PUMA BIOTECHNOLOGY, INC.
Form 10-Q
August 10, 2015

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, 2015

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. 32,310,605 shares of Common Stock, par value $0.0001 per share, were outstanding as of August 3, 2015.

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 anticipated timing of regulatory filings;
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 intention to vigorously defend against a purported securities class action lawsuit;
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, 2014 and Part II, Item 1A. “Risk Factors” of this Quarterly Report on Form 10-Q 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

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	June 30, 2015	December 31, 2014
	(unaudited)	(Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 59,837	$ 38,539
Marketable securities	222,531	102,788
Prepaid expenses and other, current	5,416	6,292
Licensor receivable	—	1,760
Total current assets	287,784	149,379
Property and equipment, net	2,579	2,157
Prepaid expenses and other, long-term	10,783	10,007
Restricted cash	1,215	1,215
Total assets	$ 302,361	$ 162,758
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,444	$ 14,997
Accrued expenses	15,655	29,444
Total current liabilities	26,099	44,441
Deferred rent	1,484	1,269
Total liabilities	27,583	45,710
Stockholders' equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 32,213,198 shares issued and outstanding at June 30, 2015 and 30,548,309 issued and outstanding at December 31, 2014	3	3
Additional paid-in capital	673,505	399,191
Receivables from the exercises of options	(185)	(835)
Accumulated other comprehensive loss	(181)	(95)
Accumulated deficit	(398,364)	(281,216)
Total stockholders' equity	274,778	117,048
Total liabilities and stockholders' equity	$ 302,361	$ 162,758

See Accompanying Notes to the Condensed Consolidated Financial Statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands except share and per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Operating expenses:				
General and administrative	$5,532	$3,904	$13,403	$7,429
Research and development	59,381	35,001	104,109	51,295
Totals	64,913	38,905	117,512	58,724
Loss from operations	(64,913)	(38,905)	(117,512)	(58,724)
Other income (expenses):				
Interest income	213	66	336	112
Other income (expense)	6	(5)	28	(26)
Totals	219	61	364	86
Net loss	$(64,694)	$(38,844)	$(117,148)	$(58,638)
Net loss applicable to common stock	$(64,694)	$(38,844)	$(117,148)	$(58,638)
Net loss per common share—basic and diluted	$(2.01)	$(1.29)	$(3.68)	$(1.96)
Weighted-average common shares outstanding—basic and diluted	32,158,108	30,117,819	31,874,346	29,843,966

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net loss	$(64,694)	$(38,844)	$(117,148)	$(58,638)
Other comprehensive loss				
Unrealized loss on available-for-sale securities	(92)	(71)	(86)	(80)
Comprehensive loss	$(64,786)	$(38,915)	$(117,234)	$(58,718)

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(in thousands except share data)

(unaudited)

	Common Stock		Additional Paid-in	Receivables from the Exercises of	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Options	Loss	Deficit	Total
Balance at December 31, 2014	30,548,309	$ 3	$ 399,191	$ (835)	$ (95)	$ (281,216)	$ 117,048
Stock-based compensation	—	—	48,297	—	—	—	48,297
Exercises of stock options	509,924	—	20,884	650	—	—	21,534
Issuance of performance shares	4,965	—	—	—	—	—	—
Issuance of shares of common stock through equity placement at $190.00 per share, net of issuance costs	1,150,000	—	205,133	—	—	—	205,133
Unrealized loss on available for sale securities	—	—	—	—	(86)	—	(86)
Net loss	—	—	—	—	—	(117,148)	(117,148)
Balance at June 30, 2015	32,213,198	$ 3	$ 673,505	$ (185)	$ (181)	$ (398,364)	$ 274,778

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2015	2014
Operating activities:		
Net loss	$(117,148)	$(58,638)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	369	279
Build-out allowance received from landlord	179	—
Stock-based compensation	48,297	12,330
Changes in operating assets and liabilities:		
Licensor receivable	1,760	8,053
Prepaid expenses and other	100	(5,096)
Accounts payable	(4,553)	8,105
Accrued expenses	(13,789)	556
Accrual of deferred rent	215	(9)
Net cash used in operating activities	(84,570)	(34,420)
Investing activities:		
Purchase of property and equipment	(791)	(426)
Expenditures for leasehold improvements	(179)	(110)
Purchase of available-for-sale securities	(186,720)	(125,520)
Sale/maturity of available-for-sale securities	66,891	43,348
Net cash used in investing activities	(120,799)	(82,708)
Financing activities:		
Net proceeds from issuance of common stock	205,133	129,440
Net proceeds from exercise of options	21,534	—
Net cash provided by financing activities	226,667	129,440
Net increase in cash and cash equivalents	21,298	12,312
Cash and cash equivalents, beginning of period	38,539	43,044
Cash and cash equivalents, end of period	$59,837	$55,356

