

PUMA BIOTECHNOLOGY, INC.

Form 10-Q

May 15, 2012

[Table of Contents](#)

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 March 31, 2012 March 31, 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: 000-52811

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Edgar Filing: PUMA BIOTECHNOLOGY, INC. - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)
10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024
(Address of principal executive offices)
(424) 248-6500
(Registrant's telephone number, including area code)

77-0683487
(I.R.S. Employer
Identification Number)

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 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
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. **20,040,000 shares of Common Stock, par value \$0.0001 per share, were outstanding as of May 8, 2012.**

Table of Contents

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 our Annual Report on Form 10-K for the year ended December 31, 2011, and in this Quarterly Report on Form 10-Q, in each case, under the caption Item 1A. Risk Factors, that could cause our actual results to differ materially from those in the forward-looking statements. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document. The risks discussed in this Quarterly Report should be considered in evaluating our prospects and future financial performance.

Table of Contents

PUMA BIOTECHNOLOGY, INC.

- INDEX -

	Page
<u>PART I FINANCIAL INFORMATION:</u>	
Item 1. <u>Financial Statements:</u>	
<u>Condensed Balance Sheets as of March 31, 2012 (Unaudited) and December 31, 2011</u>	1
<u>Condensed Statements of Operations for the Three Months Ended March 31, 2012 and March 31, 2011 and from September 15, 2010 (Inception) to March 31, 2012 (Unaudited)</u>	2
<u>Condensed Statements of Stockholders' Equity for the period from September 15, 2010 (Inception) through March 31, 2012 (Unaudited)</u>	3
<u>Condensed Statements of Cash Flows for the Three Months Ended March 31, 2012 and March 31, 2011 and from September 15, 2010 (Inception) to March 31, 2012 (Unaudited)</u>	4
<u>Notes to Condensed Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	17
Item 4. <u>Controls and Procedures</u>	17
<u>PART II OTHER INFORMATION:</u>	
Item 1. <u>Legal Proceedings</u>	18
Item 1A. <u>Risk Factors</u>	18
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
Item 3. <u>Defaults Upon Senior Securities</u>	18
Item 4. <u>Mine Safety Disclosure</u>	18
Item 5. <u>Other Information</u>	18
Item 6. <u>Exhibits</u>	19
<u>Signatures</u>	20

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

PUMA BIOTECHNOLOGY, INC.

(A Development Stage Company)

CONDENSED BALANCE SHEETS

	March 31, 2012 (unaudited)	December 31, 2011 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 50,173,262	\$ 53,381,734
Prepaid expenses and other assets	537,599	281,096
Total current assets	50,710,861	53,662,830
Property and equipment, net	1,057,015	682,053
Restricted cash	1,053,810	1,053,284
Total assets	\$ 52,821,686	\$ 55,398,167
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 566,680	\$ 86,669
Accrued expenses	8,916,099	499,542
Total current liabilities	9,482,779	586,211
Deferred rent	743,706	439,421
Total liabilities	10,226,485	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 March 31, 2012 and December 31, 2011	2,004	2,004
Additional paid-in capital	64,659,119	64,610,340
Deficit accumulated during the development stage	(22,065,922)	(10,239,809)
Total stockholders' equity	42,595,201	54,372,535
Total liabilities and stockholders' equity	\$ 52,821,686	\$ 55,398,167

SEE ACCOMPANYING NOTES TO THE CONDENSED FINANCIAL STATEMENTS

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31, 2012	Three Months Ended March 31, 2011	Period from September 15, 2010 (date of inception) to March 31, 2012
Operating expenses:			
General and administrative	\$ 1,234,626	\$ 3,942	\$ 10,561,144
Research and development	10,568,382		11,394,754
Depreciation and amortization	48,741		59,443
Totals	11,851,749	3,942	22,015,341
Loss from operations	(11,851,749)	(3,942)	(22,015,341)
Other income (expenses):			
Interest income	25,636		29,419
Other income (expense)			(80,000)
Totals	25,636		(50,581)
Net loss	\$ (11,826,113)	\$ (3,942)	\$ (22,065,922)
Net loss applicable to common stock	\$ (11,826,113)	\$ (3,942)	\$ (22,065,922)
Net loss per common share basic and diluted	\$ (0.59)	\$ (0.001)	
Weighted-average common shares outstanding basic and diluted	20,040,000	4,000,000	

