PUMA BIOTECHNOLOGY, INC.
Form 10-Q
November 14, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2012

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0683487**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024

(Address of principal executive offices)

(424) 248-6500

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date. **28,665,000 shares of Common Stock, par value $0.0001 per share, were outstanding as of November 9, 2012.**

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward looking. These forward-looking statements include, but are not limited to, statements about:

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

These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, ongoing, expect, believe, intend and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report on Form 10-Q, including, in Part I, the section entitled Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations. These forward-looking statements involve risks and uncertainties, including the risks discussed in this Quarterly Report on Form 10-Q in Part II in the section entitled Item 1A. Risk Factors, that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

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PART I FINANCIAL INFORMATION:

Item 1. Financial Statements:

PUMA BIOTECHNOLOGY, INC.

(A Development Stage Company)

CONDENSED BALANCE SHEETS

	September 30, 2012 (unaudited)	December 31, 2011 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,346,638	$ 53,381,734
Prepaid expenses and other assets	769,879	281,096
Total current assets	34,116,517	53,662,830
Property and equipment, net	1,168,963	682,053
Restricted cash	1,211,787	1,053,284
Total assets	$ 36,497,267	$ 55,398,167
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,018,052	$ 86,669
Accrued expenses	25,641,870	499,542
Total current liabilities	26,659,922	586,211
Deferred rent	834,809	439,421
Total liabilities	27,494,731	1,025,632
Commitments and contingencies (Note 6)		
Stockholders equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 20,040,000 shares issued and outstanding at September 30, 2012 and December 31, 2011	2,004	2,004
Additional paid-in capital	71,680,257	64,610,340
Deficit accumulated during the development stage	(62,679,725)	(10,239,809)
Total stockholders equity	9,002,536	54,372,535
Total liabilities and stockholders equity	$ 36,497,267	$ 55,398,167

SEE ACCOMPANYING NOTES TO THE CONDENSED FINANCIAL STATEMENTS

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended		Nine Months Ended		Period from September 15, 2010 (date of inception) to September 30, 2012
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011	
Operating expenses:					
General and administrative	$ 8,025,241	$ 333,766	$ 10,961,744	$ 371,804	$ 20,288,262
Research and development	17,779,419		41,353,708		42,180,080
Depreciation and amortization	68,824	168	187,060	336	197,762
Totals	25,873,484	333,934	52,502,512	372,140	62,666,104
Loss from operations	(25,873,484)	(333,934)	(52,502,512)	(372,140)	(62,666,104)
Other income (expenses):					
Interest income	14,444		62,596		66,379
Other expense		(13,500)		(13,500)	(80,000)
Totals	14,444	(13,500)	62,596	(13,500)	(13,621)
Net loss	$ (25,859,040)	$ (347,434)	$ (52,439,916)	$ (385,640)	$ (62,679,725)
Net loss applicable to common stock	$ (25,859,040)	$ (347,434)	$ (52,439,916)	$ (385,640)	$ (62,679,725)
Net loss per common share basic and diluted	$ (1.29)	$ (0.09)	$ (2.62)	$ (0.10)	
Weighted-average common shares outstanding basic and diluted	20,040,000	4,000,000	20,040,000	4,000,000	

SEE ACCOMPANYING NOTES TO THE CONDENSED FINANCIAL STATEMENTS

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF STOCKHOLDERS EQUITY

THE PERIOD FROM SEPTEMBER 15, 2010 (DATE OF INCEPTION) THROUGH SEPTEMBER 30, 2012

(unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
Balances, beginning		$	$	$	$
Common stock issued for cash at $0.0001 per share	4,000,000	400			400
Paid-in capital			6,531		6,531
Net loss				(6,931)	(6,931)
Balance at December 31, 2010	4,000,000	400	6,531	(6,931)	
Paid-in capital			61,983		61,983
Issuance of shares of common stock through private placements at $3.75 per share, net of issuance costs	16,000,000	1,600	56,739,208		56,740,808
Conversion of stockholder s note payable to equity	40,000	4	149,996		150,000
Stock option compensation			67,022		67,022
Anti-dilutive warrant			7,585,600		7,585,600
Net loss				(10,232,878)	(10,232,878)
Balance at December 31, 2011	20,040,000	2,004	64,610,340	(10,239,809)	54,372,535
Stock option compensation			820,052		820,052
Anti-dilutive warrant			6,249,865		6,249,865
Net loss				(52,439,916)	(52,439,916)
Balance at September 30, 2012	20,040,000	$ 2,004	$ 71,680,257	$ (62,679,725)	$ 9,002,536

SEE ACCOMPANYING NOTES TO THE CONDENSED FINANCIAL STATEMENTS

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PUMA BIOTECHNOLOGY, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,		Period from September 15, 2010 (date of inception) to September 30,
	2012	2011	2012
Operating activities:			
Net loss	$ (52,439,916)	$ (385,640)	$ (62,679,725)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	187,060	336	197,762
Build-out allowance received from landlord	236,533		675,954
Stock option expense	820,052		887,074
Anti-dilutive warrant	6,249,865		13,835,465
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(488,783)	(9,897)	(769,879)
Accounts payable and accrued expenses	26,073,711	212,048	26,659,922
Accrual of deferred rent	158,856		158,856
Net cash used in operating activities	(19,202,622)	(183,153)	(21,034,571)
Investing activities:			
Purchase of property and equipment	(437,438)	(3,363)	(690,772)
Expenditures for leasehold improvements	(236,533)		(675,954)
Restricted cash	(158,503)		(1,211,787)
Net cash used in investing activities	(832,474)	(3,363)	(2,578,513)
Financing activities:			
Proceeds from issuance of stockholder s convertible note payable		150,000	150,000
Net proceeds from issuance of common stock			56,741,208
Capital contributions by stockholder		61,983	68,514
Net cash provided by financing activities		211,983	56,959,722
Net increase (decrease) in cash and cash equivalents	(20,035,096)	25,467	33,346,638
Cash and cash equivalents, beginning of period	53,381,734		
Cash and cash equivalents, end of period	$ 33,346,638	$ 25,467	$ 33,346,638
Supplemental disclosures of non-cash investing and financing activities:			
Conversion of stockholder s note payable to common stock	$	$	$ 150,000