See Accompanying Notes to the Condensed Consolidated Financial Statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or Puma, is a biopharmaceutical company based in Los Angeles, California. 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, or Private Puma, for periods prior to the merger of Private Puma with Public Puma (as defined below), which took place on October 4, 2011, or the Merger, and Puma Biotechnology, Inc., a Delaware company formed on April 27, 2007, and formerly known as Innovative Acquisitions Corp., or Public Puma, for periods following the Merger. The Company is a biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. 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 initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive, breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. The Company has reported a net loss of approximately $64.7 million and $117.1 million and negative cash flows from operations of approximately $34.4 million and $84.6 million for the three and six months ended June 30, 2015, respectively. 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 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, 2015, or for any subsequent period. These unaudited condensed consolidated interim financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014. The condensed consolidated balance sheet at December 31, 2014, has been derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

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, 2015, the Company's financing was primarily through public offerings of

Company common stock and private equity placements. The Company sold additional shares of its common stock through an underwritten public offering in January 2015 (see Note 6). As a result, the Company received net proceeds of approximately $205.1 million. Given the current and desired pace of clinical development of its product candidates, management believes that the cash and cash equivalents and marketable securities on hand at June 30, 2015, are sufficient to fund clinical development through 2016 and into 2017. The Company may need additional financing until it can achieve profitability, if ever. There can be no assurance that additional 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.

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 accounting principles generally accepted in the United States, or 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 accrued expenses for 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 used to record accrued expenses and to value the stock-based compensation 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:

The Pfizer, Inc., or Licensor, receivable represents the remaining 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. The balance of licensor receivable at December 31, 2014, of approximately $1.8 million, was fully collected during the three months ended June 30, 2015.

Investment Securities:

The Company classifies all investment securities (short term and long term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management’s strategies. These securities are carried at fair value, with the unrealized gains and losses 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, or ASC 820, provides a single definition of fair value and a common framework for measuring fair value as well as new disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid by a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transaction costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

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

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

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

Following are the major categories of assets measured at fair value on a recurring basis as of June 30, 2015 and December 31, 2014, 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, 2015	Level 1	Level 2	Level 3	Total
Cash equivalents	$54,839	$—	$ —	$54,839
Agency bond	—	5,008	—	5,008
Commercial paper	—	3,149	—	3,149
Marketable securities - U.S. government	—	11,511	—	11,511
Marketable securities - corporate bonds	—	202,863	—	202,863
	$54,839	$222,531	$ —	$277,370

December 31, 2014	Level 1	Level 2	Level 3	Total
Cash equivalents	$20,874	$—	$ —	$20,874
Marketable securities - U.S. government	—	11,496	—	11,496
Marketable securities - corporate bonds	—	91,292	—	91,292
	$20,874	$102,788	$ —	$123,662

The Company’s investments in agency bonds, commercial paper, corporate bonds and U.S. government securities are exposed to price fluctuations. The fair value measurements for agency bonds, commercial paper, corporate bonds and U.S. government securities are based upon the quoted prices of similar items 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, 2015, were approximately $62.2 million. The Company does not believe it is exposed to any significant credit risk due to the quality of the financial instruments in which the money is held. Pursuant to the Company’s internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor’s Corporation and Moody’s Investors Service at the time of purchase.

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, 2015.

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 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 other 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.

Stock-Based Compensation:

Stock option awards:

ASC 718, Compensation-Stock Compensation, or ASC 718, requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each option award is estimated on the 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 seven 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. Option forfeitures are 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. The option expense is "trued-up" upon the actual forfeiture of a stock option grant. 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 on the vesting dates will be lower or higher than the Company's common stock price on the grant date. 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, 2015, potentially dilutive securities excluded from the calculations were 4,124,009 issuable upon exercise of options, 18,942 shares issuable as performance awards and 2,116,250 shares issuable upon exercise of a warrant. For the three and six months ended June 30, 2014, potentially dilutive securities excluded from the earnings per common share calculation were 3,375,807 issuable upon exercise of options, 28,411 issuable as performance shares and 2,116,250 shares issuable upon exercise of a 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.