SEE ACCOMPANYING NOTES TO THE CONDENSED FINANCIAL STATEMENTS

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A Development Stage Company)

CONDENSED STATEMENTS OF STOCKHOLDERS EQUITY

(Unaudited)

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
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 notes 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			198,060		198,060
Anti-dilutive warrant			(149,281)		(149,281)
Net loss				(11,826,113)	(11,826,113)
Balance at March 31, 2012	20,040,000	\$ 2,004	\$ 64,659,119	\$ (22,065,922)	\$ 42,595,201

SEE ACCOMPANYING NOTES TO THE CONDENSED FINANCIAL STATEMENTS

Table of Contents

PUMA BIOTECHNOLOGY, INC.

(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,		Period from September 15, 2010 (date of inception) to March 31, 2012
	2012	2011	
Operating activities:			
Net loss	\$ (11,826,113)	\$ (3,942)	\$ (22,065,922)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	48,741		59,443
Build out allowance received from landlord	236,533		675,954
Stock option expense	198,060		265,082
Anti-dilutive warrant	(149,281)		7,436,319
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(256,503)		(537,599)
Accounts payable and accrued expenses	8,896,568		9,482,779
Accrual of deferred rent	67,753		67,753
Net cash used in operating activities	(2,784,242)	(3,942)	(4,616,191)
Investing activities:			
Purchase of property and equipment	(187,171)		(440,505)
Expenditures for leasehold improvements	(236,533)		(675,954)
Restricted cash	(526)		(1,053,810)
Net cash used in investing activities	(424,230)		(2,170,269)
Financing activities:			
Proceeds from issuance of stockholder convertible note payable			150,000
Net proceeds from issuance of common stock			56,741,208
Capital contributions by stockholder		3,942	68,514
Net cash provided by financing activities		3,942	56,959,722
Net increase (decrease) in cash and cash equivalents	(3,208,472)		50,173,262
Cash and cash equivalents, beginning of period	53,381,734		
Cash and cash equivalents, end of period	\$ 50,173,262	\$	\$ 50,173,262
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

Table of Contents

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 March 31, 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 2011 Annual Report on Form 10-K.

The Company has reported a net loss of \$11,826,113 and negative cash flows from operating activities of \$2,784,242 for the three months ended March 31, 2012. The net loss from the date of inception, September 15, 2010, to March 31, 2012, amounted to \$22,065,922, and negative cash flows from operating activities amounted to \$4,616,191 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 March 31, 2012, the Company's financing has been primarily through private equity placements. The Company will continue to fund operations through sources of capital similar to those previously described. The Company can give no assurances that any additional capital that it is able to obtain will be sufficient to meet its needs. Given the current and desired pace of clinical development of its three product candidates, management estimates that the Company has sufficient cash on hand to fund clinical development through 2012 and into 2013. The Company will need additional financing thereafter until it can achieve profitability, if ever. The Company may choose to raise additional capital before 2013 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. 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.

Table of Contents

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).

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 paid \$40,000 for IAC's professional fees associated with the Merger, directly to the service providers. 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 accounting principles generally accepted in the United States of America 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. Significant estimates include the valuation of the warrant issued to the CEO (Note 4). The value of the warrant includes estimates based on future events which are difficult to predict. It is at least reasonably possible that a change in the estimates used to value the warrant will occur in the near term. Significant estimates also include the cost of services provided by consultants who conduct research 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.

Table of Contents**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, transactions 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 March 31, 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):

March 31, 2012	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 49,978,414	\$	\$	\$ 49,978,414
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.

Table of Contents

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 limit at March 31, 2012 were approximately \$50,851,800 due to the Temporary Liquidity Guarantee Program. 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 March 31, 2012.

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 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 date of the grant (grant date) and are recognized in the statement of operations over the requisite service period. When the requisite

Table of Contents

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 equity stock based compensation transaction. The warrant is then 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. Potentially dilutive securities excluded from the calculations amounted to 1,152,500 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.

