PUMA BIOTECHNOLOGY, INC.
Form 10-Q
August 11, 2014

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 June 30, 2014

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	x	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 x.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 30,117,819 shares of Common Stock, par value $0.0001 per share, were outstanding as of August 7, 2014.

PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements within the meaning of 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, these state 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, 2013, 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.

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)

	June 30, 2014 (unaudited)	December 31, 2013 (note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,356	$ 43,044
Marketable securities	122,996	40,904
Licensor receivable	1,760	9,813
Prepaid expenses and other, current	3,493	2,635
Total current assets	183,605	96,396
Property and equipment, net	1,941	1,684
Prepaid expenses and other, long-term	9,318	5,080
Restricted cash	1,214	1,214
Total assets	$ 196,078	$ 104,374
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 18,797	$ 10,692
Accrued expenses	9,135	8,579
Total current liabilities	27,932	19,271
Deferred rent	1,107	1,116
Total liabilities	29,039	20,387
Stockholders' equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 30,117,819 issued and outstanding at June 30, 2014, and 28,991,289 issued and outstanding at December 31, 2013	3	3
Additional paid-in capital	365,002	223,232
Accumulated other comprehensive income	(77)	3
Deficit accumulated during the development stage	(197,889)	(139,251)
Total stockholders' equity	167,039	83,987
Total liabilities and stockholders' equity	$ 196,078	$ 104,374

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 share and per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from September 15, 2010 (date of inception) to June 30,
	2014	2013	2014	2013	2014
Operating expenses:					
General and administrative	$3,904	$2,267	$7,429	$4,541	$51,368
Research and development	35,001	10,440	51,295	19,972	146,803
Totals	38,905	12,707	58,724	24,513	198,171
Loss from operations	(38,905)	(12,707)	(58,724)	(24,513)	(198,171)
Other income (expenses):					
Interest income	66	96	112	119	386
Other (expense)	(5)	(39)	(26)	(36)	(104)
Totals	61	57	86	83	282
Net loss	$(38,844)	$(12,650)	$(58,638)	$(24,430)	$(197,889)
Net loss applicable to common stock	$(38,844)	$(12,650)	$(58,638)	$(24,430)	$(197,889)
Net loss per common share—basic and diluted	$(1.29)	$(0.44)	$(1.96)	$(0.85)	
Weighted-average common shares outstanding—basic and diluted	30,117,819	28,676,666	29,843,966	28,676,666	

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	Three Months Ended		Six Months Ended		Period from September 15, 2010 (date of inception) to
	June 30,		June 30,		June 30,
	2014	2013	2014	2013	2014
Net loss	$(38,844)	$(12,650)	$(58,638)	$(24,430)	$(197,889)
Other comprehensive income (loss):					
Unrealized gain (loss) on available-for-sale securities	(71)	(49)	(80)	(74)	(77)
Comprehensive loss	$(38,915)	$(12,699)	$(58,718)	$(24,504)	$(197,966)

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

FOR THE PERIOD FROM SEPTEMBER 15, 2010 (DATE OF INCEPTION) THROUGH JUNE 30, 2014

(in thousands except share data)

(unaudited)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Deficit Accumulated During the Development	
	Shares	Amount	Capital	Income	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 placement 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
Stock option compensation	—	—	7,519	—	—	7,519
Exercises of stock options	314,623	—	2,215	—	—	2,215
Unrealized gain on available for sale securities	—	—	—	3	—	3

Net loss	—	—	—	—	(54,659)	(54,659)
Balance at December 31, 2013	28,991,289	3	223,232	3	(139,251)	83,987
Stock option compensation	—	—	12,330	—	—	12,330
Issuance of shares of common stock through equity placement at $122.50 per share, net of issuance costs	1,126,530	—	129,440	—	—	129,440
Unrealized loss on available for sale securities	—	—	—	(80)	—	(80)
Net loss	—	—	—	—	(58,638)	(58,638)
Balance at June 30, 2014	30,117,819	$ 3	$ 365,002	$ (77)	$ (197,889)	$ 167,039