Issuance of Common Stock Upon Exercise of Stock Option Grants:

When a stock option grant or partial stock option grant is exercised, the Company notifies its transfer agent to release the required number of common stock shares from the reserve for the Company's 2011 Incentive Award Plan. The Company records the transaction for the cash received and the issuance of common shares. Should there be a delay in the cash receipts due to the settlement period, the Company records a receivable from the exercise of an option as part of stockholders' equity on the condensed consolidated balance sheet.

Recently Issued Accounting Standards

In August 2014, the Financial Accounting Standards Board, or the FASB, issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance (1) provides a definition for the term "substantial doubt," (2) requires an evaluation every reporting period, interim periods included, (3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, (4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, (5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and (6) requires an assessment period of one year from the date the financial statements are issued. The standard is effective for the Company's reporting year beginning January 1, 2017 and early adoption is permitted. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: (1) identify the contract, (2) identify performance obligations, (3) determine the transaction price, (4) allocate the transaction price, and (5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. The Company is currently evaluating the impact, if any, that this standard will have on its consolidated financial statements. On July 9, 2015, the FASB voted to defer the effective date of the above mentioned revenue recognition guidance by one year to December 15, 2017 for interim and annual reporting periods beginning after the date and permitted early adoption of the standard, but not before the original effective date of December 15, 2016.

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 stockholders' 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 adopted this standard on December 31, 2014, and it did not have a material impact on its consolidated financial statements.

Note 3—Prepaid Expenses and Other:

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

	June 30, 2015	December 31, 2014
Current:		
CRO services	$1,646	$ 2,451
Other clinical development	2,685	2,525
Insurance	522	1,007
Other	563	309
	5,416	6,292
Long-term:		
CRO services	7,282	6,352
Other clinical development	3,353	3,464
Insurance	97	130
Other	51	61
	10,783	10,007
Totals	$16,199	$ 16,299

Note 4—Property and Equipment:

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

Property and Equipment:	June 30, 2015	December 31, 2014
Leasehold improvements	$1,502	$ 1,217
Computer equipment	1,456	1,272
Telephone equipment	152	145
Furniture and fixtures	1,163	848
	4,273	3,482
Less: accumulated depreciation and amortization	(1,694)	(1,325)
Totals	$2,579	$ 2,157

Note 5—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Accrued CRO services	$9,697	$ 7,764
Accrued other clinical development	2,197	2,541
Accrued legal fees	273	195
Accrued compensation	3,127	2,449
Payroll taxes withheld for options exercised	147	16,414
Other	214	81
Totals	$15,655	$ 29,444

Accrued CRO services represent the Company's estimate of such costs 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:

January 2015 Common Stock Offering. On January 21, 2015, the Company entered into an underwriting agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated and J.P. Morgan Securities LLC, as representatives of several underwriters, providing for the offer and sale in a firm-commitment underwritten public offering of 1,000,000 shares of the Company's common stock, par value $0.0001 per share, at a price of $190.00 per share, less the underwriting discount. The underwriters exercised the option granted to the underwriters to purchase an additional 150,000 shares of Company common stock from the Company at $190.00 per share, less the underwriting discount. The transaction was completed on January 27, 2015; the Company received net proceeds of approximately $205.1 million, which is comprised of gross proceeds of approximately $218.5 million, offset by the underwriting discount and offering expenses of $13.4 million 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 was adopted by the Board of Directors on June 4, 2014 and the stockholders of the Company on June 10, 2014 which increased the number of shares reserved from 3,529,412 to 6,529,412. A second amendment to the 2011 Plan was adopted by the Board of Directors on April 20, 2015 and the stockholders of the Company on June 9, 2015, which increased the shares reserved from 6,529,412 to 10,529,412. 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, 2015 and 2014, were as follows (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Stock-based compensation:				
Options -				
Research and development, or R&D	$25,472	$5,738	$40,726	$8,964
General and administrative, or G&A	2,722	1,363	7,426	2,704
Performance shares: R&D	—	66	145	662
Total stock-based compensation expense	$28,194	$7,167	$48,297	$12,330
Impact on basic and diluted net loss per share	$0.88	$0.24	$1.52	$0.41
Weighted average shares (basic and diluted)	32,158,108	30,117,819	31,874,346	29,843,966

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 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. On December 15, 2014, the first vesting occurred and the calculations were performed. As a result, 4,965 shares of common stock were issued to the employees and 4,504 performance shares were cancelled.