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*, 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 its financial condition, profitability, and cash flows.

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 eliminates that 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 its financial condition.

Table of Contents**Note 3 Accrued Expenses:**

Accrued expenses consisted of the following:

	March 31, 2012	December 31, 2011
Accrued licensor transition costs	\$ 7,873,000	\$
Accrued clinical cost	283,028	
Accrued compensation	501,601	308,936
Accrued legal fees	222,798	149,055
Other	35,672	41,551
Totals	\$ 8,916,099	\$ 499,542

In accordance with the license agreement, Puma requested that the licensor continue direct management of the ongoing clinical trials until such time as operational responsibility could be absorbed by Puma and/or its agents. The accrued licensor transition cost represents our estimate of such costs for the three months ended March 31, 2012, and will be adjusted accordingly as the actual costs become known.

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 shares of 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 quoted and began trading on the OTC Bulletin Board and the OTCQB under the symbol PBYI on April 20, 2012, 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. 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 \$6,900,000 at the time of issuance and recorded to the statement of operations. The warrant was revalued at approximately \$7,600,000 on December 31, 2011, in accordance with ASC

Table of Contents

718. The fair market value of the warrant as of March 31, 2012, using the below assumptions, was approximately \$7,436,300 resulting in an adjustment to the fair value of (\$149,290) which is included in general and administrative expense in the accompanying condensed statement of operations for the three months ended March 31, 2012. The Company will continue to revalue the warrant each reporting period until such time as the grant date of the warrant is determined.

The fair market value was determined by the following assumptions using the Monte Carlo Simulation method:

	2012
Dividend yield	0.00%
Expected volatility	77.70%
Risk-free interest rate	2.23%
Warrant term in years	10

Additionally, the fair value was estimated based on projected equity raises ranging from \$15 million to \$100 million in 2013 using weighted probability factors.

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 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 March 31, 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 in the three months ended March 31, 2012, 482,500 stock options 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 March 31, 2012, 1,152,500 shares of the Company's common stock are issuable upon the exercise of outstanding awards granted under the 2011 Plan, and 2,377,412 shares of the Company's common stock are available for future issuance under that 2011 Plan.

The fair value of options granted to employees was estimated using the Black-Scholes option-pricing model (see Note 2) with the following weighted-average assumptions used during the period ended March 31:

	2012
Dividend yield	0.0%
Expected volatility	86.0%
Risk-free interest rate	1.1%
Expected life in years	5.81

During the three months ended March 31, 2012, the Company recognized expense (fair value of the stock option grants) of \$198,060, of which \$77,405 was recorded as general and administrative expense and \$120,655 was recorded as research and development expense.

Table of Contents

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 period ended March 31, 2012	482,500	3.75		
Outstanding at March 31, 2012	1,152,500	\$ 3.75	9.8	\$
Unvested at March 31, 2012	1,152,500	\$ 3.75	9.8	\$
Exercisable at March 31, 2012		\$		\$

At March 31, 2012, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was \$2,374,428, which is expected to be recognized over a weighted-average period of 1.4 years. The weighted average grant date fair value of options granted during the three months ended March 31, 2012 was \$2.66 per share.

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. During the three months ended March 31, 2012, the Company incurred expenses of approximately \$20,500, for employer matching contributions.

Note 6 Commitments and Contingencies:**Employment Contracts:**

On January 19, 2012, the Company entered into an employment agreement with Alan H. Auerbach, the Company's President and CEO. The employment agreement governs the terms of Mr. Auerbach's employment since September 15, 2010 and expires on September 1, 2014, unless earlier terminated, with automatic one-year renewal terms, unless either the Company or Mr. Auerbach gives written notice of termination 60 days prior to the end of the term. The employment agreement provides that Mr. Auerbach will receive an annual base salary of \$470,000, retroactively effective to September 1, 2011, and will be eligible to receive an annual discretionary bonus in an amount up to 50% of his base salary. Per the employment agreement, Mr. Auerbach was granted an option to purchase 200,000 shares of Company common stock, which will vest as to 1/3 of the shares underlying the option on January 19, 2013, and as to 1/36 of the shares underlying the option on each monthly anniversary thereafter, subject to Mr. Auerbach's continued employment through the vesting dates.

