of the several Underwriters to purchase the relevant Option Securities, may be terminated by the Representatives by notice to the Company at any time at or prior to Closing Time or such Date of Delivery, as the case may be, and such termination shall be without liability of any party to any other party except as provided in Section 4 and except that Sections 1, 6, 7, 8, 11, 13, 14, 15, 16 and 19 shall survive any such termination and remain in full force and effect.

#### SECTION 6. Indemnification.

(a) Indemnification of Underwriters. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates (as such term is defined in Rule 501(b) under the 1933 Act (each, an Affiliate)), its selling agents and each person, if any, who controls any Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, arising out of any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including the Rule 430A Information, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or arising out of any untrue statement or alleged untrue statement of a material fact included (A) in any preliminary prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto), or (B) in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities ( Marketing Materials ), including any roadshow or investor presentations made to investors by the Company (whether in person or electronically), or the omission or alleged omission in any preliminary prospectus, Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, Prospectus or in any Marketing Materials of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 6(d) below) any such settlement is effected with the written consent of the Company;

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel chosen by the Representatives), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above;

provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(b) *Indemnification of Company, Directors and Officers.* Each Underwriter severally agrees to indemnify and hold harmless the Company, its directors, each of its officers who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act, against any and all loss, liability, claim, damage and expense described in the indemnity contained in subsection (a) of this Section, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) or any Issuer Free Writing Prospectus in reliance upon and in conformity with the Underwriter Information.

(c) *Actions against Parties; Notification.* Each indemnified party shall give notice as promptly as reasonably practicable to each indemnifying party of any action commenced against it in respect of which indemnity may be sought hereunder, but failure to so notify an indemnifying party shall not relieve such indemnifying party from any liability hereunder to the extent it is not materially prejudiced as a result thereof and in any event shall not relieve it from any liability which it may have

otherwise than on account of this indemnity agreement. In the case of parties indemnified pursuant to Section 6(a) above, counsel to the indemnified parties shall be selected by the Representatives, and, in the case of parties indemnified pursuant to Section 6(b) above, counsel to the indemnified parties shall be selected by the Company. An indemnifying party may participate at its own expense in the defense of any such action; provided, however, that counsel to the indemnifying party shall not (except with the consent of the indemnified party) also be counsel to the indemnified party. In no event shall the indemnifying parties be liable for fees and expenses of more than one counsel (in addition to any local counsel) separate from their own counsel for all indemnified parties in connection with any one action or separate but similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification or contribution could be sought under this Section 6 or Section 7 hereof (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) *Settlement without Consent if Failure to Reimburse.* If at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a)(ii) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

**SECTION 7. Contribution.** If the indemnification provided for in Section 6 hereof is for any reason unavailable to or insufficient to hold harmless an indemnified party in respect of any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount of such losses, liabilities, claims, damages and expenses incurred by such indemnified party, as incurred, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Securities pursuant to this Agreement or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and of the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations.

The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Securities pursuant to this Agreement shall be deemed to be in the same respective proportions as the total net proceeds from the offering of the Securities pursuant to this Agreement (before deducting expenses) received by the Company, on the one hand, and the total underwriting discount received by the Underwriters, on the other hand, in each case as set forth on the cover of the Prospectus, bear to the aggregate public offering price of the Securities as set forth on the cover of the Prospectus.

The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 7 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 7. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above in this Section 7 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission.

Notwithstanding the provisions of this Section 7, no Underwriter shall be required to contribute any amount in excess of the underwriting commissions received by such Underwriter in connection with the Securities underwritten by it and distributed to the public.

No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

For purposes of this Section 7, each person, if any, who controls an Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act and each Underwriter's Affiliates and selling agents shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act shall have the same rights to contribution as the Company. The Underwriters' respective obligations to contribute pursuant to this Section 7 are several in proportion to the number of Initial Securities set forth opposite their respective names in Schedule A hereto and not joint.

**SECTION 8. Representations, Warranties and Agreements to Survive.** All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company and (ii) delivery of and payment for the Securities.

**SECTION 9. Termination of Agreement.**

(a) *Termination.* The Representatives may terminate this Agreement, by notice to the Company, at any time at or prior to the Closing Time (i) if there has been, in the judgment of the Representatives, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company, whether or not arising in the ordinary course of business, or (ii) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the completion of the offering or to enforce contracts for the sale of the Securities, or (iii) if trading in any securities of the Company has been

suspended or materially limited by the Commission or the New York Stock Exchange, or (iv) if trading generally on the New York Stock Exchange or in the Nasdaq Global Market has been suspended or materially limited, or minimum or maximum prices for trading have been fixed, or maximum ranges for prices have been required, by any of said exchanges or by order of the Commission, FINRA or any other governmental authority, or (v) a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States, or (vi) if a banking moratorium has been declared by either Federal or New York authorities.

(b) *Liabilities*. If this Agreement is terminated pursuant to this Section, such termination shall be without liability of any party to any other party except as provided in Section 4 hereof, and provided further that Sections 1, 6, 7, 8, 11, 13, 14, 15, 16 and 19 shall survive such termination and remain in full force and effect.

**SECTION 10. Default by One or More of the Underwriters**. If one or more of the Underwriters shall fail at the Closing Time or a Date of Delivery to purchase the Securities which it or they are obligated to purchase under this Agreement (the "Defaulted Securities"), the Representatives shall have the right, within 24 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other underwriters, to purchase all, but not less than all, of the Defaulted Securities in such amounts as may be agreed upon and upon the terms herein set forth; if, however, the Representatives shall not have completed such arrangements within such 24-hour period, then:

(i) if the number of Defaulted Securities does not exceed 10% of the number of Securities to be purchased on such date, each of the non-defaulting Underwriters shall be obligated, severally and not jointly, to purchase the full amount thereof in the proportions that their respective underwriting obligations hereunder bear to the underwriting obligations of all non-defaulting Underwriters, or

(ii) if the number of Defaulted Securities exceeds 10% of the number of Securities to be purchased on such date, this Agreement or, with respect to any Date of Delivery which occurs after the Closing Time, the obligation of the Underwriters to purchase, and the Company to sell, the Option Securities to be purchased and sold on such Date of Delivery shall terminate without liability on the part of any non-defaulting Underwriter.

No action taken pursuant to this Section shall relieve any defaulting Underwriter from liability in respect of its default.