Performance shares	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2014	18,942	$ 102.46
Granted	—	—
Vested/Issued	—	—
Cancelled	—	—
Nonvested shares at June 30, 2015	18,942	$ 102.46

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, 2015 and 2014:

	2015	2014
Dividend yield	0.0 %	0.0 %
Expected volatility	63.1%	81.3%
Risk-free interest rate	1.6 %	1.8 %
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, 2014	3,978,126	$ 89.55	8.7	$ 431,635
Granted	785,411	$ 200.95	9.5	—
Forfeited	(161,577)	$ 197.51	—	—
Exercised	(509,924)	$ 40.69	—	$ 78,671
Expired	(2,041)	$ 126.52		
Outstanding at June 30, 2015	4,089,995	$ 112.75	8.5	$ 176,726
Nonvested at June 30, 2015	2,614,856	$ 160.58	9.2	$ 48,086
Exercisable at June 30, 2015	1,475,139	$ 28.23	7.4	$ 128,640

At June 30, 2015, total estimated unrecognized employee compensation cost related to nonvested stock options and performance shares granted prior to that date were approximately $208.3 million and $0.7 million, respectively. These unrecognized expenses are expected to be recognized over a weighted-average period of 2.3 years for stock options and 1.1 years for performance shares. The weighted-average grant date fair value of options granted during the six months ended June 30, 2015 and 2014, were $115.49 per share and $65.85 per share, respectively.

Weighted Average

Stock options	Shares	Grant-Date Fair Value
Nonvested shares at December 31, 2014	2,591,565	$ 81.33
Granted	785,411	115.49
Vested/Issued	(600,543)	44.21
Forfeited	(161,577)	115.44
Nonvested shares at June 30, 2015	2,614,856	97.49

Note 7—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 $0.3 million and $0.2 million for the six months ended June 30, 2015 and 2014, respectively.

Note 8—Subsequent Events:

In July 2015, the Company agreed to an amendment to its lease with CA-10880 Wilshire Limited Partnership to expand the rented square feet in its Los Angeles office by approximately 26,000 square feet. The amendment will be countersigned by CA-10880 Wilshire Limited Partnership during August 2015. The lease will commence on or about April 1, 2016, and increases the monthly rent in the Los Angeles location by approximately $111,000 per month with annual increases of approximately 3% per year for the 10-year lease term.

In addition, in July 2015, the Company agreed to an amendment to its office lease with PR 701 Gateway, LLC (as successor in interest to DWF III Gateway, LLC) to expand the rented square feet in its South San Francisco location by approximately 13,000 square feet. The amendment will be countersigned by PR 701 Gateway, LLC during August 2015. The lease will commence on or about April 1, 2016, and increases the monthly rent in the South San Francisco location by approximately $45,000 with annual increases of approximately 3% per year for the 10-year lease term.

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 consolidated 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, 2014.

Unless otherwise provided in this Quarterly Report, references to the "Company," "we," "us," and "our" refer to Puma Biotechnology, Inc., a Delaware corporation, together with its wholly owned subsidiary, Puma Biotechnology Ltd.

Overview

We are a 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, or R&D, 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. 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 2016.

We currently license the rights to three drug candidates:

PB272 (neratinib (oral)), which we are developing for the treatment of patients with human epidermal growth factor receptor type 2, or 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 Pfizer, Inc., or the Licensor. 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)), 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, 2015, from our accounting policies at December 31, 2014, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

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 consist primarily of Clinical Research Organizations, or CROs, who assist with managing the clinical trials on our behalf, other clinical development costs and salaries and related personnel costs (including stock-based compensation expense) and include costs associated with services provided by consultants who conduct clinical services on our behalf and contract organizations for manufacturing of clinical materials. We expense our R&D costs as they are incurred.

Results of Operations

Three Months Ended June 30, 2015 Compared to Three Months Ended June 30, 2014

General and administrative expenses:

For the three months ended June 30, 2015, G&A expenses were approximately $5.5 million, compared to approximately $3.9 million for the three months ended June 30, 2014. G&A expenses for the three months ended June 30, 2015 and 2014 were as follows:

General and administrative expenses (in thousands)	2015	2014	Annual percentage change 2015/2014	
Payroll and related costs	$831	$745	11.5	%
Professional fees and expenses	755	759	(0.5	%)
Facility and equipment costs	564	463	21.8	%
Employee stock-based compensation expense	2,722	1,363	99.7	%
Other	660	574	15.0	%
	$5,532	$3,904	41.7	%

