PUMA BIOTECHNOLOGY, INC.
Form 10-Q
November 12, 2013
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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, 2013

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) (Zip code)

(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.

Large accelerated filer ¨	Accelerated filer x
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 x.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date. **28,689,304 shares of Common Stock, par value $0.0001 per share, were outstanding as of November 7, 2013.**

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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 organizations and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to market any of our products;
- our history of operating losses;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing.

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, thes

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 Part I, Item 1A Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2012, 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. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	September 30, 2013 (unaudited)	December 31, 2012 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,261	$ 137,408
Marketable securities	44,377	
Licensor receivable	11,294	10,612
Prepaid expenses and other assets	3,644	952
Total current assets	110,576	148,972
Property and equipment, net	1,619	1,479
Deposits	1,701	36
Restricted cash	1,213	1,212
Total assets	$ 115,109	$ 151,699
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 9,730	$ 482
Accrued expenses	9,496	21,219
Total current liabilities	19,226	21,701
Deferred rent	1,123	1,089
Total liabilities	20,349	22,790
Stockholders equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 28,689,304 issued and outstanding at September 30, 2013 and 28,676,666 issued and outstanding at December 31, 2012	3	3
Additional paid-in capital	218,070	213,498
Accumulated other comprehensive loss	(8)	
Deficit accumulated during the development stage	(123,305)	(84,592)

Total stockholders equity	94,760	128,909
Total liabilities and stockholders equity	$ 115,109	$ 151,699

See accompanying notes to the condensed consolidated financial statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands except per share data)

(unaudited)

	Three Months Ended		Nine Months Ended		Period from September 15, 2010 (date of inception) to
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012	September 30, 2013
Operating expenses:					
General and administrative	$ 2,263	$ 8,094	$ 6,804	$ 11,149	$ 40,956
Research and development	12,068	17,779	32,040	41,354	82,502
Totals	14,331	25,873	38,844	52,503	123,458
Loss from operations	(14,331)	(25,873)	(38,844)	(52,503)	(123,458)
Other income (expenses):					
Interest income	9	14	128	63	230
Other income (expense)	39		3		(77)
Totals	48	14	131	63	153
Net loss	$ (14,283)	$ (25,859)	$ (38,713)	$ (52,440)	$ (123,305)
Net loss applicable to common stock	$ (14,283)	$ (25,859)	$ (38,713)	$ (52,440)	$ (123,305)
Net loss per common share basic and diluted	$ (0.50)	$ (1.29)	$ (1.35)	$ (2.62)	
Weighted-average common shares outstanding basic and diluted	28,682,055	20,040,000	28,678,439	20,040,000	

See accompanying notes to the condensed consolidated financial statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 15, 2010 (date of inception) to September 30,
	2013	2012	2013	2012	2013
Net loss	$ (14,283)	$ (25,859)	$ (38,713)	$ (52,440)	$ (123,305)
Other comprehensive loss					
Unrealized loss on available-for-sale securities	66		(8)		(8)
Comprehensive loss	$ (14,217)	$ (25,859)	$ (38,721)	$ (52,440)	$ (123,313)

See accompanying notes to the condensed consolidated financial statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

THE PERIOD FROM SEPTEMBER 15, 2010 (DATE OF INCEPTION) THROUGH SEPTEMBER 30, 2013

(in thousands, except share data)

(unaudited)

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total
Balances, beginning		$	$	$	$	$
Common stock issued for cash at $0.0001 per share	4,000,000					
Paid-in capital			7			7
Net loss					(7)	(7)
Balance at December 31, 2010	4,000,000		7		(7)	
Paid-in capital			61			61
Issuance of shares of common stock through private placements at $3.75 per share, net of issuance costs	16,000,000	2	56,739			56,741
Conversion of stockholder s note payable to equity	40,000		150			150
Stock option compensation			67			67
Anti-dilutive warrant			7,586			7,586
Net loss					(10,233)	(10,233)
Balance at December 31, 2011	20,040,000	2	64,610		(10,240)	54,372
Issuance of shares of common stock through equity offering at $16.00 per share, net of issuance costs	8,625,000	1	129,213			129,214
Stock option compensation			1,408			1,408
Anti-dilutive warrant			18,222			18,222
Exercises of stock options	11,666		45			45
Net loss					(74,352)	(74,352)
Balance at December 31, 2012	28,676,666	3	213,498		(84,592)	128,909
Unrealized loss on available for sale securities				(8)		(8)

Stock option compensation				4,426						4,426
Exercises of stock options	12,638			146						146
Net loss								(38,713)		(38,713)
Balance at September 30, 2013	28,689,304	$	3	$ 218,070	$	(8)	$	(123,305)	$	94,760

See accompanying notes to the condensed consolidated financial statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,		Period from September 15, 2010 (date of inception) to September 30,
	2013	2012	2013
Operating activities:			
Net loss	$ (38,713)	$ (52,440)	$ (123,305)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	298	187	574
Build-out allowance received from landlord		237	903
Stock option expense	4,426	820	5,901
Anti-dilutive warrant		6,250	25,808
Changes in operating assets and liabilities:			
Licensor receivable	(682)		(11,294)
Prepaid expenses and other assets	(4,357)	(489)	(5,345)
Accounts payable	9,248	931	9,730
Accrued expenses	(11,723)	25,142	9,496
Accrual of deferred rent	34	159	220
Net cash used in operating activities	(41,469)	(19,203)	(87,312)
Investing activities:			
Purchase of property and equipment	(435)	(437)	(1,280)
Expenditures for leasehold improvements	(3)	(236)	(913)
Purchase of marketable securities	(44,385)		(44,385)
Restricted cash	(1)	(159)	(1,213)
Net cash used in investing activities	(44,824)	(832)	(47,791)
Financing activities:			
Proceeds from issuance of stockholder s convertible note payable			150
Net proceeds from issuance of common stock			185,955
Net proceeds from exercise of stock options	146		191