SEE ACCOMPANYING NOTES TO THE CONDENSED FINANCIAL STATEMENTS

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PUMA BIOTECHNOLOGY, INC.

(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS

Note 1 Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc. is a development-stage biopharmaceutical company based in Los Angeles, California. References in these Notes to Condensed Financial Statements to the Company refer to Puma Biotechnology, Inc., a private Delaware company formed on September 15, 2010, for periods prior to the Merger (as defined below), which took place on October 4, 2011, and Puma Biotechnology, Inc., a Delaware company formed on April 27, 2007 and formerly known as Innovative Acquisitions Corp., for periods following the Merger. The Company s strategy is to license and develop novel therapeutics for the treatment of cancer that have previously been tested in clinical trials, enabling it to obtain an initial indication of the drug s safety and biological activity in humans before committing capital to the drug s development.

Basis of Presentation:

The Company is a development-stage enterprise since it has not yet generated any revenue from the sale of products and, through September 30, 2012, its primary focus has been the transition of operational responsibility for its lead drug candidate from the licensor to the Company (see the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2011 for details of the license agreement). The accompanying unaudited condensed interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP), pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, for interim financial information. Accordingly, the financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed interim financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the year ending December 31, 2012, or for any subsequent period. These unaudited condensed interim financial statements should be read in conjunction with the Company s audited financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011. The condensed balance sheet at December 31, 2011 has been derived from the audited financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

The Company has reported a net loss of approximately $25.9 million and approximately $52.4 million for the three and nine months ended September 30, 2012, respectively. The Company also reported negative cash flows from operating activities of approximately $19.2 million for the nine months ended September 30, 2012. The net loss from the date of inception, September 15, 2010 to September 30, 2012, amounted to approximately $62.7 million and negative cash flows from operating activities amounted to approximately $21.0 million for the same period. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process.

The Company s continued operations will depend on its ability to raise funds through various potential sources such as equity and debt financing. Through September 30, 2012, the Company s financing was primarily through private equity placements. Given the current and desired pace of clinical development of its three product candidates, management estimates that the Company has sufficient cash on hand (see Note 7 Subsequent Events - Financing) to fund clinical development through 2014 and into 2015. The Company will need additional financing thereafter until it can achieve profitability, if ever. The Company may choose to raise additional capital before 2015 in order to fund its future development activities. There can be no assurance that such capital will be available on favorable terms or at all or that any additional capital that the Company is able to obtain will be sufficient to meet its needs. If it is unable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

Merger with Public Company:

On September 29, 2011, the Company entered into an agreement and plan of merger (the Merger Agreement) with Innovative Acquisitions Corp. (IAC) and IAC s wholly-owned subsidiary, IAC Merger Corporation (Merger Sub). On October 4, 2011, the Company completed a reverse merger in which Merger Sub merged with and into the Company and the Company became a wholly-owned subsidiary of IAC (the Merger).

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At the effective time of the Merger, the Company s then issued and outstanding 18,666,733 shares of common stock were exchanged for 18,666,733 shares of common stock of IAC and each share of the Company s common stock that was outstanding immediately prior to the effective time was cancelled, with one share of the Company common stock issued to IAC. Concurrently, IAC redeemed all of its shares from its pre-Merger stockholders in exchange for an aggregate consideration of $40,000 paid by the Company. The Company also paid $40,000 for IAC s professional fees associated with the Merger, directly to legal counsel for IAC s former stockholders. Following the Merger and the redemption, the Company s prior stockholders owned the same percentage of IAC s common stock as they held of the Company s common stock prior to the Merger.

Upon completion of the Merger, the Company merged with and into IAC, and IAC adopted the Company s business plan and changed its name to Puma Biotechnology, Inc. Further, upon completion of the Merger, the existing officers and directors of IAC resigned and the existing officers and directors of the Company were appointed officers and directors of IAC.

The Merger was accounted for as a reverse acquisition with the Company as the accounting acquirer and IAC as the accounting acquiree. The merger of a private operating company into a non-operating public shell corporation with nominal net assets is considered to be a capital transaction, in substance, rather than a business combination for accounting purposes. Accordingly, the Company treated this transaction as a capital transaction without recording goodwill or adjusting any of its other assets or liabilities. Consideration in the amount of $80,000 paid to the former stockholders of IAC and their attorney was recorded as an other expense item and included in the Company s net loss for the year ending December 31, 2011.