For the three months ended June 30, 2015, G&A expenses increased approximately $1.6 million compared to the same period in 2014. Approximately $1.3 million of this increase is related to stock-based compensation expense, which has increased as a result of our increased headcount, as well as the increase in our stock price per share which affects the valuation of new grants. The remaining G&A increase for the three months ended June 30, 2015, compared to the same period in 2014, is approximately $0.3 million. Of this, payroll and related costs increased approximately $0.1 million for the three months ended June 30, 2015, compared to the same period in 2014, as administrative headcount increased to 15 from 13 to support our corporate growth. Facility and equipment costs for the three months ended June 30, 2015, increased approximately $0.1 million when compared to the same period in 2014. We have continued to lease additional suites in our Los Angeles and South San Francisco office locations to support the overall growth of the Company and therefore expect our facility costs to continue to increase (see Note 8 – Subsequent Events regarding the office lease amendments). Additionally, we expect payroll and related costs and professional fees and expenses to continue to increase as we prepare to support our activities related to the filing of a NDA with the FDA during the first quarter of 2016 and as we prepare for commercial approval.

Research and development expenses:

For the three months ended June 30, 2015, R&D expenses were approximately $59.4 million, compared to approximately $35.0 million for the three months ended June 30, 2014. R&D expenses for the three months ended June 30, 2015 and 2014 were as follows:

Research and development expenses	Annual percentage change

(in thousands)	2015	2014	2015/2014	
Clinical trial expenses	$23,715	$21,895	8.3	%
Consultants and contractors	2,120	1,365	55.3	%
Internal clinical development	5,659	3,802	48.8	%
Internal regulatory affairs and quality assurance	2,162	1,903	13.6	%
Internal chemical manufacturing	252	232	8.6	%
Employee stock-based compensation	25,473	5,804	338.9	%
	$59,381	$35,001	69.7	%

For the three months ended June 30, 2015, R&D expenses increased approximately $24.4 million compared to the same period in 2014. Approximately $19.7 million of this increase is related to the increase in stock-based compensation expense which has increased as a result of our increased headcount as well as the increase in our stock price per share which affects the valuation of new grants. Clinical trial expenses increased to approximately $23.7 million from approximately $21.9 million. This increase was comprised of an increase of approximately $1.3 million for investigator initiated clinical trials, approximately $0.8 million drug supply, logistics and testing, approximately $0.7 million for CRO pass-through costs, approximately $0.7 million for toxicity studies, approximately $0.6 million for Company-initiated clinical trial expenses and offset by a decrease in licensor legacy clinical trial expense of approximately $2.3 million. Internal clinical development, internal regulatory affairs and quality assurance, and internal chemical manufacturing accounted for approximately $2.1 million of the increase in R&D expenses. This increase represents an increase in full-time R&D headcount to 119 from 84 for the three months ended June 30, 2015, compared to the same period in 2014. We expect R&D expenses to continue to increase as we recognize the additional expenses associated with the ongoing clinical trials and as we hire additional R&D employees during the remainder of 2015 and into 2016 to support the filing of an NDA with the FDA and a Marketing Authorization Application with the European Medicines Agency.

Six Months Ended June 30, 2015 Compared to Six Months Ended June 30, 2014

General and administrative expenses:

For the six months ended June 30, 2015, G&A expenses were approximately $13.4 million, compared to approximately $7.4 million for the six months ended June 30, 2014. G&A expenses for the six months ended June 30, 2015 and 2014 were as follows:

General and administrative expenses (in thousands)	2015	2014	Annual percentage change 2015/2014	
Payroll and related costs	$1,864	$1,496	24.6	%
Professional fees and expenses	1,729	1,348	28.3	%
Facility and equipment costs	1,115	880	26.7	%
Employee stock-based compensation expense	7,426	2,704	174.6	%
Other	1,269	1,001	26.8	%
	$13,403	$7,429	80.4	%

For the six months ended June 30, 2015, G&A expenses increased approximately $6.0 million compared to the same period in 2014. Approximately $4.7 million of this increase is related to stock-based compensation expense, which has increased as a result of our increased headcount, as well as the increase in our stock price per share which affects the valuation of new grants. The remaining G&A increase for the six months ended June 30, 2015, compared to the same period in 2014, is approximately $1.3 million. Of this, payroll and related costs increased approximately $0.4 million for the six months ended June 30, 2015, compared to the same period in 2014, as administrative headcount increased to 15 from 13 to support our corporate growth. Professional fees and expenses increased approximately $0.4 million for the six months ended June 30, 2015, compared to the same period in 2014. 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 for the six months ended June 30, 2015, increased approximately $0.2 million compared to the same period in 2014. We have continued to lease additional suites in our Los Angeles and South San Francisco office locations to support the overall growth of the Company and therefore expect our facility costs to continue to increase (see Note 8 – Subsequent Events regarding the office lease amendments). Additionally, we expect payroll and related costs and professional fees and expenses to continue to increase as we prepare to support our activities related to the filing of a NDA, with the FDA during the first quarter of 2016 and as we prepare for commercial approval.