Capital contributions by stockholder			68
Net cash provided by financing activities	146		186,364
Net increase (decrease) in cash and cash equivalents	(86,147)	(20,035)	51,261
Cash and cash equivalents, beginning of period	137,408	53,382	
Cash and cash equivalents, end of period	$ 51,261	$ 33,347	$ 51,261
Supplemental disclosures of non-cash investing and financing activities:			
Conversion of stockholder s note payable to common stock	$	$	$ 150

See accompanying notes to the condensed consolidated financial statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or Puma, is a development stage biopharmaceutical company based in Los Angeles, California that acquires and develops innovative products for the treatment of various forms of cancer. References in these Notes to Condensed Consolidated 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 focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use.

In November 2012, the Company established and incorporated Puma Biotechnology Ltd, 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.

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, 2013, its primary focus has been the transition of operational responsibility for its lead drug candidate, PB272 (neratinib (oral)), from Pfizer, Inc., or the Licensor, to the Company (see the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2012, for details of the license agreement) along with the initiation of a Phase III clinical trial in HER2-positive metastatic breast cancer, a Phase II clinical trial in non-small cell lung cancer and a Phase II clinical trial in HER2-mutation positive solid tumors. The accompanying unaudited condensed consolidated interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or 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 consolidated 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, 2013, or for any subsequent period. These unaudited condensed consolidated 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, 2012. The condensed consolidated balance sheet at December 31, 2012, has been derived from the audited financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

The Company has reported a net loss of approximately $14.3 million and $38.8 million and negative cash flows from operations of approximately $12.0 million and $41.5 million for the three and nine months ended September 30, 2013, respectively. The net loss from the date of inception, September 15, 2010, to September 30, 2013, amounted to approximately $123.3 million while the negative cash flows from operations from the date of inception amounted to

approximately $87.3 million. Currently, the Company s negative cash flows from operations are being adversely impacted by a timing difference related to the payment of cap cost expenses to vendors and receipt from the Licensor for said expenses (see Note 2 Significant Accounting Policies: Research and Development Reimbursement). 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, 2013, the Company s financing was primarily through a public offering of Company common stock and 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 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.

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Merger with Public Company:

On September 29, 2011, the Company entered into an agreement and plan of merger, or the Merger Agreement, with Innovative Acquisitions Corp., or IAC, and IAC s wholly-owned subsidiary, IAC Merger Corporation, or 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, or 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 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 ended December 31, 2011.

Note 2 Significant Accounting Policies:

The significant accounting policies followed in the preparation of these condensed consolidated 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. Significant estimates 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. The value of stock-based compensation includes estimates based on future events which are difficult to predict. It is at least reasonably possible that a change in the estimates will occur in the near term.

Principles of Consolidation:

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

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.

Licensor Receivable:

Licensor receivable represents external out of pocket clinical trial costs in excess of an agreed upon cap for clinical trials that were ongoing at the time the licensing agreement with the Licensor was reached. The licensing agreement allows the Company to bill the Licensor for all external out of pocket costs in excess of the cap cost on a quarterly basis. The Licensor, per the license agreement, has 60 days to review the invoice and supporting documentation. Licensor receivable includes both invoiced and non-invoiced costs in excess of the cap. The Company has not established a reserve against this receivable (approximately $11.3 million at September 30, 2013).

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Marketable 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.

Assets Measured at Fair Value on a Recurring Basis:

Accounting Standards Codification, or ASC 820, *Fair Value Measurement*, 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, 2013 and December 31, 2012, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

September 30, 2013	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 50,584	$	$	$ 50,584
Corporate bonds		44,377		44,377

Total	$ 50,584	$ 44,377	$	$ 94,961

December 31, 2012	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 134,867	$	$	$ 134,867
Total	$ 134,867	$	$	$ 134,867

The Company s investments in short-term investment securities are exposed to price fluctuations. The fair value measurements for short-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, 2013, were approximately $52.6 million. The Company does not believe it is exposed to any significant credit risk.

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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 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, 2013.

Research and Development Expenses:

Research and development expenses are charged to operations as incurred. The major components of research and development costs include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and clinical research organization, or CRO, costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company s cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. The objective of the Company s accrual policy is to match the recording of expenses in the condensed consolidated financial statements to the actual services received and efforts expended. As actual costs become known, the Company adjusts its accruals in that period.

In instances where the Company enters into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded to prepaid expenses and deposits in the accompanying condensed consolidated balance sheets and expensed as services are performed or as the underlying goods are delivered. If the Company does not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

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.