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,		Period from September 15, 2010 (date of inception) to June 30,
	2014	2013	2014
Operating activities:			
Net loss	$(58,638)	$(24,430)	$(197,889)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	279	189	978
Build-out allowance received from landlord	—	—	903
Stock option expense	12,330	2,620	21,324
Anti-dilutive warrant	—	—	25,808
Changes in operating assets and liabilities:			
Licensor receivable	8,053	(4,161)	(1,760)
Prepaid expenses and other	(5,096)	(1,842)	(12,811)
Accounts payable	8,105	7,142	18,797
Accrued expenses	556	(9,020)	9,135
Accrual of deferred rent	(9)	47	204
Net cash used in operating activities	(34,420)	(29,455)	(135,311)
Investing activities:			
Purchase of property and equipment	(426)	(354)	(1,895)
Expenditures for leasehold improvements	(110)	(4)	(1,024)
Restricted cash	—	(1)	(1,214)
Purchase of available-for-sale securities	(125,520)	(46,692)	(174,867)
Sale/maturity of available-for-sale securities	43,348	—	51,794
Net cash used in investing activities	(82,708)	(47,051)	(127,206)
Financing activities:			
Proceeds from issuance of stockholder's convertible note payable	—	—	150
Net proceeds from issuance of common stock	129,440	—	315,395
Net proceeds from exercise of stock options	—	—	2,260
Capital contributions by stockholder	—	—	68
Net cash provided by financing activities	129,440	—	317,873
Net increase (decrease) in cash and cash equivalents	12,312	(76,506)	55,356

Cash and cash equivalents, beginning of period	43,044	137,408	—
Cash and cash equivalents, end of period	$55,356	$60,902	$55,356
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

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 June 30, 2014, 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, 2013 and Note 7 to these Condensed Consolidated Financial Statements, for additional information on the license agreement) along with the execution of clinical trials in HER2-positive metastatic breast cancer, HER2-positive neoadjuvant breast cancer, HER2-positive adjuvant breast cancer as well as clinical trials in advanced cancer patients with tumors that have HER2-mutations including non-small cell lung cancer, HER2-negative breast cancer, and other 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, 2014, 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, 2013. The condensed consolidated balance sheet at December 31, 2013, has been derived from the audited financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

The Company has reported a net loss of approximately $38.8 million and $58.6 million and negative cash flows from operations of approximately $17.4 million and $34.4 million for the three and six months ended June 30, 2014, respectively. The net loss from the date of inception, September 15, 2010, to June 30, 2014, amounted to approximately $197.9 million, while the negative cash flows from operations from the date of inception amounted to approximately $135.3 million. For the three and six months ended June 30, 2014, the Company's net loss was impacted by the amendment to the license agreement signed during July 2014, which resulted in the Company recognizing the expenses incurred in connection with the ongoing clinical trials after December 31, 2013 (see Note 7—Subsequent Events). 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 June 30, 2014, the Company's financing was primarily through public offerings of Company common stock and private equity placements. Given the current and desired pace of clinical development of its product candidates, management estimates that the Company has sufficient cash on hand to fund clinical development through 2015 and into 2016. The Company will need additional financing thereafter until it can achieve profitability, if ever. The Company may choose to raise additional capital before 2016 in order to fund its future development activities. There can be no assurance that such capital will be available on favorable terms, or at all, or that any additional capital that the Company is able to obtain will be sufficient to meet its needs. If it is unable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

Merger with Public Company:

On September 29, 2011, the Company entered into an agreement and plan of merger, 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 the remaining 2013 and prior 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. In July 2014, the license agreement was amended to make the Company solely responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013 and to fix the future royalty rate that must be paid to the Licensor upon commercialization in the low- to mid-teens (see Note 7 – Subsequent Events). The Company has not established a reserve against this receivable as it is deemed to be fully collectible.

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 June 30, 2014, and December 31, 2013, 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):

June 30, 2014	Level 1	Level 2	Level 3	Total
Cash equivalents	$53,733	$—	$ —	$53,733

Marketable securities - corporate bonds	—	91,926	—	91,926
Marketable securities - US government		11,493		11,493
Marketable securities - commercial paper	—	19,577	—	19,577
	$53,733	$122,996	$ —	$176,729

December 31, 2013	Level 1	Level 2	Level 3	Total
Cash equivalents	$41,598	$—	$ —	$41,598
Marketable securities - corporate bonds	—	40,904	—	40,904
	$41,598	$40,904	$ —	$82,502

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 June 30, 2014, were approximately $56.4 million. The Company does not believe it is exposed to any significant credit risk.

Property and Equipment:

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

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been 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 June 30, 2014.