In the event of any such default which does not result in a termination of this Agreement or, in the case of a Date of Delivery which is after the Closing Time, which does not result in a termination of the obligation of the Underwriters to purchase and the Company to sell the relevant Option Securities, as the case may be, either (i) the Representatives or (ii) the Company shall have the right to postpone Closing Time or the relevant Date of Delivery, as the case may be, for a period not exceeding seven days in order to effect any required changes in the Registration Statement, the General Disclosure Package or the Prospectus or in any other documents or arrangements. As used herein, the term "Underwriter" includes any person substituted for an Underwriter under this Section 10.

**SECTION 11. Notices**. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted by any standard form of telecommunication. Notices to the Underwriters shall be directed to the Representatives c/o Merrill Lynch, Pierce, Fenner & Smith Incorporated, One Bryant Park, New York, New York 10036, attention of Syndicate Department (facsimile: (646) 855-3073) with a copy to ECM Legal (facsimile: (212) 230-8730) and c/o Leerink Swann LLC, One Federal Street, 37<sup>th</sup> Floor, Boston, Massachusetts 02110, attention of

Timothy A.G. Gerhold, Esq. (facsimile: (714) 755-8290), with a copy to Syndicate (facsimile: (617) 918-4900); notices to the Company shall be directed to it at 10880 Wilshire Blvd, Suite 2150, Los Angeles, California 90024 (facsimile: (424) 248-6501, attention of Chief Executive Officer, with a copy to Latham & Watkins LLP, 650 Town Center Drive, 20<sup>th</sup> Floor, Costa Mesa, California 92626 (facsimile: (714) 755-8290).

**SECTION 12. No Advisory or Fiduciary Relationship.** The Company acknowledges and agrees that (a) the purchase and sale of the Securities pursuant to this Agreement, including the determination of the public offering price of the Securities and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering of the Securities and the process leading thereto, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company or its stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Securities or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company on other matters) and no Underwriter has any obligation to the Company with respect to the offering of the Securities except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering of the Securities and the Company has consulted its own respective legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

**SECTION 13. Parties.** This Agreement shall each inure to the benefit of and be binding upon the Underwriters and the Company and their respective successors. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, firm or corporation, other than the Underwriters and the Company and their respective successors and the controlling persons and officers and directors referred to in Sections 6 and 7 and their heirs and legal representatives, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the Underwriters and the Company and their respective successors, and said controlling persons and officers and directors and their heirs and legal representatives, and for the benefit of no other person, firm or corporation. No purchaser of Securities from any Underwriter shall be deemed to be a successor by reason merely of such purchase.

**SECTION 14. Trial by Jury.** The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

**SECTION 15. GOVERNING LAW.** THIS AGREEMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK WITHOUT REGARD TO ITS CHOICE OF LAW PROVISIONS.

**SECTION 16. Consent to Jurisdiction; Waiver of Immunity.** Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ( Related Proceedings ) shall be instituted in (i) the federal courts of the United States of America located in the City and County of New York, Borough of Manhattan or (ii) the courts of the State of New York located in the City and County of New York, Borough of Manhattan (collectively, the Specified Courts ), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to



the enforcement of a judgment of any such court (a Related Judgment ), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party s address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

SECTION 17. TIME. TIME SHALL BE OF THE ESSENCE OF THIS AGREEMENT. EXCEPT AS OTHERWISE SET FORTH HEREIN, SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME.

SECTION 18. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement.

SECTION 19. Effect of Headings. The Section headings herein are for convenience only and shall not affect the construction hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement among the Underwriters and the Company in accordance with its terms.

Very truly yours,

PUMA BIOTECHNOLOGY, INC.

By /s/ Alan H. Auerbach  
Title: CEO / President

CONFIRMED AND ACCEPTED,

as of the date first above written:

MERRILL LYNCH, PIERCE, FENNER &

SMITH INCORPORATED

By /s/ James Cooney  
Authorized Signatory

LEERINK SWANN LLC

By /s/ Daniel Dubin  
Authorized Signatory

For themselves and as Representatives of the other Underwriters named in Schedule A hereto.

## SCHEDULE A

The public offering price per share for the Securities shall be \$16.00.

The purchase price per share for the Securities to be paid by the several Underwriters shall be \$15.04, being an amount equal to the public offering price set forth above less \$0.96 per share, subject to adjustment in accordance with Section 2(b) for dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities.

Name of Underwriter	Number of Initial Securities
Merrill Lynch, Pierce, Fenner & Smith Incorporated	3,000,000
Leerink Swann LLC	2,250,000
Stifel, Nicolaus & Company, Incorporated	750,000
Cowen and Company, LLC	750,000
UBS Securities LLC	750,000
Total	7,500,000

SCHEDULE B-1

Pricing Terms

1. The Company is selling 7,500,000 shares of Common Stock.
2. The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional 1,125,000 shares of Common Stock.
3. The public offering price per share for the Securities shall be \$16.00.

SCHEDULE B-2

Free Writing Prospectuses

NONE

SCHEDULE C

List of Persons and Entities Subject to Lock-up

Alan H. Auerbach

Thomas R. Malley

Jay M. Moyes

Charles R. Eyler

Richard P. Bryce

Richard Phillips, Ph.D.

FORM OF OPINION AND NEGATIVE ASSURANCE LETTER OF COMPANY S COUNSEL

TO BE DELIVERED PURSUANT TO SECTION 5(b)

FORM OF OPINION OF COMPANY'S INTELLECTUAL PROPERTY COUNSEL

TO BE DELIVERED PURSUANT TO SECTION 5(C)

FORM OF LOCK-UP AGREEMENT

September \_\_\_\_\_, 2012

Merrill Lynch, Pierce, Fenner & Smith Incorporated

Leerink Swann LLC

as Representatives of the several

Underwriters to be named in the

within-mentioned Underwriting Agreement

c/o Merrill Lynch, Pierce, Fenner & Smith Incorporated

One Bryant Park

New York, New York 10036

Re: Proposed Public Offering by Puma Biotechnology, Inc.