Research and Development Reimbursement:

The licensing agreement set a cap on the amount of external expenses the Company would incur, beginning January 1, 2012, in completing the clinical trials transferred from the Licensor to the Company. The license agreement stipulates that the Licensor would be responsible for all external expenses associated with the transferred clinical trials and that the Company would invoice for such costs on a quarterly basis. The Licensor has 60 days to review the invoice and

supporting documentation. All amounts reimbursed from the Licensor represent charges for services provided by third parties and not the Company. Accordingly, the Company has elected to treat the reimbursed costs as pass-through expenses billable to the Licensor and as an offset to research and development expenses. Research and development expenses are recorded net of any excess cap costs billed to the Licensor. The Company recognized approximately $3.4 million and $13.1 million of excess cap costs during the three months and nine months ended September 30, 2013, respectively.

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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, or grant date, and those valuations do not change once they have been established. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing 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 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. When the terms of the warrant become fixed, the Company values the warrant using the Black-Scholes Option Pricing 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 eight to 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 of the warrant until the terms are fixed, 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 value of the warrant at the time of issuance as an equity stock-based compensation transaction. The warrant is revalued each reporting period up to the grant date when the final fair value of the warrant is established and recorded. The grant date is determined when all pertinent information, such as exercise price and quantity, is known.

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 are the same as basic earnings per share because the assumed exercise of the Company s outstanding options are anti-dilutive. For the three and nine months ended September 30, 2013, potentially dilutive securities excluded from the calculations were 2,373,309 shares issuable upon exercise of options and 2,116,250 shares issuable upon exercise of an outstanding warrant. For the three and nine months ended September 30, 2012, potentially dilutive securities excluded from the earnings per common share calculation were 1,422,500 shares issuable upon exercise of options.

Deferred Rent:

The Company has entered into operating lease agreements for its corporate offices in Los Angeles and South San Francisco that contain provisions for future rent increases, leasehold improvement allowances and rent abatements. 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 consolidated 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.

Reclassifications:

Certain amounts for 2012 have been reclassified to conform to the current year s presentation.

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Note 3 Property and Equipment:

Property and equipment consisted of the following (in thousands):

	September 30, 2013	December 31, 2012
Leasehold improvements	$ 913	$ 910
Computer equipment	710	535
Telephone equipment	57	34
Furniture and fixtures	513	276
	2,193	1,755
Less: accumulated depreciation and amortization	(574)	(276)
Totals	$ 1,619	$ 1,479

Note 4 Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	September 30, 2013	December 31, 2012
Accrued CRO/licensor services	$ 5,887	$ 19,846
Accrued other clinical development	1,371	389
Accrued legal fees	294	121
Accrued compensation	1,866	787
Other	78	76
	$ 9,496	$ 21,219

Accrued CRO/licensor services represent the Company s estimate of such costs as of September 30, 2013, and will be adjusted in the period the actual costs become known. Accrued compensation includes estimated bonus and earned but unused vacation for full-time employees. When actual performance bonuses are paid out to employees on the employee s anniversary of hire, the bonus expense will be adjusted to reflect the actual expense for the year. Additionally, vacation is accrued at the rate the employee earns vacation and reduced as the vacation is used by the employee.

Note 5 Stockholders Equity:

Warrants:

Following a private placement of the Company s common stock in October 2011, Alan H. Auerbach, the Company s founder, Chairman, Chief Executive Officer 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 entered into in

connection with this private placement, 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 raised capital through the sale of its securities in the future.

The warrant has a ten-year term and became exercisable upon the first subsequent financing, excluding certain types of financings set forth in the warrant, that resulted in gross cash proceeds to the Company of at least $15 million. The warrant s exercise price equals the price 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. The warrant may be exercised any time up to the ten-year expiration date of October 4, 2021. The Company determined that the warrant had an implied service requisite period in 2011 that was 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 could only occur if there is a subsequent financing.

In connection with the closing of a public offering of the Company s common stock on October 24, 2012, the exercise price and number of shares underlying the warrant issued to Mr. Auerbach were established and, accordingly, the final value of the warrant became fixed. Pursuant to the terms of the warrant, Mr. Auerbach may exercise the warrant to acquire 2,116,250 shares of the Company s common stock at $16.00 per share until October 4, 2021.

The warrant was valued at approximately $6.9 million at the time of issuance and $7.6 million at December 31, 2011, using the Monte Carlo Simulation Method, as both the exercise price per share and the number of shares were unknown at

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that time, and recorded to the consolidated statements of operations. The warrant was revalued at approximately $13.8 million on September 30, 2012, using the below Monte Carlo Simulation Method. The revaluation resulted in an adjustment to the fair value of approximately $6.5 million and $6.2 million, which was included in general and administrative expense in the accompanying condensed consolidated statement of operations for the three and nine months ended September 30, 2012, respectively.

The fair value of the warrant during the quarter ended September 30, 2012, was determined by the following assumptions using the Monte Carlo Simulation Method:

	September 30, 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 value of the warrant at September 30, 2012, was estimated based on an assumption that 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, 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.

Once the terms of the warrant became fixed, the fair value of the warrant as of October 24, 2012, using the Black-Scholes Option Pricing Method, was approximately $25.8 million and resulted in an adjustment to the fair value of the warrant of $18.2 million for the year ended December 31, 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 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 value of such shares on the date of grant. Through September 30, 2013, a total of 3,529,412 shares of the Company s common stock have been reserved for issuance under the 2011 Plan.