Research and Development Expenses:

Research and development, or R&D, expenses are charged to operations as incurred. The major components of R&D 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 was

amended in July 2014 which made the Company solely responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013. In addition, as part of the amended license agreement, the Company will pay the Licensor a fixed royalty rate in the low- to mid- teens upon commercialization of licensed products (see Note 7 – Subsequent Events for additional information). The license agreement originally stipulated 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 R&D expenses. R&D expenses are recorded net of any excess cap costs billed to the Licensor. The Company recognized approximately $5.1 million and $9.7 million of excess cap costs during the three months and six months ended June 30, 2013, respectively. Pursuant to the amendment to the license agreement (see Note 7 – Subsequent Events) no reduction in the expenses related the licensor legacy clinical trials that were in excess of a cap on such expenses set forth in the license agreement was recorded in the three and six months ended June 30, 2014. “Excess cap costs” for the three months ended March 31, 2014 totaling $3.5 million, which were previously recorded as an offset to R&D expenses and licensor receivable, were recorded as a period cost in the three and six months ended June 30, 2014 as a result of the amendment.

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.

Performance shares:

The performance shares are valued on the grant date and the fair value of the performance award is equal to the market price of the Company's common stock on the grant date. The performance share expense is recognized based on the Company's estimate of a range of probabilities that the Company's closing common stock price will be lower or higher than the Company's common stock price on the grant date on the vesting dates. Based on the range of probabilities, the expense is calculated and recognized over the three-year vesting period.

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 six months ended June 30, 2014, potentially dilutive securities excluded from the calculations were 3,375,807 shares issuable upon exercise of options, 28,411 performance shares issuable upon attainment of stock price objectives over the vesting period of the performance share awards and 2,116,250 shares issuable upon exercise of an outstanding warrant. For the three and six months ended June 30, 2013, potentially dilutive securities excluded from the earnings per common share calculation were 2,234,531 shares issuable upon exercise of options and 2,116,250 shares issuable upon exercise of an outstanding warrant.

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.

Recently Issued Accounting Pronouncements:

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09 Revenue from Contracts with Customers, or ASU No. 2014-09, which will supersede nearly all existing revenue recognition guidance under GAAP. ASU No. 2014-09 provides that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU No. 2014-09 allows for either full retrospective or modified retrospective adoption and will become effective for the Company in the first quarter of 2018. The Company is a development stage entity and will evaluate the effects of this update on its consolidated financial statements when it generates revenues.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities, or ASU No. 2014-10, which eliminated certain financial reporting requirements of companies previously identified as development stage entities (Topic 915). The amendments in this ASU simplify accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments also reduce data maintenance and, for those entities subject to audit, audit costs by eliminating the

requirement for development stage entities to present inception-to-date information in the statements of income, cash flows, and stockholder equity. For public entities, these amendments begin to be effective for periods after December 31, 2014. Early application of each of the amendments is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities). Upon adoption, entities will no longer present or disclose any information required by Topic 915. The Company will adopt this standard in future presentations. The financial impact on the Company is expected to be negligible.

Note 3—Prepaid Expenses and Other:

Prepaid expenses and other consisted of the following (in thousands):

	June 30, 2014	December 31, 2013
Short-term:		
CRO services	$983	$ 863
Other clinical development	2,011	1,089
Insurance	353	554
Other	146	129
	3,493	2,635
Long-term:		
CRO services	6,508	1,509
Other clinical development	2,584	3,359
Insurance	170	142
Other	56	70
	9,318	5,080
Totals	$12,811	$ 7,715

Note 4—Property and Equipment:

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

	June 30, 2014	December 31, 2013
Leasehold improvements	$1,024	$ 914
Computer equipment	1,130	874
Telephone equipment	86	82
Furniture and fixtures	679	513
	2,919	2,383
Less: accumulated depreciation and amortization	(978)	(699)

Totals	$1,941	$ 1,684

Note 5—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	June 30, 2014	December 31, 2013
Accrued CRO/licensor services	$3,812	$ 4,801
Accrued other clinical development	2,190	2,369
Accrued legal fees	284	84
Accrued compensation	2,417	1,066
Other	432	259
	$9,135	$ 8,579

Accrued CRO/licensor services represent the Company's estimate of such costs as of June 30, 2014, 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 vacation is used by the employee.