Dear Sirs:

The undersigned, an officer, director and/or stockholder of Puma Biotechnology, Inc., Delaware corporation (the Company), understands that Merrill Lynch, Pierce, Fenner & Smith Incorporated (Merrill Lynch) and Leerink Swann LLC (Leerink, and together with Merrill Lynch, the Representatives) propose to enter into an Underwriting Agreement (the Underwriting Agreement) with the Company providing for the public offering (the Offering) of shares (the Securities) of the Company's common stock, par value \$0.0001 per share (Common Stock). In recognition of the benefit that the Offering will confer upon the undersigned as an officer, director and/or stockholder of the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each underwriter to be named in the Underwriting Agreement (collectively, the Underwriters) that, during the period beginning on the date hereof and ending on the date that is 90 days from the date of the Underwriting Agreement (subject to extensions as discussed below), the undersigned will not, without the prior written consent of the Representatives, directly or indirectly, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant for the sale of, or otherwise dispose of or transfer any shares of the Company's Common Stock or any securities convertible into or exchangeable or exercisable for Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition (collectively, the Lock-Up Securities), or exercise any right with respect to the registration of any of the Lock-up Securities, or file or cause to be filed any registration statement in connection therewith, under the Securities Act of 1933, as amended, or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Lock-Up Securities, whether any such swap or transaction is to be settled by delivery of Common Stock or other securities, in cash or otherwise.



If the undersigned is an officer or director of the Company, (1) the Representatives agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, the Representatives will notify the Company of the impending release or waiver, and (2) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (i) the release or waiver is effected solely to permit a transfer not for consideration and (ii) the transferee has agreed in writing to be bound by the same terms described in this letter to the extent and for the duration that such terms remain in effect at the time of the transfer.

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer the Lock-Up Securities without the prior written consent of the Representatives, provided that in the case of (i) through (v) below (1) the Representatives receive a signed lock-up agreement for the balance of the lockup period from each donee, trustee, executor, administrator, distributee or transferee, as the case may be, (2) any such transfer shall not involve a disposition for value, (3) such transfers are not required to be reported with the Securities and Exchange Commission on Form 4 in accordance with Section 16 of the Securities Exchange Act of 1934, as amended (the Exchange Act), and (4) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers during the 90-day lock-up period:

- (i) as a *bona fide* gift or gifts; or
  
- (ii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this lock-up agreement, immediate family shall mean any relationship by blood, marriage or adoption, not more remote than first cousin); or
  
- (iii) as a distribution to limited partners or stockholders of the undersigned; or
  
- (iv) to the undersigned's affiliates or to any investment fund or other entity controlled or managed by the undersigned; or
  
- (v) following the death of the undersigned by will, by intestate succession or pursuant to a so-called living trust or other revocable trust established to provide for the disposition of the undersigned's property upon the undersigned's death; or
  
- (vi) to the Company (or the Company may withhold such securities) solely for tax withholding purposes in connection with the vesting of equity awards that are subject to a taxable event upon vesting.

Furthermore, the undersigned may sell shares of Common Stock of the Company purchased by the undersigned on the open market following the Offering if and only if (i) such sales during the 90-day lock-up period are not required to be reported in any public report or filing with the Securities and Exchange Commission and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales during the 90-day lock-up period or within two business days thereafter.

In addition, notwithstanding the lock-up restrictions described herein, the undersigned may at any time after the date hereof establish a 10b5-1 plan pursuant to and in accordance with Rule 10b5-1(c) under the Exchange Act, provided that (1) such plan does not provide for the transfer of Common Stock during the 90-day lock-up period, and (2) entry into the 10b5-1 plan is not required to be reported with the Securities and Exchange Commission in accordance with the Exchange Act, and no other public announcement of the 10b5-1 plan is required or voluntarily effected during the 90-day lock-up period.

The undersigned agrees that, prior to engaging in any transaction or taking any other action that is subject to the terms of this lock-up agreement during the period from the date of this lock-up agreement to and including the 34<sup>th</sup> day following the expiration of the initial 90-day lock-up period, it will give notice thereof to the Company and will not consummate such transaction or take any such action unless it has received written confirmation from the Company that the 90-day lock-up period (as may have been extended pursuant to the previous paragraph) has expired.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the Lock-Up Securities except in compliance with the foregoing restrictions.

It is understood that, if (i) the Company notifies the Representatives in writing that it does not intend to proceed with the Offering, (ii) the Underwriting Agreement is not executed on or before November 30, 2012 (which date may be extended for up to an additional 90 days by the Company by written notice to the undersigned) or (iii) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate pursuant to its terms or be terminated for any reason prior to payment for and delivery of the shares of Common Stock to be sold thereunder (other than any shares issuable upon exercise of the option granted to the Underwriters), this lock-up agreement shall immediately terminate and the undersigned shall automatically be released from all of his, her or its obligations under this lock-up agreement.

This lock-up agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof.

*[Remainder of page intentionally left blank]*

Very truly yours,

(Name of Shareholder Please Print)

(Signature)

Address:

FORM OF PRESS RELEASE

TO BE ISSUED PURSUANT TO SECTION 3(j)

PUMA BIOTECHNOLOGY, INC.

[Date]

PUMA BIOTECHNOLOGY, INC. (the "Company") announced today that BofA Merrill Lynch and Leerink Swann, the joint book-running manager in the Company's recent public sale of shares of common stock, is [waiving] [releasing] a lock-up restriction with respect to shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on , 20 , and the shares may be sold on or after such date.

**This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.**

B-1

## News Release

### **Puma Biotechnology Announces Upsizing and Pricing of \$120 Million Public Offering of Common Stock**

**LOS ANGELES, Calif., Oct. 18, 2012** Puma Biotechnology, Inc., a development stage biopharmaceutical company, announced the upsizing and pricing of its public offering. The size of the offering has been increased from the previously announced 6,500,000 shares of common stock to 7,500,000 shares of common stock at a price of \$16.00 per share. The Company has granted the underwriters for the offering a 30-day option to purchase up to 1,125,000 additional shares of common stock at the public offering price, less the underwriting discount. Puma Biotechnology's common stock, which is currently quoted for trading on the OTC Bulletin Board and the OTCQB Market, will begin trading on the New York Stock Exchange on October 19, 2012 under the ticker symbol **PBYI**.

BofA Merrill Lynch and Leerink Swann LLC are acting as joint book-running managers for the offering. Stifel Nicolaus Weisel, Cowen and Company, and UBS Investment Bank are acting as co-managers for the offering.

A registration statement on Form S-1 relating to these securities has been filed with the Securities and Exchange Commission and declared effective. The offering of these securities will be made only by means of a written prospectus forming part of the effective registration statement relating to these securities. Copies of the prospectus for this offering may be obtained, when available, by contacting BofA Merrill Lynch, 222 Broadway, New York, NY 10038, Attn: Prospectus Department, email: [dg.prospectus\\_requests@baml.com](mailto:dg.prospectus_requests@baml.com) or Leerink Swann LLC, One Federal Street, 37th Floor, Boston, MA 02110, Attn: Syndicate Department, phone: (800) 808-7525.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

#### **About Puma Biotechnology**

Puma Biotechnology, Inc. is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use. The Company is initially focused on the development of PB272 (oral neratinib), a potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2 positive metastatic breast cancer.