Note 2 Significant Accounting Policies:

The significant accounting policies followed in the preparation of these financial statements are as follows:

Use of Estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the balance sheet and reported amounts of expenses for the period presented. Accordingly, actual results could differ from those estimates. Through September 30, 2012, significant estimates included the valuation of the warrant issued to the Chief Executive Officer, or CEO (see Note 4 Stockholders Equity). The final value of the warrant was determined in connection with the public offering completed by the Company in October 2012 (see Note 7 Subsequent Events Financing). Significant estimates also include the cost of services provided by consultants who manage clinical trials and conduct research and clinical trials on behalf of the Company that are billed on a delayed basis. As the actual costs become known, the Company adjusts its estimated cost in that period.

Cash and Cash Equivalents:

The Company considers all highly-liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

Investment Securities:

The Company classifies all investment securities (short-term and long-term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management s strategies. These securities are carried at fair value, with the unrealized gains and losses, if material, reported as a component of accumulated other comprehensive income (loss) in stockholders equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

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Assets Measured at Fair Value on a Recurring Basis:

Accounting Standards Codification (ASC) 820, *Fair Value Measurement*, or ASC 820, provides a single definition of fair value and a common framework for measuring fair value as well as new disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid by a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transaction costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.

Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Following are the major categories of assets measured at fair value on a recurring basis as of September 30, 2012 and December 31, 2011, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3):

September 30, 2012	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 33,112,310	$	$	$ 33,112,310

December 31, 2011	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 53,003,450	$	$	$ 53,003,450

The Company s investments in short-term and long-term investment securities are exposed to price fluctuations. The fair value measurements for short-term and long-term investment securities are based upon the quoted price in active markets multiplied by the number of securities owned, exclusive of any transaction costs and without any adjustments to reflect discounts that may be applied to selling a large block of securities at one time.

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents. The Company s cash and cash equivalents in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at September 30, 2012 were approximately $34.2 million. The Company does not believe it is exposed to any significant credit risk.

Property and Equipment:

Property and equipment are recorded at cost and depreciated over estimated useful lives ranging from three to five years using the straight-line method. Leasehold improvements are recorded at cost and amortized over the shorter of their useful lives or the term of the lease by use of the straight-line method. Maintenance and repair costs are charged to operations as incurred.

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been an impairment by comparing the asset s carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. Should impairment exist, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through September 30, 2012.

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Research and Development Expenses:

Research and development expenses are charged to operations as incurred. Research and development expenses include costs associated with services provided by consultants who conduct clinical services on behalf of the Company, contract organizations for manufacturing of clinical materials and clinical trials. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. The Company determines the total cost of a given study based on the terms of the related contract. The Company accrues for costs incurred as services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in that period. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

Stock-Based Compensation:

Stock option awards:

ASC 718, *Compensation-Stock Compensation*, or ASC 718, requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee option grants are generally valued at the date of grant (grant date) and those valuations do not change once they have been established. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. As allowed by ASC 718 for companies with a short period of publicly-traded stock history, the Company s estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. ASC 718 does not allow companies to account for option forfeitures as they occur; instead, estimated option forfeitures must be calculated when the option is granted to reduce the option expense to be recognized over the life of the award and updated upon receipt of further information as to the amount of options expected to be forfeited. Due to its limited history, the Company uses the simplified method to determine the expected life of the option grants.

Warrants:

Warrants granted to employees are normally valued at the fair value of the instrument on the grant date and are recognized in the statement of operations over the requisite service period. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Monte Carlo Simulation method. As allowed by ASC 718 for companies with a short period of publicly-traded stock history, the Company s estimate of expected volatility is based on the average volatilities of a sampling of nine companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value, the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair market value of the warrant at the time of issuance as an equity stock-based compensation transaction. The grant date is determined when all pertinent information, such as exercise price and quantity are known. The warrant is revalued each reporting period up to the grant date when the final fair value of the warrant is established and recorded.

Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the periods presented as required by ASC 260, *Earnings Per Share*. Diluted earnings per common share have not been presented because the assumed exercise of the Company s outstanding options would have been anti-dilutive. For the three and nine months ended September 30, 2012, potentially dilutive securities excluded from the calculations were 1,422,500 shares issuable upon exercise of options.

Deferred Rent:

The Company has entered into an operating lease agreement for its corporate offices that contain provisions for future rent increases, a leasehold improvement allowance and rent abatement. The Company records monthly rent expense equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between the rent expense recorded and the amount paid is credited or charged to deferred rent, which is reflected as a separate line item in the accompanying condensed balance sheets. Additionally, the Company

recorded as deferred rent the cost of the leasehold improvements paid by the landlord, which is amortized on a straight-line basis over the term of the lease.

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Recently Issued Accounting Pronouncements:

The Company has adopted all recently issued accounting pronouncements. The adoption of the accounting pronouncements is not anticipated to have a material effect on the operations of the Company.

In May 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update (ASU) 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS,* or ASU 2011-04*,* which clarifies some existing concepts and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. ASU 2011-04 was effective for the Company beginning January 1, 2012 and the adoption of ASU 2011-04 did not have a material effect on the Company s financial condition.

In June 2011, FASB issued ASU 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income,* or ASU 2011-5, which requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income, either in a single continuous statement of comprehensive income or in two separate but consecutive statements, and which eliminates the option to present components of other comprehensive income as part of the statement of equity. In December 2011, the FASB issued ASU 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05,* or ASU 2011-12, which deferred the guidance on whether to require entities to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement where net income is presented and the statement where other comprehensive income is presented for both interim and annual financial statements. ASU 2011-12 reinstated the requirements for the presentation of reclassifications that were in place prior to the issuance of ASU 2011-05 and did not change the effective date for ASU 2011-05. ASU 2011-05 and ASU 2011-12 were effective for the Company beginning January 1, 2012 and the adoption of ASU 2011-05 and ASU 2011-12 did not have a material effect on the Company s financial condition.