The fair value of options granted to employees was estimated using the Black-Scholes Option Pricing Method (see Note 2 Significant Accounting Policies) with the following weighted-average assumptions used during the nine months ended September 30, 2013 and 2012:

	Nine Months Ended September 30,	
	2013	2012

Dividend yield	0.0%	0.0%
Expected volatility	85.4%	85.4%
Risk-free interest rate	1.3%	1.0%
Expected life in years	5.85	5.82

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Employee stock-based compensation for the three and nine months ended September 30, 2013 and 2012, were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(in thousands except per share data)			
Stock-based compensation:				
Options:				
Research and development	$ 1,333	$ 248	$ 3,072	$ 530
General and administrative, or G&A	473	101	1,354	290
Warrants: G&A		(6,575)		6,250
Total stock-based compensation expense	$ 1,806	$ (6,226)	$ 4,426	$ 7,070
Impact on basic and diluted net loss per share	$ 0.06	$ (0.31)	$ 0.15	$ 0.35
Weighted average shares (basic and diluted)	28,682,055	20,040,000	28,678,439	20,040,000

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 (in thousands)
Outstanding at December 31, 2012	1,906,334	$ 8.93	9.4	$ 18,966
Granted during the nine months ended September 30, 2013	499,475	36.80		
Forfeited during the nine months ended September 30, 2013	(19,862)	11.60		
Exercised during the nine months ended September 30, 2013	(12,638)	11.60		
Outstanding at September 30, 2013	2,373,309	14.76	8.8	$ 90,329
Nonvested at September 30, 2013	1,615,623	$ 19.42	9.0	$ 64,490
Exercisable at September 30, 2013	757,686	$ 4.82	8.4	$ 37,007

At September 30, 2013, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $19.0 million, which is expected to be recognized over a weighted-average period of 2.4 years. The intrinsic value of stock options exercised during the nine months ended September 30, 2013 was approximately $486,000. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2013 and 2012, was $25.95 per share and $4.63 per share, respectively.

Stock options	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2012	1,659,399	$ 7.03
Granted	499,475	25.95
Vested/Issued	(523,389)	3.86
Forfeited	(19,862)	8.12
Nonvested shares at September 30, 2013	1,615,623	

Note 6 401(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 $97,000 and $200,600 for the three and nine months ended September 30, 2013, respectively. For the three and nine months ended September 30, 2012, the Company incurred expenses for employer matching contributions of approximately $40,800 and $97,400, respectively.

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Note 7 Marketable Securities:

Marketable securities consist primarily of corporate bonds and are classified as available for sale. Available for sale securities are reported at fair value based on quoted market prices, with unrealized gains and losses reported in accumulated other comprehensive income (loss) within stockholders equity. The cost of a security sold or the amount reclassified out of accumulated other comprehensive income (loss) into earnings is determined using specific identification. The Company may pay a premium or receive a discount upon the purchase of marketable securities. Interest earned and gains/losses realized on marketable securities and amortization of discounts received and accretion of premiums paid on the purchase of marketable securities are included in investment income/expense. The weighted-average maturity of the Company s current marketable securities as of September 30, 2013 was approximately four months.

Available-for-sale marketable securities consisted of the following (in thousands):

	September 30, 2013			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Corporate bond investments Current	$ 44,385	$ 4	$ (12)	$ 44,377

Note 8 Subsequent Events:

During October 2013, the Company entered into an agreement with a clinical research organization, or CRO. This CRO will provide services for initiating, managing and conducting a new Phase II clinical trial for patients with HER2-mutated solid tumors using PB272. The Company shall pay the CRO up to approximately $2.2 million over the life of the agreement (approximately 37 months). The Company may cancel the agreement at any time with a 30-day written notice. The Company would be obligated to pay for any services previously rendered, with any prepaid, unused funds returned to the Company.

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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 consolidated 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, 2012.

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., together with its wholly-owned subsidiary, Puma Biotechnology Ltd, and all references to Former Puma refer to Puma Biotechnology, Inc., a privately held Delaware corporation formed on September 15, 2010 that merged with and into us on October 4, 2011. This transaction was accounted for as a reverse acquisition whereby Former 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 Former 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 Former Puma and us and the operations of Former Puma and us.

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.

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We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients, non-small cell lung cancer patients and patients with HER2 mutation-positive solid tumors;
- 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 Pfizer, Inc., or the Licensor. During this transition period, as we developed 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 for the three months ended September 30, 2013 had an impact on research and development, or R&D, operating expense of approximately $0.2 million, which consisted mainly of data management and pharmacovigilance. We anticipate these costs to decline through the duration of the clinical trials for PB272 that were ongoing at the time we entered into the license agreement with the Licensor. We refer to these clinical trials as the legacy clinical trials.

The license agreement for PB272 established a limit for our expenses related to the legacy clinical trials. This capped our out-of-pocket costs incurred beginning January 1, 2012, in conducting these existing trials. We reached the cost cap during the fourth quarter of 2012 and have recorded a reduction in our R&D expenses, as the Licensor is responsible for such costs. The Licensor will continue to be responsible for these costs until the existing trials are completed. Additionally, our expenses to date have been related to hiring of staff and development 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 and a public offering of our common stock.

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 nine months ended September 30, 2013, our R&D expenses consisted primarily of CRO costs, salaries and related personnel costs (including stock-based compensation expenses), 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

We believe there have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2013, as of the date of filing of this quarterly report, from our accounting policies at December 31, 2012, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

Emerging Growth Company

We are currently an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. On June 28, 2013, our public float exceeded $700 million. As a result, beginning January 1, 2014, we will begin reporting as a large accelerated filer and will no longer be eligible to rely on the benefits afforded to emerging growth companies under the JOBS 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 from the information that you might receive from other public reporting companies in which you hold equity interests.