#### **Contact:**

Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

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News Release

**Puma Biotechnology Announces Underwriters Full Exercise of Overallotment**

**Option, Increasing Total Offering Size to \$138 Million**

**LOS ANGELES, Calif., Oct. 22, 2012** Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced that the underwriters for its public offering of 7,500,000 shares of its common stock at \$16.00 per share have elected to exercise in full their option to purchase up to an additional 1,125,000 shares of common stock at the public offering price, less the underwriting discount. The closing for the additional purchase of 1,125,000 shares is expected to take place concurrently with the closing for the initial purchase of 7,500,000 shares on October 24, 2012, subject to customary closing conditions.

BofA Merrill Lynch and Leerink Swann LLC are acting as joint book-running managers for the offering. Stifel Nicolaus Weisel, Cowen and Company, and UBS Investment Bank are acting as co-managers for the offering.

A registration statement on Form S-1 relating to these securities has been filed with the Securities and Exchange Commission and declared effective. The offering of these securities will be made only by means of a written prospectus forming part of the effective registration statement relating to these securities. Copies of the prospectus for this offering may be obtained, when available, by contacting BofA Merrill Lynch, 222 Broadway, New York, NY 10038, Attn: Prospectus Department, email: dg.prospectus\_requests@baml.com or Leerink Swann LLC, One Federal Street, 37th Floor, Boston, MA 02110, Attn: Syndicate Department, phone: (800) 808-7525.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

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**Contact:**

Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

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## News Release

### **Puma Biotechnology Closes \$138 Million Public Offering of Common Stock**

**LOS ANGELES, Calif., Oct. 24, 2012** Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced the closing of the underwritten public offering of 8,625,000 shares of its common stock at a price to the public of \$16.00 per share. The shares of common stock issued in the offering included 1,125,000 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares. The net proceeds from the offering were approximately \$129.1 million, after deducting the underwriting discount and estimated offering expenses payable by the Company.

BofA Merrill Lynch and Leerink Swann LLC acted as joint book-running managers for the offering. Stifel Nicolaus Weisel, Cowen and Company, and UBS Investment Bank acted as co-managers for the offering.

A registration statement on Form S-1 relating to these securities has been filed with the Securities and Exchange Commission and declared effective. The offering of these securities was made only by means of a written prospectus forming part of the effective registration statement relating to these securities. Copies of the prospectus for this offering may be obtained by contacting BofA Merrill Lynch, 222 Broadway, New York, NY 10038, Attn: Prospectus Department, email: dg.prospectus\_requests@baml.com or Leerink Swann LLC, One Federal Street, 37th Floor, Boston, MA 02110, Attn: Syndicate Department, phone: (800) 808-7525.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

#### **About Puma Biotechnology**

Puma Biotechnology, Inc. is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use. The Company is initially focused on the development of PB272 (oral neratinib), a potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2 positive metastatic breast cancer.

#### **Contact:**

Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

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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. As used herein, unless the context requires otherwise, the terms we, our and us refer to Puma Biotechnology, Inc., a Delaware corporation formed on April 27, 2007 and formerly known as Innovative Acquisitions Corp., and the term Former Puma refers to Puma Biotechnology, Inc., a private Delaware corporation that merged with and into us in October 2011.*

### 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 the early stages of development and will require significant time and capital before we can even apply for approval from the FDA. Therefore, for the foreseeable future, we do not expect to achieve any product revenues and will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants, and potentially, future offerings of our securities. We believe that our cash on hand is sufficient to fund our operations for the next two years. 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;



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 that each have differing regulations. We are not permitted to market neratinib (oral) in the United States until it receives approval of a New Drug Application, or 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 advisory committee may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions;

the FDA may require development of a Risk Evaluation and Mitigation Strategy, 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.

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

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

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

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

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

***Physicians and patients may not accept and use our drugs.***

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

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

cost-effectiveness of our products relative to competing products;

availability of reimbursement for our products 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. While our drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. We are using the same third-party contractors to manufacture, supply, store and distribute drug supplies for our clinical trials. If we are unable to continue our relationships with one or more of these third-party contractors, 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 intend to 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 regulations on current good manufacturing practices, or cGMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

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

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

***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.

***We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.***

Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures despite the implementation of security measures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs and the development of our product candidates could be delayed.

*Health care reform measures may hinder or prevent our drug candidates' commercial success.*

The United States and some foreign jurisdictions have enacted or are considering enacting 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 changed and will continue to change 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 manufacturers' 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 eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;

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

new requirements to report certain financial arrangements with physicians, including reporting any transfer of value made or distributed to prescribers and other healthcare providers, 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.



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The PPACA also requires adults not covered by employer or government-sponsored insurance plans to maintain health insurance coverage or pay a penalty, a provision commonly referred to as the individual mandate. Following court challenges to the constitutionality of the individual mandate and aspects of Medicaid expansion, on June 28, 2012, the U.S. Supreme Court upheld the constitutionality of the individual mandate, and invalidated

requirements that states forfeit certain federal funding if they do not expand Medicaid coverage as prescribed by PPACA. Although the Court left the remainder of PPACA intact, Congress has proposed a number of legislative initiatives, including the possible repeal of PPACA in its entirety. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict all of the ways in which future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Nevertheless, we anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Thus, we expect to experience pricing pressures in connection with the sale of neratinib (oral), neratinib (intravenous), PB357 and any other products that we may develop, due to the trend toward managed 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 and financial condition.

***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 and the state law equivalents of such laws. 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, including private insurance programs.

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

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

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government 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 that have already been approved or are in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in the following:

developing drugs;

undertaking pre-clinical testing and clinical trials;

obtaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

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

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

government and health administration authorities;

private health maintenance organizations and health insurers; and

other 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.

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

As of June 30, 2012, we had 41 employees, including our President and Chief Executive Officer. 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. 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.

***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. If we are unable to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, the commercialization of pharmaceutical products we develop, alone or with collaborators, could be prevented or inhibited.

*Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.*

We regularly maintain cash balances at third party financial institutions in excess of the Federal Deposit Insurance Corporation (FDIC) insurance limit. While we monitor daily the cash balances in the operating accounts and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit fails or is subject to other adverse conditions in the financial or credit markets. To date we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

#### **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 licensed products in certain specified major market countries 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 continuously evolving. The coverage of patents is subject to interpretation by the courts, and this interpretation is not always consistent.

Other companies may have or may acquire intellectual property rights that could be enforced against us. If they do so, we may be required to alter our products, formulations, processes, methods or other technologies, obtain a license, assuming one can be obtained, or cease our product-related activities. If our products or

technologies infringe the intellectual property rights of others, they could bring legal action against us or our licensors or collaborators claiming damages and seeking to enjoin any activities that they believe infringe their intellectual property rights. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving the invalidity of a patent is particularly difficult in the United States, since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third-party patent, we may need to cease the commercial sale of our products.

Because patent applications can take many years to issue, there may be currently pending applications unknown to us or reissue applications that may later result in issued patents upon which our products or technologies may infringe. There could also be existing patents of which we are unaware that our products or technologies may infringe. In addition, if third parties file patent applications or obtain patents claiming products or technologies also claimed by us in pending applications or issued patents, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our filed foreign patent applications. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Additionally, any uncertainties resulting from the initiation and continuation of any litigation may have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

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

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

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

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

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

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**

***Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock. In addition, numerous other factors could result in substantial volatility in the trading price of our stock.***

Since October 19, 2012, our common stock has been listed on the New York Stock Exchange. Prior to that time, shares of our common stock have been quoted for trading on the OTC Bulletin Board and OTCQB Market in limited volumes. We cannot predict the extent to which investor interest in our company will lead to the



development or continuation of an active trading market on the New York Stock Exchange or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. As of June 30, 2012, we had 20,040,000 shares of common stock outstanding, and stockholders holding at least 5% of our stock, individually or with affiliated entities, collectively beneficially owned or controlled approximately 77.5% of such shares. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our relatively small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. Moreover, if there is no active trading market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

actual or anticipated quarterly variation in our results of operations or the results of our competitors;

announcements of medical innovations or new products by our competitors;

issuance of new or changed securities analysts' reports or recommendations for our stock;

developments or disputes concerning our intellectual property or other proprietary rights;

commencement of, or our involvement in, litigation;

market conditions in the biopharmaceutical industry;

timing and announcement of regulatory approvals;

any future sales of our common stock or other securities in connection with raising additional capital or otherwise;

any major change to the composition of our board of directors or management; and

general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of technology-based companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

***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.

***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 incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We will also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or the SEC, or the New York Stock Exchange or any other 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.

***We are an emerging growth company, and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.***

We are an emerging growth company, as defined by the JOBS Act. For as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various public company reporting requirements. These exemptions include, but are not limited to, (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements, and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years after the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act, which such fifth anniversary will occur in 2017. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenues exceed \$1.0 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, we have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.***

We are subject to the rules and regulations of the SEC, including those rules and regulations mandated by the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to include in their annual report a statement of management's responsibilities for establishing and maintaining adequate internal control over financial reporting, together with an assessment of the effectiveness of those internal controls. Section 404 also requires the independent auditors of certain public companies to attest to, and report on, this management assessment; however, as a smaller reporting company and an emerging growth company, we are not yet subject to this attestation requirement. 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.

***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.***

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 who 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 us at or above the price you paid for them.

***Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.***

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. Furthermore, our ability to utilize NOLs of any companies we may acquire in the future may be subject to limitations. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability.

## BUSINESS

*As used herein, 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., and the term Former Puma refers to Puma Biotechnology, Inc., a private Delaware corporation that merged with and into us in October 2011.*

### Company Overview

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 in 2013. We are initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2, positive metastatic breast cancer. Studies show that approximately 20% to 25% of breast cancer tumors have an over-expression of the HER2 protein. Women with breast cancer that over-expresses HER2, referred to as HER2 positive breast cancer, are at greater risk for disease progression and death than women whose tumors do not over-express HER2. Therapeutic strategies, such as the use of Herceptin (trastuzumab) and Perjeta (pertuzumab), both produced by Genentech, and Tykerb (lapatinib), produced by GlaxoSmithKline, 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 site distinct from those targeted by pertuzumab, trastuzumab, and lapatinib and by acting via a mechanism different from those of other HER2 active drugs.

Currently, the FDA approved first-line therapy for treatment of HER2 positive metastatic breast cancer is the combination of Perjeta plus Herceptin and taxane chemotherapy. The current FDA-approved second-line therapy is Tykerb, given in combination with the chemotherapy drug capecitabine. As a single agent in patients who have failed first line treatment, Tykerb has demonstrated an objective response rate of approximately 5% to 7% and a progression free survival of between eight and nine weeks. 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%. Another treatment regimen that is used in patients who have failed first line treatment is the combination of the chemotherapy drug vinorelbine given in combination with Herceptin, which has been shown to have an objective response rate of approximately 25% and a progression free survival of 22 weeks.

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 PFS of 22.3 weeks for patients who had previously been treated with trastuzumab, and an objective response rate of 56% and median PFS of 39.6 weeks for patients who had not previously been treated with trastuzumab. Additionally, data from over 3,000 patients treated with neratinib, either as a single agent or in combination with other anti-cancer drugs, also suggests a manageable safety profile. Diarrhea has been the most common side effect, but appears to be manageable with antidiarrheal agents and dose modification.

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

commence Phase III clinical trials to evaluate 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 mutated non-small cell lung cancer and in patients with a newly identified breast cancer mutation in HER2 negative breast cancer;

continue the ongoing Phase II clinical trial of neratinib in the neoadjuvant treatment of HER2 positive breast cancer and the ongoing Phase II trial of neratinib in patients with HER2 positive metastatic breast cancer that has metastasized to the brain; and

continue to evaluate the application of neratinib in the treatment of other forms of HER resistant cancers where there may be unmet medical needs.

Our President and Chief Executive Officer, Alan Auerbach, has extensive experience in identifying and developing drug candidates for use in the treatment of cancer. He was the founder, President and Chief Executive Officer of Cougar Biotechnology, Inc., or Cougar, where he was responsible for in-licensing and developing abiraterone acetate for the treatment of advanced prostate cancer. Mr. Auerbach progressed abiraterone acetate into two Phase III clinical trials before Cougar was purchased by Johnson & Johnson in 2009.