In April 2012, the Jumpstart Our Business Startups Act, or JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company qualifies as an emerging growth company under the JOBS Act; however, the Company has irrevocably elected not to avail itself of this extended transition period and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies.

Note 3 Accrued Expenses:

Accrued expenses consisted of the following:

	September 30, 2012	December 31, 2011
Accrued licensor transition costs	$ 17,045,988	$
Accrued clinical cost	6,989,799	
Accrued compensation	1,246,773	308,936
Accrued legal fees	254,127	149,055
Other	105,183	41,551
Totals	$ 25,641,870	$ 499,542

In accordance with the license agreement, the Company requested that the licensor continue direct management of the ongoing clinical trials until such time as operational responsibility could be absorbed by the Company and/or its agents. The accrued licensor transition costs represent the Company s estimate of such costs for the nine months ended September 30, 2012 and will be adjusted accordingly as the actual costs become known.

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Note 4 Stockholders Equity:

Warrants:

In October 2011, the Company issued anti-dilutive warrants to 27 investors pursuant to a securities purchase agreement. These warrants were exercisable only if the Company sold securities at a price below $3.75 per share on or prior to the date on which the Company s common stock was first quoted in an over-the-counter market or listed for quotation on a national securities exchange or trading system. The Company s common stock was approved for quotation on April 18, 2012, and began trading on April 20, 2012 on the OTC Bulletin Board and the OTCQB under the symbol PBYI and the Company did not sell securities at a price below $3.75 per share on or prior to such date. Accordingly, these warrants subsequently terminated unexercised in accordance with their terms.

Following the October 2011 private placement, Alan H. Auerbach, the Company s founder, CEO and President held approximately 21% of the 18,666,733 outstanding shares of the Company s common stock. Pursuant to the terms of the Securities Purchase Agreement, the Company issued an anti-dilutive warrant to Mr. Auerbach, as the Company s founder. The warrant was issued to provide Mr. Auerbach with the right to maintain ownership of at least 20% of the Company s common stock in the event that the Company raises capital through the sale of its securities in the future.

The warrant has a ten-year term and is exercisable only in the event of the first subsequent financing, excluding certain types of financings set forth in the warrant, that results in gross cash proceeds to the Company of at least $15 million (see Note 7 Subsequent Event Financing). The warrant has an exercise price equal to the price paid per share in such financing and is exercisable for the number of shares of the Company s common stock necessary for Mr. Auerbach to maintain ownership of at least 20% of the outstanding shares of Company common stock after such financing. Upon the occurrence of the first subsequent financing of at least $15 million, the warrant may be exercised any time up to the ten year expiration date of October 4, 2021. The grant date of the warrant will occur on the date of the subsequent financing when the aggregate number of shares exercisable and the price per share will be determined. The Company determined that the warrant has an implied service requisite period in 2011 that is prior to its grant date. The Company also determined that a market condition subsequent to the implied service period exists as the exercise or partial exercise of the warrant can only occur if there is a subsequent financing.

The warrant was valued at approximately $6.9 million at the time of issuance and recorded to the statement of operations. The warrant was revalued at approximately $7.6 million on December 31, 2011, in accordance with ASC 718. The fair market value of the warrant as of September 30, 2012, using the below assumptions, was approximately $13.8 million and resulted in an adjustment to the fair value of $6.5 million and $6.2 million, which are included in general and administrative expense in the accompanying condensed statements of operations for the three and nine months ended September 30, 2012, respectively.

The fair market value at September 30, 2012, was determined by the following assumptions using the Monte Carlo Simulation method:

	2012
Common stock price	$ 15.00
Dividend yield	0.00%
Expected volatility	75.70%
Risk-free interest rate	1.65%
Warrant term in years	10

The fair market value of the warrant at September 30, 2012 was estimated based on the assumption the Company would complete an equity financing between $86 million and $100 million during October or November 2012. In conjunction with a public offering that closed in October 2012 (see Note 7 Subsequent Events - Financing), the warrant was deemed to be granted as the quantity and exercise price of the warrant were determined to be 2,116,250 shares of the Company s common stock at a price of $16.00 per share. The fair value of the warrant on the date of the closing using the Black-Scholes pricing model was approximately $25.8 million. The increase in the fair value of the warrant totaling approximately $12 million will be recorded as an expense in the fourth quarter of 2012.

Stock-Based Compensation:

The Company s 2011 Incentive Award Plan, or the 2011 Plan, was adopted by the Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term

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of stock options granted under the 2011 Plan is 10 years. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair market value of such shares on the date of grant. Through September 30, 2012, a total of 3,529,412 shares of the Company s common stock have been reserved for issuance under the 2011 Plan.

In February 2012, the Company granted, in aggregate, 670,000 stock options to employees hired prior to December 31, 2011. The vesting period for the option grants commenced on each employee s date of hire (i.e., the commencement of their respective service periods). The Company also granted 482,500 stock options in the three months ended March 31, 2012, 240,000 stock options in the three months ended June 30, 2012, and 50,000 stock options for the three months ended September 30, 2012 to employees hired during 2012. The Company awarded only plain vanilla options as determined by the SEC Staff Accounting Bulletin 107, *Share Based Payment*. As of September 30, 2012, 1,422,500 shares of the Company s common stock are issuable upon the exercise of outstanding awards granted under the 2011 Plan and 2,106,912 shares of the Company s common stock are available for future issuance under the 2011 Plan.