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Results of Operations

Three Months Ended September 30, 2013 Compared to Three Months Ended September 30, 2012

General and administrative expenses:

For the three months ended September 30, 2013, G&A expenses were approximately $2.3 million, compared to approximately $8.1 million for the three months ended September 30, 2012. G&A expenses for the three months ended September 30, 2013 and 2012 were as follows:

General and administrative expenses in thousands ($000)	Three Months Ended September 30, 2013	2012
Professional fees	$ 554	$ 588
Payroll and related costs	644	511
Facility and equipment costs	290	212
Employee stock-based compensation	473	6,575
Other	302	208
	$ 2,263	$ 8,094

The decrease in G&A expenses for the three months ended September 30, 2013, compared to the three months ended September 30, 2012, consisted primarily of a decrease in employee stock-based compensation of approximately $6.1 million. During the three months ended September 30, 2012, we recognized approximately $6.6 million in employee stock-based compensation expense that reflected the increase in the value of the outstanding anti-dilutive warrant held by our Chief Executive Officer and President. In October 2012, we closed a public offering of our common stock, which resulted in a final fair value determination for the warrant of $25.8 million. We recognized the increase in the fair value of the warrant, approximately $12 million, in the fourth quarter of 2012. Because the final fair value of the warrant was determined and recognized in 2012, there is no corresponding expense in the three months ended September 30, 2013, and we do not expect the 2012 level of stock-based compensation to repeat in the future. G&A expenses for the three months ended September 30, 2013 compared to the three months ended September 30, 2012, also included an increase in payroll and related costs of approximately $0.1 million due to an increase of two full-time employees. Additionally, facility and equipment costs increased approximately $0.1 million from the increase in our rented square footage for office space as well as the cost of maintaining two office locations. We expect facility and equipment costs should remain at least at comparable levels to the three months ended September 30, 2013 for the remainder of 2013. However, we are currently looking for additional office space to accommodate our increased headcount. While professional fees were consistent for the three months ended September 30, 2013 compared to the three months ended September 30, 2012, we expect an increase going forward as we are no longer eligible for the benefits afforded to emerging growth company under the JOBS Act and as such, are required to be fully compliant with the Sarbanes-Oxley Act, which we expect will increase our professional fees as our independent auditors will evaluate the effectiveness of our internal control over financial reporting.

Research and development expenses:

For the three months ended September 30, 2013, R&D expenses were approximately $12.1 million compared to approximately $17.8 million for the three months ended September 30, 2012. R&D expenses for the three months ended September 30, 2013 and 2012 were as follows:

Research and development expenses in thousands ($000)	Three Months Ended September 30, 2013	2012
Outside CRO/Licensor services	$ 2,972	$ 13,626
Outside other clinical development	3,711	1,852
Internal regulatory affairs and quality assurance	1,720	1,083
Internal clinical development	2,132	895
Internal chemical manufacturing	200	75
Employee stock-based compensation	1,333	248
	$ 12,068	$ 17,779

For the three months ended September 30, 2013, R&D expenses for our lead drug candidate consisted primarily of outside other clinical development costs that increased to approximately $3.7 million for the three months ended September 30, 2013, compared to approximately $1.9 million for the three months ended September 30, 2012. The increase of approximately $1.8 million is primarily due to an increase of approximately $1.4 million related to data management and biostatistics services, an increase of approximately $0.2 million for clinical services and consultants, and an increase of approximately $0.2 million for regulatory affairs and quality assurance. Outside CRO/Licensor services decreased to approximately $3.0 million compared to approximately $13.6 million for the three months ended September 30, 2012. The decrease in outside CRO/Licensor services is due to reaching the clinical trial cost cap in the fourth quarter of 2012 (see Note 2 to the Condensed Consolidated Financial Statements Significant Accounting Policies: Research and Development Reimbursement). Additionally, Licensor services provided in maintaining and transitioning the legacy clinical trials have

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decreased dramatically and are expected to cease completely as the legacy trials are completed. Of the approximately $2.9 million in CRO/Licensor expenses incurred in the three months ended September 30, 2013, approximately $0.2 million is related to the Licensor legacy clinical trials with the remaining approximately $2.7 million related to the Company-initiated clinical trials. Because the Company initiated trials began in April 2013, we expect to continue to see an increase in CRO and supporting activities through 2014. The increase in internal regulatory affairs and quality assurance, internal clinical development and internal chemical manufacturing expenses is related to the increase in headcount required to support Company-initiated clinical trials. We expect to continue to hire additional employees focused on R&D activities during 2013 in support of additional Company-initiated clinical trials. The increase in employee stock-based compensation to approximately $1.3 million for the three months ended September 30, 2013, from approximately $0.2 million for the three months ended September 30, 2012, was due to the increase in employee headcount, and additional option grants to existing, eligible employees.

Interest income:

For the three months ended September 30, 2013, we recognized approximately $9,000 in interest income compared to approximately $14,000 for the three months ended September 30, 2012. This decrease in interest income is due to having moved funds from the money market account into short-term investments, such as corporate bonds. Based on market conditions, we placed our excess funds in money market accounts, high yield savings accounts and other marketable securities, per our investment policy.