## **Our Strategy**

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

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

*Expand our product pipeline by pursuing additional applications of neratinib.* We believe there are additional applications for neratinib in the treatment of HER2 mutated non-small cell lung cancer, which we also believe may be underserved by current treatment alternatives, in the treatment of patients with a newly identified breast cancer mutation in HER2 negative breast cancer and in the treatment of tumor types where HER2 is overexpressed, 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**

#### **Breast Cancer Overview**

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

Trastuzumab and pertuzumab are monoclonal antibodies that bind to the HER2 protein and thereby cause the cells to cease reproducing. Trastuzumab and pertuzumab given in combination with chemotherapy is the current first line standard of care for HER2 positive metastatic breast cancer. Lapatinib is a small molecule that also binds to the HER2 protein and causes the cell to cease reproducing. The current FDA-approved second-line therapy is lapatinib given in combination with the chemotherapy drug capecitabine. Unfortunately, most patients with HER2 positive breast cancer eventually develop resistance to these treatments, resulting in disease progression. For these reasons, there is a need for alternatives to block HER2 signaling in patients who fail pertuzumab, trastuzumab and lapatinib. PB272 is an orally active small molecule that inhibits HER2 at a different site and uses a different mechanism than trastuzumab. As a result, we believe that PB272 may have utility in patients with HER2 positive metastatic breast cancer who have failed treatment with trastuzumab.



The following chart shows each of our current drug candidates and their clinical development stage:

***PB272 (neratinib (oral)) Breast Cancer***

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

*Advantages of Neratinib*

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

*Clinical Trials of Neratinib in Patients with Metastatic Breast Cancer*

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

The trial involved a total of 136 patients, 66 of whom had received prior treatment with trastuzumab and 70 of whom had not received prior treatment with trastuzumab. The results of the study showed that neratinib was reasonably well tolerated among both the pretreated patients and the patients who had not received prior treatment with trastuzumab. Diarrhea was the most common side effect, but was manageable with antidiarrheal agents and dose modification. Efficacy results from the trial showed that the objective response rate was 24% for patients who had received prior trastuzumab treatment and 56% for patients with no prior trastuzumab treatment. Furthermore, the median PFS was 22.3 weeks for the patients who had received prior trastuzumab and 39.6 weeks for the patients who had not received prior trastuzumab.

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

Pfizer also presented data from a second Phase II trial at the 2010 San Antonio Breast Cancer Symposium, which evaluated the safety and efficacy of neratinib when given in combination with the anti-cancer drug vinorelbine in patients with HER2 positive metastatic breast cancer. In the 56 patients who had not been previously treated with the anti-HER2 therapy lapatinib, treatment with the combination of vinorelbine plus neratinib resulted in an overall response rate of 57% and PFS was 44.1 weeks. For those patients who had received prior treatment with lapatinib, the overall response rate was 50%. The combination of vinorelbine and neratinib was generally well tolerated.

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

Puma anticipates initiating a Phase III trial of neratinib plus capecitabine in HER2 positive metastatic breast cancer patients who have failed first-line therapy in late 2012 or early 2013. We anticipate that this trial will be a randomized trial of neratinib plus capecitabine versus lapatinib plus capecitabine.

In 2010, Pfizer also initiated a Phase I/II trial of neratinib in combination with the anti-cancer drug temsirolimus, or Torisel, in patients with HER2 positive metastatic breast cancer who have failed multiple prior treatments. The study enrolled patients with either HER2 positive metastatic breast cancer and disease progression on trastuzumab or with triple negative breast cancer. The preliminary Phase II results of this trial were presented at the 2011 San Antonio Breast Cancer Symposium. The results of the study showed that the combination of PB272 and temsirolimus had acceptable tolerability. The efficacy results from the trial showed that for the 15 patients with HER2 positive disease, nine patients, or 60%, experienced a partial response and one patient, or 7%, experienced stable disease for greater than six months, which translates to a clinical benefit rate of 67%. Patients who experienced a partial response to the combination of neratinib plus temsirolimus demonstrated a maximum change in the size of their target lesions of between 33% and 83%. None of the five patients with triple-negative breast cancer demonstrated a partial response or stable disease for greater than six months. We anticipate that data from this trial will be presented in the fourth quarter of 2012 and, in the first quarter of 2013, we expect to commence a Phase III trial of neratinib in combination with temsirolimus in patients with HER2 positive metastatic breast cancer who have failed multiple prior treatments.

Approximately one-third of the patients with HER2 positive metastatic breast cancer develop metastases that spread to their brain. The current antibody based treatments, including Herceptin and Perjeta, do not enter the brain and therefore are not believed to be effective in treating these patients. In a Phase II trial with Tykerb given as a single agent, Tykerb demonstrated a 6% objective response rate in the patients with HER2 positive metastatic breast cancer whose disease spread to their brains. In January 2012, a Phase II trial of neratinib as a single agent in patients with HER2 positive metastatic breast cancer that has spread to their brains was initiated in conjunction with the Dana Farber Translational Breast Cancer Research Consortium. We anticipate that results from this trial will be presented in 2013.

At the 2010 San Antonio Breast Cancer Symposium, the results of the Neoadjuvant Lapatinib and/or Trastuzumab Treatment Optimisation) Study, or the Neo-ALTTO study, were presented. In this trial, patients with HER2 positive breast cancer were randomized to receive either the combination of paclitaxel plus trastuzumab, the combination of paclitaxel plus lapatinib or the combination of paclitaxel plus trastuzumab plus lapatinib, and neoadjuvant (preoperative) therapy. The results of the trial demonstrated that the patients who received the combination of paclitaxel plus trastuzumab demonstrated a pathological complete response rate of 29.5%, the patients who received paclitaxel plus lapatinib had a pathological complete response rate of 24.7% and the patients who received the combination of paclitaxel plus trastuzumab plus lapatinib had a pathological complete response rate of 51.3%.

In 2010, Pfizer, in collaboration with the National Surgical Adjuvant Breast and Bowel Project, or NSABP, a clinical trials cooperative group supported by the National Cancer Institute, or NCI, initiated a study to investigate the use of neratinib as a neoadjuvant (preoperative) therapy for newly diagnosed HER2 positive breast cancer. In this trial, a total of 129 patients are randomized to receive either neratinib plus the chemotherapy drug paclitaxel or trastuzumab plus paclitaxel prior to having surgery to remove their tumors. The purpose of this study is to test whether adding neratinib to paclitaxel chemotherapy is better than trastuzumab plus paclitaxel chemotherapy before having surgery. This trial has been modified to include a third treatment arm where patients will receive the combination of neratinib plus trastuzumab plus paclitaxel prior to having surgery to remove their tumors. We anticipate that enrollment in all three arms of this trial will continue through the end of 2012 and that results from this trial will be presented in 2013.