The fair value of options granted to employees was estimated using the Black-Scholes pricing model (see Note 2 Significant Accounting Policies) with the following weighted-average assumptions used during the nine month period ended September 30, 2012:

	2012
Dividend yield	0.0%
Expected volatility	85.4%
Risk-free interest rate	1.0%
Expected life in years	5.82

The Company recognized expense (fair value of the stock option grants) of $358,277 and $820,052 for the three and nine months ended September 30, 2012, respectively. For the three and nine months ended September 30, 2012, $110,118 and $288,840, respectively, were recorded as general and administrative expense and $248,159 and $531,212, respectively were recorded as research and development expense.

Activity with respect to options granted under the 2011 Plan is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2011				$
Options granted in the period ended March 31, 2012 for which compensation was recognized during 2011	670,000	$ 3.75		
Granted in the three month period ended March 31, 2012	482,500	$ 3.75		
Granted in the three month period ended June 30, 2012	240,000	$ 10.81		
Granted in the three month period ended September 30, 2012	50,000	$ 13.50		
Forfeited in the three month period ended September 30, 2012	(20,000)	$ 3.75		
Outstanding at September 30, 2012	1,422,500	$ 5.28	9.5	$ 13,821,875
Unvested at September 30, 2012	1,390,001	$ 5.32	9.5	$ 13,456,261
Exercisable at September 30, 2012	32,499	$ 3.75	9.4	$ 365,614

At September 30, 2012, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $3.7 million, which is expected to be recognized over a weighted-average period of 1.3 years. The weighted-average grant date fair value of options granted during the three and nine months ended September 30, 2012 was $9.41 and $4.63 per share, respectively.

Note 5 401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately $40,800 and $97,400 for the three and nine months ended September 30, 2012, respectively.

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Note 6 Commitments and Contingencies:

Office Lease:

On June 7, 2012, the Company entered into a long-term lease agreement for office space in South San Francisco, California. The initial term of the lease is seven years and commenced on November 1, 2012. The base rent is approximately $20,250 per month during the first year and will increase over the course of the initial term, up to approximately $30,820 per month during the seventh year. In addition, the Company has an option to extend the lease for an additional five-year term, which would commence upon the expiration of the initial term. In the event the Company elects to extend the lease, the minimum monthly rent payable for the additional term will be the then-current fair market rent calculated in accordance with the terms of the lease. The Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $150,000. The stand-by letter of credit is collateralized by a high-yield savings account in the amount of approximately $157,000, which is classified as restricted cash on the accompanying condensed balance sheets.

Note 7 Subsequent Events:

Clinical Research Organization Contract:

During October 2012, the Company entered into a Master Service Agreement with a Clinical Research Organization, or CRO. This CRO will provide services for initiating, managing and conducting the ongoing clinical trials for PB272. The Company shall pay the CRO up to approximately $22.8 million over the life of the agreement. The Company may cancel the Master Service Agreement at any time upon a 45 day written notice to the CRO. The Company would be obligated to pay of any services previously rendered with any prepaid, unused funds being returned to the Company.

Financing:

On October 18, 2012, 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, at a price of $16 per share, less the underwriting discount. On October 19, 2012, representatives of the Underwriters exercised the overallotment option (the Overallotment Option) granted to the Underwriters in the Underwriting Agreement to purchase an additional 1,125,000 shares of Company common stock from the Company at $16 per share, less the underwriting discount.

The transactions contemplated by the Underwriting Agreement were completed on October 24, 2012. The net proceeds received by the Company from the sale of 8,625,000 shares of Company common stock were approximately $129.1 million after deducting the underwriting discount and estimated offering expenses payable by the Company. The 8,625,000 shares were registered with the New York Stock Exchange and the Company began trading on the New York Stock Exchange on October 26, 2012.

In connection with the closing of the Offering, the exercise price and number of shares underlying the warrant (see Note 4 Stockholders Equity - Warrants) issued to Mr. Auerbach were established. Pursuant to the terms of the warrant, until October 2021, Mr. Auerbach may exercise the warrant to acquire 2,116,250 shares of the Company s common stock at $16 per share through October 2021.

Foreign Subsidiary:

In October 2012, the Company established and incorporated Puma Biotechnology Limited, a wholly owned subsidiary, for the sole purpose of serving as Puma s legal representative in the United Kingdom and the European Union in connection with Puma s clinical trial activity in those countries.

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and the notes thereto included in Item 1 in this Quarterly Report on Form 10-Q. The following discussion should also be read in conjunction with our audited financial statements and the notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2011.

Unless otherwise provided in this Quarterly Report, references to the Company, we, us, and our refer to Puma Biotechnology, Inc., a Delaware corporation formed on April 27, 2007 and formerly known as Innovative Acquisitions Corp., and all references to Puma refer to Puma Biotechnology, Inc., a privately-held Delaware corporation formed on September 15, 2010, prior to giving effect to the reverse merger transaction between the Company and Puma that closed on October 4, 2011. This transaction was accounted for as a reverse acquisition whereby Puma was deemed to be the acquirer for accounting and financial reporting purposes and we were deemed to be the acquired party. Consequently, our financial statements prior to the reverse merger transaction reflect the assets and liabilities and the historical operations of Puma from its inception on September 15, 2010 through the closing of the reverse merger transaction on October 4, 2011. Our financial statements after completion of the reverse merger transaction include the assets and liabilities of us and Puma, the historical operations of Puma, and our operations following the closing date of the reverse merger transaction.