Table of Contents

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 gastric 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 2012.

A large portion of our expenses to date have been related to our assuming 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, there was a duplication of efforts that took place which resulted in higher than normal operating expenses. The transition has largely been completed and therefore the operating expenses incurred due to this transition, which was the major expense for the first quarter of 2012, will decrease significantly over subsequent quarters.

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 internal research and development expenses along with expenses relating 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 research and development 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.

Edgar Filing: PUMA BIOTECHNOLOGY, INC. - Form 10-Q

Research and development, or 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

Table of Contents

clinical trials. During the three months ended March 31, 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.

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 three months ended March 31, 2012 from our accounting policies at December 31, 2011, as reported in our 2011 Annual Report as filed on Form 10-K.

Results of Operations*Three Months Ended March 31, 2012 Compared to Three Months Ended March 31, 2011**General and administrative expenses:*

For the three months ended March 31, 2012, G&A expenses were approximately \$1.2 million. G&A expenses for the three months ended March 31, 2011, were nominal as we had not commenced meaningful operations during that period. G&A expenses for the three months ended March 31, 2012, were as follows:

General and administrative expenses	
Payroll and related costs	\$ 489,899
Professional fees	508,193
Facility and equipment costs	146,521
Employee stock-based compensation	(71,876)
Other	161,889
	\$ 1,234,626

G&A expenses for the three months ended March 31, 2012 consisted primarily of payroll and payroll-related costs of approximately \$490,000, professional fees and expenses of approximately \$508,000, and facility and equipment costs of approximately \$147,000. 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 remain at least at comparable levels to the three months ended March 31, 2012, for the next several months; however, we are currently looking for satellite office space in the San Francisco area. Employee stock-based compensation for the three months ended March 31, 2012 was approximately \$77,000, offset by a reduction in the valuation of the outstanding anti-dilutive warrant held by our President and Chief Executive Officer of approximately \$149,000, compared to \$0 for the three months ended March 31, 2011. All other costs such as IT support, travel, recruiting and postage were approximately \$162,000 for the three months ended March 31, 2012.

Table of Contents*Research and development expenses:*

For the three months ended March 31, 2012, R&D expenses were approximately \$10.6 million compared to \$0 for the three months ended March 31, 2011. R&D expenses for the three months ended March 31, 2012 were as follows:

Research and development expenses	
Outside clinical development services	\$ 8,156,028
Regulatory affairs and quality assurance	1,424,124
Internal clinical development	760,084
Employee stock-based compensation	120,655
Contract manufacturing	107,491
	\$ 10,568,382

For the three months ended March 31, 2012, R&D expenses consisted primarily of outside clinical development costs of approximately \$8.2 million relating to the transition of clinical trial responsibility to us from the licensor of our three drug candidates, and regulatory affairs and quality assurance expenses of \$1.4 million, which includes a one-time cost of approximately \$0.4 million related to the installation and configuration of software to aid in the creation, storage, and submission of documents to the FDA and other regulatory agencies. Outside clinical development costs are expected to decrease significantly in subsequent quarters as the transition has been completed and duplicate expenses incurred by us, our CRO, the licensor and other consultants in connection with the transition of clinical trial responsibility will be eliminated. Other R&D expenses include payroll and employee related expenses and expenses for travel and other consultant services. Employee stock based compensation for the three months ended March 31, 2012, was approximately \$121,000. Contract manufacturing costs were approximately \$107,000, and consist primarily of employee and employee related expenses and expenses for travel and consulting services.

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 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

Edgar Filing: PUMA BIOTECHNOLOGY, INC. - Form 10-Q

the costs, requirements, timing of, and ability to secure regulatory approvals.

Interest income:

For the three months ended March 31, 2012, we recognized approximately \$26,000 in interest income compared to \$0 of interest income for the three months ended March 31, 2011. Based on market conditions, we placed our excess funds in money market accounts and high yield savings accounts.