Note 6—Stockholders' Equity:

Common Stock:

On February 14, 2014, the Company completed an underwritten public offering of 1,126,530 shares of the Company's common stock (including an additional 146,938 shares of Company common stock issued and sold pursuant to the underwriters' option to purchase additional shares), par value $0.0001 per share, at a price of $122.50 per share, less the underwriting discount. The net proceeds received by the Company were approximately $129.4 million after deducting the underwriting discount and offering expenses payable by the Company.

Stock-Based Compensation:

The Company's 2011 Incentive Award Plan, or the 2011 Plan, was adopted by the Board of Directors and stockholders of the Company on September 15, 2011. An amendment to the 2011 Plan, or the 2011 Plan Amendment, was adopted by the Board of Directors on June 4, 2014 and the stockholders of the Company on June 10, 2014. The 2011 Plan Amendment increased the number of shares reserved from 3,529,412 to 6,529,412. Pursuant to the amended 2011 Plan (referred to hereafter as the 2011 Plan), the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation such as performance shares. 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. The performance shares are valued at market value less par value and vest over three years with the number of shares to be issued determined by the market price on the vesting date. The maximum number of shares issuable pursuant to a performance share award is established on the grant date.

Employee stock-based compensation for the three and six months ended June 30, 2014 and 2013, were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Stock-based compensation:	(in thousands except share and per share data)			
Options-				
Research and development	$5,738	$1,002	$8,964	$1,739
General and administrative, or G&A	1,363	443	2,704	881
Performance shares - R&D	66	—	662	—
Total share-based compensation expense	$7,167	$1,445	$12,330	$2,620
Impact on basic and diluted net loss per share	$0.24	$0.05	$0.41	$0.09
Weighted average shares (basic and diluted)	30,117,819	28,676,666	29,843,966	28,676,666

Performance Shares:

During January 2014, performance share awards were granted to certain employees that provide for a maximum of 28,411 common stock shares to be issued. These shares vest over three years on the first, second and third anniversary of December 15, 2013. On each vesting date, if the Company's closing common stock per share price is equal to $102.46 per share, one-third of the 28,411 shares will be awarded. If the Company's closing common stock price is either lesser or greater than $102.46 per share, the number of common stock shares to be issued will be adjusted to be less than one-third of the 28,411 shares. No shares will be awarded if the Company's closing common stock price is less than $47.53 per share at the vesting dates. The performance shares are valued on the grant date and the fair value of the performance award is equal to the market price of the Company's common stock on the grant date. The performance share expense is recognized based on the Company's estimate of a range of probabilities that the Company's closing common stock price will be lower or higher than $102.46 on the vesting dates. Based on the range of probabilities, the expense is calculated and recognized over the three-year vesting period.

Stock Options:

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 six months ended June 30, 2014 and 2013:

	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
Dividend yield	0.0 %	0.0 %
Expected volatility	81.3 %	86.9 %
Risk-free interest rate	1.8 %	1.0 %
Expected life in years	5.85	5.85

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, 2013	2,604,224	$ 23.31		
Granted during 2014	806,583	$ 95.19		
Forfeited during 2014	(35,000)	$ 58.20		
Exercised during 2014	—	$ —		
Outstanding at June 30, 2014	3,375,807	$ 39.59	8.7	$ 115,733
Unvested at June 30, 2014	2,143,635	$ 56.26	9.1	$ 47,441
Exercisable at June 30, 2014	1,232,172	$ 10.58	8.0	$ 68,292

At June 30, 2014, total estimated unrecognized employee compensation cost related to non-vested stock options and performance shares granted prior to that date was approximately $69.3 million and $1.7 million, respectively. This unrecognized expense is expected to be recognized over a weighted-average period of 2.5 years for stock options and 1.6 years for performance shares. The weighted-average grant date fair value of options granted during the six months ended June 30, 2014 and 2013, was $65.85 per share and $20.55 per share, respectively.

	Weighted Average Grant-Date

Stock options	Shares	Fair Value
Nonvested shares at December 31, 2013	1,838,633	$ 20.18
Granted	806,583	65.85
Vested/Issued	(466,581)	10.97
Forfeited	(35,000)	40.71
Nonvested shares at June 30, 2014	2,143,635	$ 39.03

Performance shares	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2013	—	$ —
Granted	28,411	102.46
Vested/Issued	—	—
Forfeited	—	—
Nonvested shares at June 30, 2014	28,411	$ 102.46

Note 7—Subsequent Events:

In July 2014, the Company signed an amendment to the license agreement with the Licensor. The amendment to the license agreement provides that the Company will now be solely responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013. These costs were previously the responsibility of the Licensor.