Overview

We are a development-stage biopharmaceutical company based in Los Angeles, California with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. We aim to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. Our efforts and resources to date have been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. As a development-stage company, we have had no product sales to date and we will have no product sales until we receive approval from the United States Food and Drug Administration, or FDA, or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Developing pharmaceutical products, however, is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety issues during the course of developing our product candidates, we do not expect to receive approval of a product candidate until approximately 2015.

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 plan to evaluate for further development in 2013.

A large portion of our expenses to date have been related to the clinical development of our lead product candidate, PB272 (neratinib (oral)), and the transition of the neratinib program from the licensor. During this transition period, as we built up our infrastructure and assumed responsibility for the neratinib program, a duplication of effort took place that resulted in higher than normal operating expenses. We estimate the duplication of effort had an impact on research and development, or R&D, expense for the nine months ended September 30, 2012, of approximately $4.3 million. We anticipate that the transition will be completed by December 31, 2012.

The license agreement for PB272 established a limit for our expenses related to the clinical trials for PB272 that were ongoing at the time of the agreement. This capped our out-of-pocket costs incurred beginning January 1, 2012, in conducting these existing trials. We anticipate that we will reach the cost cap during the fourth quarter of 2012 which will result in a reduction of its expenses related to these existing clinical trials, and hence a reduction in our R&D expenses, as the licensor will be responsible for such costs. The licensor will be responsible for these expenses until the existing trials are completed. Additionally, our expenses to date have been related to hiring staff and the build out of our corporate infrastructure. As we proceed with clinical development of PB272 (neratinib (oral)), and as we further develop PB272 (neratinib (intravenous)) and PB357, our second and third product candidates, respectively, we expect our R&D expenses and expenses related to our third-party contractors will increase.

To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance R&D will increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance product development. Our major sources of working capital have been proceeds from private sales of our common stock.

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R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for manufacturing of clinical materials and clinical trials. During the three and nine months ended September 30, 2012, our R&D expenses consisted primarily of transition costs, as clinical trial responsibilities shifted to us and our outside clinical research organization, or CRO, salaries and related personnel costs, and fees paid to other consultants. We expense our R&D costs as they are incurred.

General and administrative, or G&A, expenses consist primarily of salaries and related personnel costs including stock-based compensation expense, professional fees, business insurance, rent, general legal activities, and other corporate expenses.

Emerging Growth Company

We are and will remain an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, until the earliest to occur of (1) the last day of the fiscal year during which our total annual gross revenues equal or exceed $1 billion (subject to adjustment for inflation), (2) the last day of our fiscal year following the fifth anniversary of the date of 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, (3) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt, or (4) the date on which we are deemed a large accelerated filer under the Exchange Act.

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies; however, we have elected to take advantage of certain of the reduced disclosure obligations and may elect to take advantage of other reduced burdens in future filings. 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.

Critical Accounting Policies

As of the date of the filing of this quarterly report, we believe there have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2012 from our accounting policies at December 31, 2011, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

Results of Operations

Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011

General and administrative expenses:

For the three months ended September 30, 2012, G&A expenses were approximately $8.0 million. G&A expenses for the three months ended September 30, 2011 were approximately $333,800, as we had not commenced meaningful operations during that period. G&A expenses for the three months ended September 30, 2012 were as follows:

General and administrative expenses	in thousands ($000)
Professional fees	$ 588
Payroll and related costs	511
Business taxes and licenses	21
Facility and equipment costs	143
Employee stock-based compensation	6,575
Other	187
	$ 8,025

Major expenses incurred in professional fees were legal fees for SEC filings, intellectual property review, contract review and general legal support. We expect to continue to incur significant legal fees in the coming periods. We expect the facility expense to increase compared to the

three months ended September 30, 2012, as we have recently entered into a lease for satellite office space in the San Francisco area and will have additional rent expense beginning in November 2012 for the term of the lease. The monetary increase in rent expense will be approximately $20,250 per month in the first year and up to

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approximately $30,820 per month during the seventh year, the life of the lease. Employee stock-based compensation included in G&A expenses for the three months ended September 30, 2012 included approximately $110,100 related to employee stock option grants and approximately $6.5 million reflecting the increase in the valuation of the outstanding anti-dilutive warrant held by our CEO and President, compared to $0 for the three months ended September 30, 2011. The warrant was valued based on the assumption that we would be completing an equity financing of between $86 million and $100 million during October or November 2012 (see Note 4 in the accompanying notes to the condensed financial statements) using a Monte Carlo Simulation method. Previous valuations were based on projected equity raises of $15 million to $100 million in 2013 using weighted probability factors. The increase in the projected equity raise from June 30, 2012 to September 30, 2012 produced the $6.5 million increase in the warrant noted above.

In connection with the closing of the public offering that we completed in October 2012 (see Note 7 in the accompanying notes to the condensed financial statements), the exercise price and the number of shares underlying the warrant were established. Pursuant to the terms of the warrant, until October 2021, the warrant may be exercised to acquire 2,116,250 shares of our common stock at a price of $16 per share. The fair value of the warrant on the date of the equity closing using the Black-Scholes pricing model was approximately $25.8 million. The increase in the fair value of the warrant of approximately $12 million will be recorded as an expense in the fourth quarter of 2012.

All other costs such as IT support, travel, recruiting and postage were approximately $187,300 for the three months ended September 30, 2012. We estimate that we will need approximately $6 million to $7 million for G&A expenses over the next 12 months.