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

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

#### ***PB272 (neratinib (oral)) Other Potential Applications***

Approximately 2% to 4% of patients with non-small cell lung cancer have a HER2 mutation in the kinase domain. This mutation is believed to narrow the ATP binding cleft which results in increased tyrosine kinase activity. The mutation is also believed to result in increased PI3K activity and mTOR activation. Published data suggests that patients with HER2 mutated non-small cell lung cancer do not respond to platinum chemotherapy and do not respond to EGFR inhibitors. Pfizer previously conducted a Phase I trial of neratinib given in combination with the anticancer drug temsirolimus in patients with solid tumors. In this trial, seven patients with HER2 mutated non-small cell lung cancer were enrolled in the trial. These patients had received a median of three prior treatments for their disease. The results from the trial were presented at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting and at the 2012 International Association for the Study of Lung Cancer meeting and demonstrated that for the six evaluable patients, two (33%) patients demonstrated a partial radiological response and three patients had stable disease evidenced by tumor shrinkage of between approximately 5% and 28%. We anticipate initiating a Phase II randomized trial of neratinib plus temsirolimus in patients with HER2 mutated non-small cell lung cancer in the fourth quarter of 2012.

In September 2012, a new mutation in patients with HER2 negative breast cancer was identified as part of a study performed by the Cancer Genome Atlas Network and published in Nature. We believe this mutation may occur in an estimated 2% of patients with HER2 negative breast cancer. We are aware of results from third party preclinical studies that we believe suggest that neratinib is active in HER2 negative breast cancer cells that have this mutation and that neratinib has more anticancer activity than either trastuzumab or lapatinib in cells with this mutation. We anticipate that this preclinical data will be presented in the fourth quarter of 2012. In the fourth quarter of 2012 or the first quarter of 2013, we anticipate initiating a Phase II trial of neratinib in HER2 negative breast cancer patients who have this newly identified mutation.

#### ***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, and this may translate into enhanced efficacy. We plan to file the IND for the intravenous formulation of neratinib in 2013.

#### ***PB357***

PB357 is an orally administered agent that is an irreversible TKI that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2, and HER4. PB357 is structurally similar to PB272. Pfizer completed single dose Phase I trials of PB357. We are evaluating PB357 and considering options relative to its development in 2013.

#### **Plan of Development**

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

We also plan to conduct a Phase II clinical trial of neratinib in HER2 mutated non-small cell lung cancer patients and in HER2 negative breast cancer patients with a newly identified mutation 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 FDA to be followed in conducting clinical trials. Additionally, our pre-clinical and clinical testing completed in the European Union is conducted in accordance with applicable EU standards, such as the EU Clinical Trials Directive (Directive 2001/20/EC of April 4, 2001), or the EU Clinical Trials Directive, and the national laws of the Member States of the EU implementing its provisions.

#### **Competition**

The development and commercialization of new products to treat cancer is highly competitive, and we expect considerable competition from major pharmaceutical, biotechnology and specialty cancer companies. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new cancer products. Our potential competitors include, but are not limited to,

Genentech, GlaxoSmithKline, Roche, Boehringer Ingelheim, Takeda, Array Biopharma and Ambit Biosciences. We are an early-stage company with no history of operations and we only recently acquired the rights to the drug candidates we expect to develop. Many of our competitors have substantially more resources than we do, including both financial and technical. In addition, many of our competitors have more experience than we have in pre-clinical and clinical development, manufacturing, regulatory and global commercialization. We are also competing with academic institutions, governmental agencies and private organizations that are conducting research in the field of cancer. We anticipate that we will face intense competition.

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

### **Intellectual Property and License Agreements**

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

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

If we obtain marketing approval for neratinib or other drug candidates in the U.S. or in certain jurisdictions outside the U.S., we may be eligible for regulatory protection, such as five years of new chemical entity exclusivity, and as mentioned above, up to five years of patent term extension potentially available in the United States under the Hatch-Waxman Act. In addition, eight to 11 years of data and marketing exclusivity potentially are available for new drugs in the European Union; up to five years of patent extension are potentially available in Europe (Supplemental Protection Certificate), and eight years of data exclusivity are potentially available in Japan. There can be no assurance that we will qualify for any such regulatory exclusivity, or that any such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies. See [Government Regulation](#) below.

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

We depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how, which is not patentable, and inventions for which patents may be difficult to obtain or enforce, we rely

on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

### **License Agreements**

In August 2011, Former Puma entered into an agreement pursuant to which Pfizer agreed to grant to Former Puma a worldwide license for the development, manufacture and commercialization of neratinib (oral), neratinib (intravenous), PB357, and certain related compounds. Pursuant to the terms of the agreement, the license would not become effective until Former Puma closed a capital raising transaction in which it raised at least \$25 million in aggregate net proceeds and had a net worth of at least \$22.5 million. Upon the closing of the financing that preceded the Merger, this condition was satisfied.

We assumed the license agreement, in accordance with its terms, in the Merger. The license is exclusive with respect to certain patent rights owned or licensed by Pfizer. Under the license agreement, Pfizer is obligated to transfer to us certain information, records, regulatory filings, materials and inventory controlled by Pfizer and relating to or useful for developing these compounds and to continue to conduct certain ongoing clinical studies until a certain time. After that time, we are obligated to continue such studies pursuant to an approved development plan, including after the license agreement terminates for reasons unrelated to Pfizer's breach of the license agreement, subject to certain specified exceptions. We are also obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and use commercially reasonable efforts to complete such trial and achieve certain milestones as provided in a development plan. If certain of our out-of-pocket costs in completing such studies exceed a mutually agreed amount, Pfizer will pay for certain additional out-of-pocket costs to complete such studies. We must use commercially reasonable efforts to develop and commercialize products containing these compounds in specified major-market countries and other countries in which we believe it is commercially reasonable to develop and commercialize such products.

As consideration for the license, we are required to make payments totaling \$187.5 million upon the achievement of certain milestones if all such milestones are achieved. Should we commercialize any of the 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, in some circumstances, to certain reductions. Our royalty obligation continues, on a product-by-product and country-by-country basis, until the later of (i) the last to expire valid claim of a licensed patent covering the applicable licensed product in such country, or (ii) the earlier of generic competition for such licensed product reaching a certain level of sales in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that we sublicense the rights granted to us under the license agreement with Pfizer to a third party, the same milestone and royalty payments are required.