In addition, under the amended agreement, annual royalties to be paid on net sales of licensed products were reduced from a tiered royalty rate structure ranging between 10 to 20 percent to a fixed rate in the low- to mid- teens and the Licensor and the Company have agreed to continue to cooperate to effect the transfer to the Company of certain records, regulatory filings, materials and inventory controlled by the Licensor as promptly as reasonably practicable.

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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, 2013.

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. 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 us and Former Puma 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.

We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of patients with HER2 positive breast cancer, and patients with non-small cell lung cancer, breast cancer and other solid tumors that have a HER2 mutation;
- PB272 (neratinib (intravenous)), which we are developing for the treatment of patients with advanced cancer; and
- PB357, which we believe can serve as a backup compound to PB272, and which we are evaluating for further development.

A large portion of our expenses to date have been related to the clinical development of our lead product candidate, PB272 (neratinib (oral)), and the transition of the neratinib program from the licensor. During this transition period, we built up our infrastructure and assumed responsibility for the neratinib program.

The license agreement for PB272 established a limit for our expenses related to the licensor-initiated clinical trials for PB272 that were ongoing at the time of the agreement and which we refer to as the legacy clinical trials. This capped our "out-of-pocket" costs incurred in conducting the legacy clinical trials beginning January 1, 2012. The cap cost was reached during the fourth quarter of 2012 with the Licensor becoming responsible for the cost to complete the licensor legacy clinical trials. The license agreement was amended in July 2014 whereby we became solely responsible for the

costs incurred or accrued in conducting the legacy clinical trials after December 31, 2013. The license amendment also adjusted the future royalty rate from a tiered royalty rate structure ranging between 10 to 20 percent to a fixed rate in the low- to mid- teens. Additionally, our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure. As we proceed with clinical development of PB272 (neratinib (oral)), recognize expenses associated with the legacy clinical trials 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 continue to 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 public offerings of our common stock and sales of our common stock in private placements.

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 six months ended June 30, 2014 from our accounting policies at December 31, 2013, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

Summary of Expenses

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.

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, including, as of December 31, 2013, the legacy clinical trials. During the three and six months ended June 30, 2014, our R&D expenses consisted primarily of CRO costs, other clinical development costs and salaries and related personnel costs (including stock-based compensation expenses). We expense our R&D costs as they are incurred.

Results of Operations

Three Months Ended June 30, 2014 Compared to the Three Months Ended June 30, 2013

General and administrative expenses:

For the three months ended June 30, 2014, G&A expenses were approximately $3.9 million, compared to approximately $2.3 million for the three months ended June 30, 2013. G&A expenses for the three months ended June 30, 2014 and 2013 were as follows:

General and administrative expenses (in thousands)	Three Months Ended June 30, 2014	2013	Percentage Change 2014/2013	
Payroll and related costs	$745	$605	23	%
Professional fees and expenses	759	511	49	%
Facility and equipment costs	463	324	43	%
Employee stock-based compensation expense	1,363	443	208	%
Insurance and business licenses/taxes	184	104	77	%
Other	390	280	39	%
	$3,904	$2,267	72	%

For the three months ended June 30, 2014, G&A expenses increased approximately $1.6 million compared to the same period in 2013. Payroll and related costs increased to approximately $0.7 million for the three months ended June 30, 2014 from approximately $0.6 million for the same period in 2013 as headcount increased to 13 from nine to support our corporate growth. Professional fees and expenses increased to approximately $0.8 million for the three months ended June 30, 2014 from approximately $0.5 million for the same period in 2013. Professional fees and expenses consist of legal, auditing and consulting fees for compliance with the Sarbanes-Oxley Act of 2002, as

amended, or Sarbanes-Oxley, and investor relations. Facility and equipment costs increased to approximately $0.5 million as we added leased office space. We recently leased an additional suite in our Los Angeles office and are currently in negotiations for additional office space in our South San Francisco location. Employee stock-based compensation increased to approximately $1.4 million for the three months ended June 30, 2014 compared to approximately $0.4 million for the same period in 2013. The increase reflects the increase in our stock price as well as the increase in the number of option grants issued to employees. Insurance and business taxes increased to approximately $0.2 million for the three months ended June 30, 2014 compared to approximately $0.1 million for the same period in 2013 due to increased levels of insurance held by the Company and increased business taxes. We expect G&A expenses to continue to increase moderately as we increase headcount to support anticipated growth.