Research and development expenses:

For the three months ended September 30, 2012, R&D expenses were approximately $17.8 million compared to $0 for the three months ended September 30, 2011 as we had not commenced meaningful operations during that period. R&D expenses for the three months ended September 30, 2012 were as follows:

Research and development expenses	in thousands ($000)
Outside CRO/licensor services	$ 13,626
Outside other clinical development	1,975
Internal regulatory affairs and quality assurance	1,042
Internal clinical development	817
Internal contract manufacturing	71
Employee stock-based compensation	248
	$ 17,779

Ongoing outside CRO and licensor service expense of approximately $13.6 million was incurred during the three months ended September 30, 2012. This included approximately $1.3 million of duplicate costs from licensor services for the ongoing clinical trials. When the transition is complete, we expect these duplicate charges to cease. We accrued approximately $1.3 million for licensor services provided during the three months ended September 30, 2012 and approximately $8.8 million for pass-through costs related to the clinical trials. We also incurred approximately $3.5 million for services rendered by our CRO for managing our existing clinical trials. The licensor transition and clinical trial cost represent our estimate of such costs for the three months ended September 30, 2012, and will be adjusted accordingly as the actual costs become known.

Outside other clinical development expenses, which are comprised of costs for data management, outside consultants, contract manufacturing and other clinical services, of approximately $2.0 million were incurred during the three months ended September 30, 2012. Internal expenses, which include all employee-related costs such as payroll, benefits and travel, were approximately $1.0 million for regulatory affairs and quality assurance, approximately $0.8 million for clinical development and approximately $71,100 for contract manufacturing. Employee stock-based compensation included in R&D expenses for the three months ended September 30, 2012, was approximately $248,200. Given the current and desired pace of clinical development of our three product candidates, over the next 12 months we estimate that our research and development spending will be approximately $35 million to $40 million.

Interest income:

For the three months ended September 30, 2012, we recognized approximately $14,500 in interest income. We did not recognize any interest income for the three months ended September 30, 2011. Based on market conditions, we placed our excess funds in money market accounts and

high yield savings accounts.

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Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011

General and administrative expenses:

For the nine months ended September 30, 2012, G&A expenses were approximately $11.0 million. G&A expenses for the nine months ended September 30, 2011, were approximately $371,800, as we had not commenced meaningful operations during that period. G&A expenses for the nine months ended September 30, 2012, were as follows:

General and administrative expenses	in thousands ($000)
Professional fees	$ 1,744
Payroll and related costs	1,505
Facility and equipment costs	423
Business taxes and licenses	177
Employee stock-based compensation	6,539
Other	574
	$ 10,962

Major expenses incurred in professional fees were legal fees for SEC filings, intellectual property review, contract review and general legal support. We expect to continue to incur significant legal fees in the coming periods. We expect the facility expense to increase compared to the nine months ended September 30, 2012, as we entered into a lease for satellite office space in San Francisco, which commenced on November 1, 2012, and will have additional rent expense for the term of the lease. Payroll and related costs were approximately $1.5 million for the nine months ended September 30, 2012. Included in this expense is the salary, bonus accrual and benefit costs for the employees within the general and administrative group. Employee stock-based compensation included in G&A expenses for the nine months ended September 30, 2012 was approximately $6.5 million consisting of an increase in the valuation of the outstanding anti-dilutive warrant held by our CEO and President of approximately $6.2 million and approximately $288,800 of employee stock-based compensation, compared to $0 for the nine months ended September 30, 2011.

All other costs such as IT support, travel, recruiting and postage were approximately $575,300 for the nine months ended September 30, 2012.

Research and development expenses:

For the nine months ended September 30, 2012, R&D expenses were approximately $41.4 million compared to $0 for the nine months ended September 30, 2011. R&D expenses for the nine months ended September 30, 2012 were as follows:

Research and development expenses	in thousands ($000)
Outside CRO/licensor services	$ 32,069
Outside other clinical development	3,377
Internal regulatory affairs and quality assurance	2,914
Internal clinical development	2,233
Internal contract manufacturing	230
Employee stock-based compensation	531
	$ 41,354

Ongoing outside CRO and licensor service expense of approximately $32.1 million was incurred during the nine months ended September 30, 2012. This included approximately $4.3 million of duplicate costs from licensor services for the ongoing clinical trials. When the transition is complete, we expect these duplicate charges to cease. We accrued approximately $7.1 million for licensor services provided during the nine months ended September 30, 2012 and approximately $18.2 million for pass-through costs related to the clinical trials. We also incurred approximately $6.7 million for services rendered by our CRO, which is taking over operational responsibility for our existing clinical trials. The licensor transition and clinical trial cost represents our estimate of such costs for the nine months ended September 30, 2012, and will be

adjusted accordingly as the actual costs become known.

Outside other clinical development expenses, which are comprised of costs for data management, outside consultants, contract manufacturing and other clinical services, totalled approximately $3.4 million during the nine months ended September 30, 2012. Regulatory affairs and quality assurance of approximately $2.9 million, clinical development of approximately $2.2 million, and contract manufacturing of approximately $230,000 consisted of internal expenses, such as employee-related costs including payroll, benefits and travel. Employee stock-based compensation included in R&D expenses for the nine months ended September 30, 2012, was approximately $531,200.

While expenditures on current and future clinical development programs, particularly our PB272 program, are expected to be substantial and to increase, they are subject to many uncertainties, including the results of clinical trials and whether we

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develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our drug candidates; and
- the costs, requirements, timing of, and ability to secure regulatory approvals.