Nine Months Ended September 30, 2013 Compared to Nine Months Ended September 30, 2012

General and administrative expenses:

For the nine months ended September 30, 2013, G&A expenses were approximately $6.8 million compared to approximately $11.1 million for the nine months ended September 30, 2012. G&A expenses for the nine months ended September 30, 2013 and 2012 were as follows:

General and administrative expenses in thousands ($000)	Nine Months Ended September 30, 2013	2012
Professional fees	$ 1,732	$ 1,744
Payroll and related costs	1,825	1,505
Facility and equipment costs	929	610
Employee stock-based compensation	1,354	6,540
Other	964	750
	$ 6,804	$ 11,149

The decrease in G&A expenses for the nine months ended September 30, 2013, compared to the nine months ended September 30, 2012, consisted primarily of a decrease in employee stock-based compensation of approximately $5.2 million. During the nine months ended September 30, 2012, we recognized approximately $6.5 million in employee stock-based compensation expense that reflected the increase in the value of the outstanding anti-dilutive warrant held by our Chief Executive Officer and President. In October 2012, we closed a public offering of our common stock, which resulted in a final fair value determination for the warrant of $25.8 million. We recognized the increase in the fair value of the warrant, approximately $12 million, in the fourth quarter of 2012. Because the final fair value of the warrant was determined and recognized in 2012, there is no corresponding expense in the nine months ended

September 30, 2013, and we do not expect the 2012 level of stock-based compensation to repeat in the future. G&A expenses for the nine months ended September 30, 2013, compared to the nine months ended September 30, 2012, also included an increase in payroll and related costs of approximately $0.3 million due to two additional employees hired. Additionally, facility and equipment costs increased approximately $0.3 million from an increase in our rented square footage for office space from approximately 13,250 square feet in the first nine months of 2012 to approximately 24,250 square feet in the first nine months of 2013. We expect facility and equipment costs should remain at least at comparable levels to the nine months ended September 30, 2013. However, we are currently looking for additional office space to accommodate our increased headcount. While professional fees were consistent for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012, we expect an increase going forward as we are no longer eligible for the benefits afforded to an emerging growth company under the JOBS Act and as such, are required to be fully compliant with the Sarbanes-Oxley Act, which we expect will increase our professional fees as our independent auditors will evaluate the effectiveness of our internal control over financial reporting.

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Research and development expenses: For the nine months ended September 30, 2013, R&D expenses were approximately $32.0 million compared to approximately $41.4 million for the nine months ended September 30, 2012. R&D expenses for the nine months ended September 30, 2013 and 2012 were as follows:

Research and development expenses in thousands ($000)	Nine Months Ended September 30, 2013	2012
Outside CRO/Licensor services	$ 8,801	$ 32,069
Outside other clinical development	10,464	2,389
Internal regulatory affairs and quality assurance	4,396	3,603
Internal clinical development	4,886	2,518
Internal chemical manufacturing	421	245
Employee stock-based compensation	3,072	530
	$ 32,040	$ 41,354

For the nine months ended September 30, 2013, R&D expenses consisted primarily of outside other clinical development costs that increased to approximately $10.5 million for the nine months ended September 30, 2013, compared to approximately $2.4 million for the nine months ended September 30, 2012. The increase of approximately $8.1 million is primarily due to increases of approximately $3.0 million related to chemical manufacturing, such as testing and validation of the active pharmaceutical ingredient of our lead drug candidate, $1.8 million for clinical services and consultants, $1.6 million for data management and biostatistics services, $0.9 million for regulatory and quality assurance and approximately $0.8 million for drug safety and pharmacovigilance services. Outside CRO/Licensor services decreased to approximately $8.8 million compared to approximately $32.1 million for the nine months ended September 30, 2012. This decrease in outside CRO/Licensor services is due to reaching the clinical trial cost cap (see Note 2 to the Condensed Consolidated Financial Statements Significant Accounting Policies: Research and Development Reimbursement). Additionally, Licensor services provided in maintaining and transitioning the legacy clinical trials have decreased dramatically and are expected to cease completely as the legacy trials are completed. Of the approximately $8.8 million of CRO/Licensor expense in the nine months ended September 30, 2013, approximately $0.5 million is related to the Licensor legacy clinical trials with the remaining approximately $8.3 million related to the Company-initiated clinical trials. Because the Company-initiated trials began in April 2013, we expect to continue to see an increase in CRO and supporting activities through 2014. The increases in internal regulatory affairs and quality assurance, internal clinical development and internal chemical manufacturing expenses are related to the increase in headcount from a limited number of employees during the nine months ended September 30, 2012 to a full staff during the nine months ended September 30, 2013. We expect to continue to hire additional employees focused on R&D activities during 2013 and in 2014. The increase in employee stock-based compensation to approximately $3.1 million for the nine months ended September 30, 2013, from approximately $0.5 million for the nine months ended September 30, 2012, was due to the increase in employee headcount, and additional option grants to existing, eligible employees.

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

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

Interest income:

We recognized approximately $128,000 in interest income during the nine months ended September 30, 2013, compared to approximately $62,600 for the nine months ended September 30, 2012. This increase in interest income is due to having a larger total balance resulting from the October 2012 equity placement prior to moving funds from the money market account into short-term investments.