Table of Contents**Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of March 31, 2012 and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources	March 31, 2012
Cash and cash equivalents	\$ 50,173,262
Working capital	41,228,082
Stockholders' equity	42,595,201
	Three months ended
	March 31, 2012
Cash provided by (used in):	
Operating activities	\$ (2,784,242)
Investing activities	(424,230)
Financing activities	
Increase (decrease) in cash	\$ (3,208,472)

Operating Activities:

We reported a net loss of approximately \$11.8 million and negative cash flows from operating activities of approximately \$2.8 million for the three months ended March 31, 2012. Our net loss from Puma's date of inception, September 15, 2010, to March 31, 2012, amounted to approximately \$22.1 million, while negative cash flows from operating activities amounted to approximately \$4.6 million for the same period.

Net cash used in operating activities through March 31, 2012, includes a net loss of \$11.8 million, reduced by approximately \$9.0 million of adjustments to reconcile net loss to net cash used in operating activities. Adjustments include non-cash items related to expense from the issuance of stock options of approximately \$198,000, adjustments to the warrant valuation of \$149,000 and an allowance received from the landlord of approximately \$236,000. Other items included in the adjustment of net loss in the operating activities were an increase in accounts payable and accrued expenses of approximately \$8.9 million related to charges from transition activities billed to us as we take over clinical trial responsibilities and represents some duplication of effort as the licensor transitioned knowledge and responsibility to us, an increase in the accrual of deferred rent of approximately \$68,000, and an increase in prepaid and other assets of approximately \$257,000.

Investing Activities:

Net cash used in investing activities was approximately \$424,000 for the three months ended March 31, 2012. Payments of approximately \$187,000 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.

Financing Activities:

We did not engage in any financing activities during the three months ended March 31, 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 anticipate that our cash on hand, including our cash equivalents as of March 31, 2012, will be sufficient to enable us to meet our anticipated expenditures for at least the next 12 months. 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 \$20 million to \$25 million. We will need approximately \$5 million to \$6 million for general and administrative expenses over the next 12 months. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control.

Table of Contents

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. Through March 31, 2012, a significant portion of our financing has been 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 (the Company's principal financial and accounting officer), as appropriate, to allow timely decisions regarding required 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, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of March 31, 2012. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance have concluded that these disclosure controls and procedures were effective as of March 31, 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 March 31, 2012, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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 in Part I, Item 1A Risk Factors of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in other reports we file with the SEC. 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. 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.

Other than the additional risks set forth below, there are no material changes from the risk factors previously disclosed in Part I, Item 1A Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2011.

Because we are quoted on the OTC Bulletin Board and the OTCQB instead of a national exchange or quotation system, our investors may experience significant volatility in the market price of our stock and have difficulty selling their shares.

Our common stock is currently quoted on the OTC Bulletin Board and the OTCQB tier of the OTC Market Group's OTC Link quotation system under the ticker symbol PBYL. The OTC Bulletin Board and the OTCQB are regulated quotation services that display real-time quotes, last sale prices and volume limitations in over-the-counter securities. Trading in shares quoted on the OTC Bulletin Board and the OTCQB is often thin and characterized by volatility in trading prices. This volatility may be caused by a variety of factors, including the lack of readily available price quotations, the absence of consistent administrative supervision of bid and ask quotations, lower trading volume and market conditions. As a result, there may be wide fluctuations in the market price of the shares of our common stock for reasons unrelated to operating performance, and this volatility, when it occurs, may have a negative effect on the market price for our securities. Moreover, the OTC Bulletin Board and the OTCQB are not stock exchanges, and trading of securities on them is often more sporadic than the trading of securities listed on a national quotation system or stock exchange. Accordingly, our stockholders may not be able to realize a fair price from their shares when they determine to sell them or may have to hold them for a substantial period of time until the market for our common stock improves.

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

During the quarter ended March 31, 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 DISCLOSURE

Not applicable.

Item 5. OTHER INFORMATION

None.

Table of Contents

Item 6. EXHIBITS

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

Exhibit	Description
10.1	Employment Agreement, dated January 19, 2012, by and between the Company and Alan H. Auerbach (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 24, 2012 and incorporated herein by reference)
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 March 31, 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 March 31, 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
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

Table of Contents

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.

Dated: May 15, 2012

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

Dated: May 15, 2012

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