Research and development expenses:

For the three months ended June 30, 2014, R&D expenses were approximately $35.0 million, compared to approximately $10.4 million for the three months ended June 30, 2013. R&D expenses for the three months ended June 30, 2014 and 2013 were as follows:

Research and development expenses (in thousands)	Three Months Ended June 30, 2014	2013	Percentage Change 2014/2013	
Outside CRO/licensor services	$16,675	$2,300	625	%
Outside other clinical development	6,561	4,255	54	%
Internal regulatory affairs and quality assurance	1,903	1,345	41	%
Internal clinical development	3,826	1,422	169	%
Internal chemical manufacturing	232	116	100	%
Employee stock-based compensation	5,804	1,002	479	%
	$35,001	$10,440	235	%

For the three months ended June 30, 2014, R&D expenses increased approximately $24.6 million compared to the same period in 2013. Approximately $14.3 million of this increase resulted from the amendment to the license agreement with the licensor (see Note 7 to the Condensed Consolidated Financial Statements). This amendment makes us solely responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013. These expenses would have previously been the licensor's responsibility. We expect an additional increase in our R&D expenses of approximately $30 million over the remaining life of the trials and further anticipate that a significant portion of this amount will occur in 2014. Outside CRO/licensor services for Company-initiated clinical trials accounted for approximately $7.8 million of the increase. Outside other clinical development increased to approximately $6.6 million for the three months ended June 30, 2014, compared to approximately $4.3 million for the same period in 2013. The approximately $2.3 million increase can be attributed to an increase in contract chemical manufacturing from approximately $1.5 million for the three months ended June 30, 2013, to approximately $3.0 million for the three months ended June 30, 2014, due to the increased activity in clinical trials. The increases in internal regulatory affairs and quality assurance, internal clinical development and internal chemical manufacturing as well as employee stock-based compensation were driven by an increase in full-time R&D headcount to 84 from 53 as of June 30, 2014 and 2013, respectively. We expect R&D expenses to continue to increase as we recognize the additional expenses associated with the legacy clinical trials and as we to hire additional R&D employees during the remainder of 2014 to support the filing of a New Drug Application, or NDA, with the FDA during 2015.

Six Months Ended June 30, 2014 Compared to the Six Months Ended June 30, 2013

General and administrative expenses:

For the six months ended June 30, 2014, G&A expenses were approximately $7.4 million, compared to approximately $4.5 million for the six months ended June 30, 2013. G&A expenses for the six months ended June 30, 2014 and 2013 were as follows:

General and administrative expenses (in thousands)	Six Months Ended June 30, 2014	2013	Percentage Change 2014/2013	
Payroll and related costs	$1,496	$1,181	27	%
Professional fees and expenses	1,348	1,178	14	%
Facility and equipment costs	880	639	38	%
Employee stock-based compensation expense	2,704	881	207	%
Insurance and business licenses/taxes	360	210	71	%
Other	641	452	42	%
	$7,429	$4,541	64	%

For the six months ended June 30, 2014, G&A expenses increased approximately $2.9 million compared to the same period in 2013. Payroll and related costs increased to approximately $1.5 million as headcount increased to 13 from nine to support our corporate growth. Professional fees and expenses increased to approximately $1.3 million for the six months ended June 30, 2014 from approximately $1.2 million for the same period in 2013. Facility and equipment costs increased to approximately $0.9 million as we added leased office space. We recently leased an additional suite in our Los Angeles office and are currently in negotiations for additional office space in our South San Francisco location. Employee stock-based compensation increased to approximately $2.7 million for the six months ended June 30, 2014 compared to approximately $0.9 million for the six months ended June 30, 2013. The

increase reflects the increase in our stock price as well as the increase in the number of option grants issued to employees. Insurance and business taxes increased to approximately $0.4 million for the six months ended June 30, 2014 compared to approximately $0.2 million for the same period in 2013 due to increased levels of insurance held by us and increased business taxes.