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Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2013, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands ($000)	September 30, 2013	December 31, 2012
Cash and cash equivalents	$ 51,261	$ 137,408
Marketable securities	44,377	
Working capital	91,350	127,271
Stockholders equity	94,760	128,909

	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Cash provided by (used in):		
Operating activities	$ (41,469)	$ (19,203)
Investing activities	(44,824)	(832)
Financing activities	146	
Increase (decrease) in cash	$ (86,147)	$ (20,035)

Operating Activities:

For the nine months ended September 30, 2013 and the nine months ended September 30, 2012, we reported net loss of approximately $38.7 million and $52.4 million, respectively, and cash flows used in operating activities of approximately $41.5 million and $19.2 million, respectively. Our net loss from Former Puma s date of inception, September 15, 2010, through September 30, 2013 amounted to approximately $123.3 million, while negative cash flow from operating activities amounted to approximately $87.3 million for the same period.

For the nine months ended September 30, 2013, the net cash used in operating activities, noted above, consisted of approximately $38.7 million of net loss excluding non-cash items, an increase in Licensor receivable of approximately $0.7 million and an increase of approximately $4.4 million in prepaid expenses and other assets. Accrued expenses and accounts payable decreased $2.5 million during the nine months ended September 30, 2013, due to the payments made during 2013 mainly related to the Licensor legacy clinical trials. The increase in Licensor receivable (see Note 2 Significant Accounting Policies: Research and Development Reimbursement) represents external charges for services provided by third parties pertaining to the legacy clinical trials. We received payments of approximately $14.6 million (including offsetting amounts to Licensor payables) related to legacy clinical trials from the Licensor. We anticipate continuing to receive payments for the remaining outstanding amounts in accordance with the terms of the license agreement. Per the license agreement, the Licensor has 60 days to review the invoices and supporting documentation. However, the Licensor review process and payment has been taking approximately 90 to 105 days. The increase in prepaid expenses and other assets of approximately $3.9 million reflects advance payments to our CROs and other service providers or suppliers as we ramp up our Phase II and Phase III trials while the remaining $0.5 million relates to insurance and other miscellaneous prepayments.

For the nine months ended September 30, 2012, the net cash used in operating activities, noted above, consisted of approximately $52.4 million of net loss excluding non-cash items, increased by a reduction in accounts payable and

accrued expenses of approximately $26.0 million related to charges from transition activities billed to us as we assume clinical trial responsibilities from the Licensor of our lead product candidate. Approximately $4.3 million of accrued expenses represents duplication of effort as the Licensor transferred clinical trial knowledge and responsibility to us.

Investing Activities:

During the nine months ended September 30, 2013, we invested approximately $44.4 million of excess cash in corporate bonds and $0.4 million in the purchase of property and equipment, compared to approximately $0.4 million in the purchase of property and equipment, $0.2 million for leasehold improvements and $0.2 million for a standby letter of credit for our office space lease for the nine months ended September 30, 2012.

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Financing Activities:

During the nine months ended September 30, 2013, we received proceeds from the exercise of stock options of $0.1 million. We did not engage in financing activities for the nine months ended September 30, 2012.

Current and Future Financing Needs:

We have incurred negative cash flow from operations since we started our business. 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 R&D efforts. Given the current and desired pace of clinical development of our six product candidates, over the next 12 months we estimate that our R&D spending will be approximately $45 million to $55 million, excluding stock-based compensation. We anticipate spending approximately $7 million to $8 million for general and administrative expenses over the next 12 months, excluding stock-based compensation. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control.

While we believe that the approximately $95.6 million in cash, cash equivalents and marketable securities and the $11.3 million Licensor receivable as of September 30, 2013, will be sufficient to enable us to meet our anticipated expenditures through 2014 and into 2015, we may seek to obtain additional capital through the sale of debt or equity securities, if necessary, especially in conjunction with opportunistic acquisitions or licensing arrangements. We expect to continue incurring significant losses for the foreseeable future and our continuing operations will depend on whether we are able to raise additional funds through additional equity or debt financing or by entering into a strategic alliance with a third party concerning one or more of our product candidates. Through September 30, 2013, a significant portion of our financing has been through a public offering and private placements of our equity securities. We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital raised will be sufficient to meet our needs. Further, 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. If we are unable to raise additional funds in the future, we may be forced to delay or discontinue the development of one or more of our product candidates and forego attractive business opportunities. Any additional sources of financing will likely involve the sale of our equity securities, which will have a dilutive effect on our stockholders.

In addition, we have based our estimate of funding on capital requirements on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. 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 it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. 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, and our business, financial condition and results of operations would be materially harmed. In such an event, we would 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.

Adjusted Statement of Operations:

The following tables present our operating results, as calculated in accordance with the accounting principles generally accepted in the United States, or GAAP, as adjusted to remove the impact of employee stock-based compensation and the outside CRO/Licensor services and outside clinical development costs associated with the Licensor legacy clinical trials that we are in the process of completing. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures. We believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. The majority of the cost associated with the Licensor legacy clinical trials related to external costs that we were responsible for but that were subject to a cap. Having reached the cap, the Licensor is responsible for all external costs associated with the legacy clinical trials going forward and we expect to have only limited costs associated with our managing these trials through completion.