We can terminate the license agreement at will at any time after April 4, 2013 or for safety concerns, in each case upon specified advance notice. Each party may terminate the license agreement if the other party fails to cure any breach of a material obligation by such other party within a specified time period. Pfizer may terminate the license agreement in the event of our bankruptcy, receivership, insolvency or similar proceeding. The license agreement contains other customary clauses and terms as are common in similar agreements in the industry.

### **Government Regulation**

#### ***United States FDA Process***

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending 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 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. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be provided to the FDA as part of a separate submission to the IND. Further, an 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 the IRB must monitor the study until it is completed. There are also requirements governing reporting of ongoing clinical trials and clinical trial results to public registries. Study subjects must sign an informed consent form before participating in a clinical trial.

Clinical trials necessary for product approval typically are conducted in three sequential phases, but the phases may overlap. Phase I usually involves the initial introduction of the investigational drug into a limited population, typically healthy humans, to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific targeted indications. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. Phase III trials, commonly referred to as pivotal studies, are undertaken in an expanded patient population at multiple, geographically dispersed clinical trial centers to further evaluate clinical efficacy and test further for safety by using the drug in its final form. There can be no assurance that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the FDA or an IRB may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Moreover, the FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Post-approval trials are typically referred to as Phase IV clinical trials.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach an agreement on the next phase of development. Sponsors typically use the end of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug. A sponsor may request a Special Protocol Assessment, or SPA, the purpose of which is to reach an agreement with the FDA that the protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. 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 except in limited circumstances such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

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 pre-clinical studies and of clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. An NDA must be accompanied by a significant user fee, which is waived for the first NDA submitted by a qualifying small business. In July 2012, the Food and Drug Administration Safety and Innovation Act, or FDASIA, was signed into law. Among other things, FDASIA reauthorizes the FDA's authority to collect user fees from industry participants to fund reviews of innovator drugs.

The testing and approval process requires substantial time, effort and financial resources. The FDA will review the NDA and may deem it to be inadequate to support approval, and we 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 inspects the facility or the facilities at which the drug and/or its active pharmaceutical ingredient 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 a Complete Response 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. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Alternatively, the FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, to mitigate risks of the drug, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. Once the FDA approves a drug, the FDA



may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

*Expedited Review and Approval.* The FDA has various programs, including Fast Track, priority review and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not 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 or life-threatening diseases or conditions and which demonstrate the potential to address an unmet medical need. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious or life-threatening diseases or conditions, including a fast track product, upon a determination that the product has an effect on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials. Pursuant to FDASIA, the FDA is required to issue draft guidance on expedited review and approval programs by July 9, 2013.

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

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

*Patent Term Restoration and Marketing Exclusivity.* Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However,

patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be requested prior to expiration of the patent. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Data and market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to all of the pre-clinical studies, adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

#### ***Foreign Regulation***

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

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

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

*National MAs* These are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, and are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the *Mutual Recognition Procedure*. If the product has not received a National MA in

any Member State at the time of application, it can be approved simultaneously in various Member States through the *Decentralized Procedure*. Under the *Decentralized Procedure*, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State. The competent authority of the Reference Member State prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling or packaging proposed by the Reference Member State, the product is subsequently granted a National MA in all the Member States (i.e., in the Reference Member State and the Member States Concerned).

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

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 eight years of data exclusivity and ten years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight 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 eight years. After eight 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 two years later (or a total of 10 years after the first marketing authorization in the EU of the innovator product), or three 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 eight-year data exclusivity period. In Japan our products may be eligible for eight years of data exclusivity. There can be no assurance that we will qualify for such regulatory exclusivity, or that such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies.

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

#### ***Pricing and Reimbursement***

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

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

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

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

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

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

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

#### *Sales and Marketing*

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

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

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

We may also be subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of

business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws.

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

### **Manufacturing**

We do not currently have our own manufacturing facilities. We intend to continue to use our financial resources to accelerate development of our drug candidates rather than diverting resources to establish our own manufacturing facilities. We intend to meet our pre-clinical and clinical trial manufacturing requirements by establishing relationships with third-party manufacturers and other service providers to perform these services for us. While our drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. We are currently using the same third-party contractors to manufacture, supply, store and distribute drug supplies for our clinical trials.

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

### ***Other Laws and Regulatory Processes***

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the United States, including laws relating to the oversight activities of the SEC, and we are also subject to the regulations of the New York Stock Exchange, the exchange on which our shares are traded. In addition, the FASB, the SEC, and other bodies that have jurisdiction over the form and content of our accounts, our financial statements and other public disclosure are constantly discussing and interpreting proposals and existing pronouncements designed to ensure that companies best display relevant and transparent information relating to their respective businesses.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, experimental use of animals, and the purchase, storage, movement, import and export, and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights or acquisitions may be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation that might result from future legislation or administrative action cannot accurately be predicted.

### **Research and Development Expenses**

Research and development activities, which include personnel costs, research supplies, clinical and preclinical study costs, are the primary source of our overall expenses. Such expenses related to the research and development of our product candidates totaled \$23.6 million for the six months ended June 30, 2012, \$0.8 million for the year ended December 31, 2011, and \$0.8 million from September 15, 2010 (Former Puma's date of inception) through December 31, 2011.

### **Employees**

As of June 30, 2012, we had 41 employees, all of whom are full-time employees. We believe our relations with our employees are good. Over the course of the next year, we anticipate hiring up to 10 additional full-time employees devoted to clinical activities, four additional full-time employees for the regulatory and quality assurance function, and two additional full-time employees for general and administrative activities. In addition, we intend to continue to use clinical research organizations and third parties to perform our clinical studies and manufacturing.

### **Properties**

We lease approximately 13,254 square feet of office space in the building located at 10880 Wilshire Boulevard for use as our corporate headquarters. Our lease commenced in December 2011 and terminates in December 2018, with an option to extend for an additional five-year term. We have also signed a lease for additional office space in South San Francisco, California. This lease is for seven years and is expected to commence on or about October 1, 2012. We believe our office space will be adequate to meet current and anticipated future requirements and that additional or substitute space will be available as needed to accommodate any expansions that our operations require.

### **Legal Proceedings**

We are not involved in any pending legal proceedings and are not aware of any threatened or contemplated legal proceedings against us.