Research and development expenses:

For the six months ended June 30, 2014, R&D expenses were approximately $51.3 million, compared to approximately $20.0 million for the six months ended June 30, 2013. R&D expenses for the six months ended June 30, 2014 and 2013 were as follows:

Research and development expenses (in thousands)	Six Months Ended June 30, 2014	2013	Percentage Change 2014/2013	
Outside CRO/licensor services	$20,606	$5,829	254	%
Outside other clinical development	10,308	6,753	53	%
Internal regulatory affairs and quality assurance	3,513	2,676	31	%
Internal clinical development	6,823	2,754	148	%
Internal chemical manufacturing	419	221	90	%
Employee stock-based compensation	9,626	1,739	454	%
	$51,295	$19,972	157	%

For the six months ended June 30, 2014, R&D expenses increased approximately $31.3 million compared to the same period in 2013. Approximately $14.3 million of this increase resulted from the amendment of the license agreement with the licensor (see Note 7 to the Condensed Consolidated Financial Statements). This amendment makes us solely responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013. These expenses would have previously been the licensor's responsibility. Of the approximately $14.8 million increase in outside CRO/licensor services, approximately $2.8 million was used for Company-initiated clinical trials. Outside other clinical development increased to approximately $10.3 million for the six months ended June 30, 2014, compared to approximately $6.8 million for the same period in 2013. Of the approximately $3.5 million increase, approximately $2.3 million was related to licensor legacy clinical trials and the remaining $1.2 million was related to Company-initiated trials due to the increased activity in these clinical trials. The increases in internal regulatory affairs and quality assurance, internal clinical development and internal chemical manufacturing, and employee stock-based compensation were driven by an increase in full-time R&D headcount to 84 from 53 as of June 30, 2014 and 2013, respectively.

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 revenue from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of other factors, including:

the number of trials and studies in a clinical program;
the number of patients who participate in the trials;

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

Interest income:

For the three and six months ended June 30, 2014, we recognized approximately $66,000 and $112,000, respectively, in interest income compared to approximately $96,000 and $119,000 for the three and six months ended June 30, 2013, respectively. This decrease in interest income is due to transferring funds from money market investments to longer-term higher yielding investments. Interest income of these longer-term investments are recorded when realized.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2014, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)		
	June 30, 2014	December 31, 2013
Cash and cash equivalents	$55,356	$43,044
Marketable securities	122,996	40,904
Working capital	155,673	77,125
Stockholders' equity	167,039	83,987
	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
Cash provided by (used in):		
Operating activities	$(34,420)	$(29,455)
Investing activities	(82,708)	(47,051)
Financing activities	129,440	—
Increase (decrease) in cash	$12,312	$(76,506)

Operating Activities:

For the six months ended June 30, 2014, and the six months ended June 30, 2013, we reported net loss of approximately $58.6 million and $24.4 million, respectively, and cash flows used in operating activities of approximately $34.4 million and $29.5 million, respectively. Our net loss from Former Puma’s date of inception, September 15, 2010, through June 30, 2014, amounted to approximately $197.9 million, while negative cash flow from operating activities amounted to approximately $135.3 million for the same period.

For the six months ended June 30, 2014, the net cash used in operating activities, noted above, consisted of approximately $12.6 million of non-cash items such as depreciation and stock option expense, a decrease in licensor receivable of approximately $8.1 million and an increase of approximately $5.1 million in prepaid expenses and other assets due to the purchase of comparator drugs for use in our clinical trials. Accrued expenses and accounts payable increased approximately $8.7 million during the six months ended June 30, 2014, due to increased activity in the licensor legacy and our clinical trials during the six months ended June 30, 2014. The decrease in licensor receivable was related to the amendment of the license agreement (see Note 7 to the Condensed Consolidated Financial Statements).

For the six months ended June 30, 2013, the net cash used in operating activities, noted above, consisted of approximately $2.8 million of non-cash items such as depreciation and stock option expense, decreased by an increase in accounts payable and accrued expenses of approximately $1.9 million. Further increasing the net loss to arrive at the net cash used in operating activities was an increase in licensor receivable of approximately $4.2 million. Prepaid expenses increased approximately $1.8 million to make up remaining cash used in operating activities as we made advance payments to CROs and other service providers as we ramped up our Phase II and Phase III trials.

Investing Activities:

During the six months ended June 30, 2014, net cash used in investing activities was approximately $82.7 million. This was made up of approximately $125.5 million used for investments of excess cash made in accordance with our investment policy, offset by $43.3 million cash received from corporate bonds that matured and approximately $0.4 million used to purchase property and equipment, approximately $0.1 million used for expenditures for leasehold improvements compared to approximately $46.7 million for the purchase of available-for-sale securities and $0.4 million in the purchase of property and equipment during the six months ended June 30, 2013.