Interest income:

For the nine months ended September 30, 2012, we recognized approximately $62,600 in interest income compared to $0 in interest income for the nine months ended September 30, 2011. Based on market conditions, we placed our excess funds in money market accounts and high yield savings accounts.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2012 and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands ($000)	September 30, 2012
Cash and cash equivalents	$ 33,347
Working capital	7,457
Stockholders equity	9,003

	Nine months ended September 30, 2012
Cash provided by (used in):	
Operating activities	$ (19,203)
Investing activities	(832)
Financing activities	
Increase (decrease) in cash	$ (20,035)

Operating Activities:

We reported a net loss of approximately $52.4 million and negative cash flows from operating activities of approximately $19.2 million for the nine months ended September 30, 2012. Our net loss from Puma s date of inception, September 15, 2010, to September 30, 2012 amounted to approximately $62.7 million, while negative cash flows from operating activities amounted to approximately $21.0 million for the same period.

Net cash used in operating activities for the nine months ended September 30, 2012 includes a net loss of $52.4 million, reduced by approximately $33.2 million of adjustments to reconcile net loss to net cash used in operating activities. Adjustments include non-cash items related to expense of approximately $820,100 from the issuance of stock options, adjustments to the warrant valuation of approximately $6.2 million, depreciation and amortization of approximately $187,000 and an allowance of approximately $236,000 received from the landlord for our corporate headquarters. Other items included in the adjustment of net loss were an increase of approximately $26.1 million in accounts payable and accrued expenses, an increase of $159,000 in the accrual of deferred rent, and an increase of $489,000 in prepaid expenses and other assets. The increase in accounts payable and accrued expenses reflects charges from transition activities billed to us as we assume clinical trial responsibilities from the licensor of the Company s lead product candidate, of which approximately $4.3 million represents duplication of effort as the licensor transferred clinical trial knowledge and responsibility to us.

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Investing Activities:

Net cash used in investing activities was approximately $832,000 for the nine months ended September 30, 2012. Payments of approximately $437,000 for the purchase of computer equipment and systems and approximately $237,000 related to leasehold improvements were included in net cash used in investing activities. Additionally, to secure the office lease located in the San Francisco area, a standby letter of credit was required. As collateral to that standby letter of credit, approximately $157,000 was moved to the restricted cash account held by Wells Fargo.

Financing Activities:

We did not engage in any financing activities during the nine months ended September 30, 2012.

Current and Future Financing Needs:

We have incurred negative cash flows from operations since we started our business, and we expect to continue incurring significant losses for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and development efforts. We completed an equity offering in October 2012 (see Note 7 in the accompanying notes to the condensed financial statements Subsequent Events Financing). As a result of this offering, we anticipate that our cash on hand, including our cash equivalents, will be sufficient to enable us to meet our anticipated expenditures for at least the next 24 months. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control.

Our continued operations will depend on whether we are able to raise additional funds through a strategic alliance with a third-party concerning one or more of our product candidates, public or private sales of equity or debt and other sources of funds. Prior to the equity offering that we completed in October 2012, a significant portion of our financing was through private placements of our equity securities. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time and in light of current economic conditions, including the lack of access to the capital markets being experienced by small companies, particularly in our industry, there can be no assurance that such capital will be available to us on favorable terms or at all. In addition, we can give no assurances that any additional capital raised will be sufficient to meet our needs. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, delay or discontinue the development of one or more of our product candidates or forego attractive business opportunities, and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet agreements, as defined by SEC regulations.

Contractual Obligations

As a smaller reporting company, we are not required to provide this information.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to disclose the information required by this Item.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the timelines specified in the SEC s rules and forms, and that such information is

accumulated and communicated to our management, including our Chief Executive Officer (the Company s principal executive officer) and Senior Vice President, Finance and Administration (the Company s principal financial and accounting officer), as appropriate, to allow timely decisions regarding required

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disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Senior Vice President, Finance and Administration, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of September 30, 2012. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance and Administration have concluded that these disclosure controls and procedures were effective as of September 30, 2012.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended September 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

Investing in our common stock is subject to a number of risks and uncertainties. You should carefully consider the risk factors described below, which amend and restate in their entirety the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, results of operations, financial condition, cash flows and future prospects and the trading price of our common stock could be harmed as a result of any of these risks, and investors may lose all or part of their investment. 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. In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2011, including our financial statements and related notes, and our other filings made from time to time with the SEC.

Risks Related to our Business

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

To date, we have generated no product revenues. Until, and unless, we receive approval from the FDA and other regulatory authorities overseas for one or more of our drug candidates, we cannot market or sell our products and will not have product revenues. Currently, our only drug candidates are neratinib (oral), neratinib (intravenous) and PB357, and none of these products 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.

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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

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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 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.

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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.

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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.

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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;

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- 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.

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

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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.

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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 September 30, 2012, we had 42 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.

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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.

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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.

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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.

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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 September 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 76.7% 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 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 also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC or 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.

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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.

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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.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the quarter ended September 30, 2012, the Company did not sell any of its equity securities without registration under the Securities Act of 1933, as amended, and did not repurchase any of its securities.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit	Description
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document

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Exhibit	Description
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

* Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

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SIGNATURES

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 thereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: November 14, 2012

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

Date: November 14, 2012

By: /s/ Charles R. Eyler
Charles R. Eyler
Senior Vice President, Finance and Administration and Treasurer
(Principal Financial and Accounting Officer)