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Reconciliation of GAAP and Non-GAAP Financial Information

(in thousands except share and per share data)

	GAAP Measure (Reported) Three Months Ended September 30, 2013	Expense Adjustments: Stock-based compensation	Expense Adjustments: Licensor legacy clinical trials	Non-GAAP Measure Three Months Ended September 30, 2013	GAAP Measure (Reported) Nine Months Ended September 30, 2013	Expense Adjustments: Stock-based compensation	Expense Adjustments: Licensor legacy clinical trials	Non-GAAP Measure Nine Months Ended September 3 2013
erating ense:								
neral and ninistrative	$ 2,263	$ (473)	$	$ 1,790	$ 6,804	$ (1,354)	$	$ 5,45
search and velopment	12,068	(1,333)	(181)	10,554	32,040	(3,072)	(706)	28,26
ss from rations	(14,331)	1,806	181	(12,344)	(38,844)	4,426	706	(33,71
ner income pense):								
erest income	9			9	128			12
ner expense	39			39	3			
als	48			48	131			13
loss	$ (14,283)	$ 1,806	$ 181	$ (12,296)	$ (38,713)	$ 4,426	$ 706	$ (33,58
loss licable to mmon stock	$ (14,283)	$ 1,806	$ 181	$ (12,296)	$ (38,713)	$ 4,426	$ 706	$ (33,58
loss per mmon re basic and uted	$ (0.50)	$ 0.06	$ 0.01	$ (0.43)	$ (1.35)	$ 0.15	$ 0.02	$ (1.1
ighted-average mmon shares standing basic diluted	28,682,055	28,682,055	28,682,055	28,682,055	28,678,439	28,678,439	28,678,439	28,678,43

	GAAP Measure (Reported) Three Months Ended September 30, 2012	Expense adjustments Stock-based compensation	Licensor legacy clinical trials	Non-GAAP Measure Three Months Ended September 30, 2012	GAAP Measure (Reported) Nine Months Ended September 30, 2012	Expense Adjustments Stock-based compensation	Licensor legacy clinical trials	Non-GAA Measure Nine Months Ended September 3 2012
erating ense:								
neral and ninistrative	$ 8,094	$ (6,575)	$	$ 1,519	$ 11,149	$ (6,540)	$	$ 4,60
search and elopment	17,779	(248)	(15,459)	2,072	41,354	(530)	(33,902)	6,92
ss from rations	(25,873)	6,823	15,459	(3,591)	(52,503)	7,070	33,902	(11,53
her income pense):								
erest income	14			14	63			6
her expense								
als	14			14	63			6
loss	$ (25,859)	$ 6,823	$ 15,459	$ (3,577)	$ (52,440)	$ 7,070	$ 33,902	$ (11,46
loss licable to mmon stock	$ (25,859)	$ 6,823	$ 15,459	$ (3,577)	$ (52,440)	$ 7,070	$ 33,902	$ (11,46
loss per mmon re basic and uted	$ (1.29)	$ 0.34	$ 0.77	$ (0.18)	$ (2.62)	$ 0.35	$ 1.69	$ (0.5
ighted-average mmon shares standing basic diluted	20,040,000	20,040,000	20,040,000	20,040,000	20,040,000	20,040,000	20,040,000	20,040,00

Off-Balance Sheet Arrangements

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investing activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing the risk of loss. Some of the investable securities permitted under our cash management policy may be subject to market risk for changes in interest rates. To mitigate this risk, we maintain a portfolio of cash equivalents and available-for-sale investments in a variety of securities, which may include investment grade

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commercial paper, money market funds, government debt issued by the United States of America, state debt, certificates of deposit and investment grade corporate debt. Presently, we are exposed to minimal market risks associated with interest rate changes because of the relatively short maturities of our investments and we do not expect interest rate fluctuations to materially affect the aggregate value of our financial instruments. We manage our sensitivity to these risks by maintaining investment grade short-term investments. We do not purchase or hold derivative or commodity instruments or other financial instruments for trading purposes. Additionally, we periodically monitor our investments for adverse material holdings related to the underlying financial solvency of the issuer. As of September 30, 2013, our investments consisted primarily of corporate obligations. Our results of operations and financial condition would not be significantly impacted by either a 10% increase or 10% decrease in interest rates due mainly to the short-term nature of our investment portfolio. We have not used derivative financial instruments in our investment portfolio. Additionally, we do not invest in foreign currencies or other foreign investments.

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 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, 2013. 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, 2013.

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, 2013 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 material pending legal proceedings. Additionally, we are not aware of any contemplated proceedings against us by any governmental authority.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2012, which was filed with the SEC on April 1, 2013, we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q. There has been no material change in our risk factors subsequent to the filing of our Annual Report. However, the risks described in our Annual Report are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

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

Recent Sales of Unregistered Securities

We did not sell any of our equity securities without registration under the Securities Act of 1933, as amended, during the quarter ended September 30, 2013.

Use of Proceeds from the Sale of Registered Securities

On October 18, 2012, our Registration Statement on Form S-1, as amended (File No. 333-184187), was declared effective for our first registered offering. As a result of the offering, we received net proceeds of approximately $129.2 million. Through September 30, 2013, approximately $26.8 million of the net proceeds from the offering have been used to fund the ongoing clinical programs for our lead drug candidate and for other general corporate purposes. We have invested the unused proceeds from the offering in a variety of capital preservation investments, including money market funds and short-term, investment grade, interest-bearing securities. There has been no material change in our planned use of proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any affiliated purchasers within the definition of Rule 10b-18(a)(3) made any purchases of our equity securities during the quarter ended September 30, 2013.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

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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, 2013
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, 2013
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

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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 12, 2013

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

Date: November 12, 2013

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