Financing Activities:

During the six months ended June 30, 2014, we received proceeds of approximately $129.4 million from the closing of the February 2014 public offering of our common stock. We did not engage in financing activities for the six months ended June 30, 2013.

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 $85 million to $100 million, excluding stock-based compensation. We anticipate spending approximately $8 million to $9 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 $178.4 million in cash, cash equivalents and marketable securities and the $1.8 million licensor receivable as of June 30, 2014, will be sufficient to enable us to meet our anticipated expenditures through 2015 and into 2016, 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 June 30, 2014, a significant portion of our financing has been through public offerings 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 our 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. 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.

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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 June 30, 2014	Expense Adjustments Stock-based compensation	Non-GAAP Measure Three Months Ended June 30, 2014	GAAP Measure (Reported) Six Months Ended June 30, 2014	Expense Adjustments Stock-based compensation	Non-GAAP Measure Six Months Ended June 30, 2014
Operating expense:						
General and administrative	$3,904	(1,363)	$2,541	$7,429	(2,704)	$4,725
Research and development	35,001	(5,804)	29,197	51,295	(9,626)	41,669
Loss from operations	(38,905)	7,167	(31,738)	(58,724)	12,330	(46,394)
Other income (expense):						
Interest income	66	—	66	112	—	112
Other expense	(5)	—	(5)	(26)	—	(26)
Totals	61	—	61	86	—	86
Net loss	$(38,844)	$7,167	$(31,677)	$(58,638)	$12,330	$(46,308)
Net loss applicable to common stock	$(38,844)	$7,167	$(31,677)	$(58,638)	$12,330	$(46,308)
Net loss per common share—basic and diluted	$(1.29)	$0.24	$(1.05)	$(1.96)	$0.41	$(1.55)
Weighted-average common shares outstanding—basic and diluted	30,117,819	30,117,819	30,117,819	29,843,966	29,843,966	29,843,966

	GAAP Measure (Reported) Three Months Ended June 30, 2013	Expense Adjustments Stock-based compensation	Non-GAAP Measure Three Months Ended June 30, 2013	GAAP Measure (Reported) Six Months Ended June 30, 2013	Expense Adjustments Stock-based compensation	Non-GAAP Measure Six Months Ended June 30, 2013
Operating expense:						
General and administrative	$2,267	$(443)	$1,824	$4,541	$(881)	$3,660
Research and development	10,440	(1,002)	9,438	19,972	(1,739)	18,233
Loss from operations	(12,707)	1,445	(11,262)	(24,513)	2,620	(21,893)
Other income (expense):						
Interest income	96	—	96	119	—	119
Other expense	(39)	—	(39)	(36)	—	(36)
Totals	57	—	57	83	—	83

Net loss	$(12,650)	$1,445	$(11,205)	$(24,430)	$2,620	$(21,810)
Net loss applicable to common stock	$(12,650)	$1,445	$(11,205)	$(24,430)	$2,620	$(21,810)
Net loss per common share—basic and diluted	$(0.44)	$0.05	$(0.39)	$(0.85)	$0.09	$(0.76)
Weighted-average common shares outstanding—basic and diluted	28,676,666	28,676,666	28,676,666	28,676,666	28,676,666	28,676,666

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 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 June 30, 2014, 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 June 30, 2014. 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 June 30, 2014.

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 June 30, 2014, that has materially affected, or is reasonably likely to materially affect, our internal control over

financial reporting.

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, 2013, which was filed with the SEC on March 3, 2014, 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 June 30, 2014.

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 June 30, 2014, approximately $80.3 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 June 30, 2014.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES
Not applicable.

Item 5. OTHER INFORMATION
None.

Item 6. EXHIBITS

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

Exhibit	Description
10.1	First Amendment to Lease, dated as of May 19, 2014, by and between DWF III Gateway, LLC and Puma Biotechnology, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 23, 2014)
10.2	First Amendment to Puma Biotechnology, Inc. 2011 Incentive Award Plan (incorporated by reference to Appendix A to the Amendment to the Definitive Proxy Statement on Schedule 14A filed with the SEC on June 4, 2014)
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 June 30, 2014
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 June 30, 2014
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

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: August 11, 2014	By:	/s/ Alan H. Auerbach Alan H. Auerbach President and Chief Executive Officer (Principal Executive Officer)
Date: August 11, 2014	By:	/s/ Charles R. Eyler Charles R. Eyler Senior Vice President, Finance and Administration and Treasurer (Principal Financial and Accounting Officer)

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