Research and development expenses:

For the six months ended June 30, 2015, R&D expenses were approximately $104.1 million, compared to approximately $51.3 million for the six months ended June 30, 2014. R&D expenses for the six months ended June 30, 2015 and 2014 were as follows:

Research and development expenses (in thousands)	2015	2014	Annual percentage change 2015/2014	
Clinical trial expenses	$43,032	$28,717	49.8	%
Consultants and contractors	4,239	2,239	89.3	%
Internal clinical development	11,286	6,780	66.5	%
Internal regulatory affairs and quality assurance	4,139	3,513	17.8	%
Internal chemical manufacturing	542	419	29.4	%
Employee stock-based compensation	40,871	9,627	324.5	%
	$104,109	$51,295	103.0	%

For the six months ended June 30, 2015, R&D expenses increased approximately $52.8 million compared to the same period in 2014. Approximately $31.3 million of this increase is related to the increase in stock-based compensation expense which has increased as a result of our increased headcount as well as the increase in our stock price per share which affects the valuation of new grants. Clinical trial expenses increased to approximately $43.0 million from approximately $28.7 million. This increase was comprised of an increase of approximately $5.2 million for CRO services, approximately $2.7 million drug supply, logistics and testing, approximately $2.2 million for toxicity studies, $1.8 million for investigator initiated clinical trials, approximately $1.6 million for Company-initiated clinical trial expenses, approximately $1.1 million increase due to no longer billing the licensor for legacy trial expense after June 30, 2014, and offset by a decrease in CRO pass-through expenses of approximately $0.4 million. Consultants and contractors supporting clinical and development activities increased approximately $2.0 million. Internal clinical development, internal regulatory affairs and quality assurance, and internal chemical manufacturing accounted for the remaining approximately $5.3 million increase in R&D expenses. This increase represents an increase in full-time R&D headcount to 119 from 84 for the six months ended June 30, 2015, compared to the same period in 2014. We expect R&D expenses to continue to increase as we recognize the additional expenses associated with the ongoing clinical trials and as we hire additional R&D employees during the remainder of 2015 and into 2016 to support the filing of an NDA with the FDA and a Marketing Authorization Application with the European Medicines Agency.

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, 2015, we recognized approximately $213,000 and approximately $336,000 in interest income, respectively, compared to approximately $66,000 and $112,000 for the same periods in 2014. The increase in interest income is due to higher cash and cash equivalents and marketable securities balances and using longer-term higher yielding investments.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2015, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	June 30, 2015	December 31, 2014
Cash and cash equivalents	$59,837	$38,539
Marketable securities	222,531	102,788
Working capital	261,685	104,938
Stockholders' equity	274,778	117,048

	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Cash provided by (used in):		
Operating activities	$(84,570)	$(34,420)
Investing activities	(120,799)	(82,708)
Financing activities	226,667	129,440
Increase in cash and cash equivalents	$21,298	$12,312

Operating Activities:

For the six months ended June 30, 2015 and June 30, 2014, we reported net loss of approximately $117.1 million and $58.6 million, respectively, and net cash used in operating activities of approximately $84.6 million and $34.4 million, respectively. Included in the approximately $84.6 million cash used in operating activities in the six months ended June 30, 2015, was an employee payroll tax payment of approximately $16.4 million related to the exercise of stock options by employees. The taxes withheld by the stockbroker were received by us during the last week of December 2014 and transmitted to the various taxing authorities in January 2015. The remaining approximately $68.2 million of cash used in operating activities reflects the increased costs associated with expanding our clinical trials and preparing for the filing of an NDA in the first quarter of 2016.

For the six months ended June 30, 2015, the net cash used in operating activities, noted above, consisted of approximately $48.8 million of non-cash items such as depreciation and amortization and stock-based compensation, an increase in the liability for deferred rent of approximately $0.2 million and a decrease in accrued expenses and accounts payable of approximately $18.3 million during

the six months ended June 30, 2015, of which approximately $16.4 million was related to the payment of payroll taxes withheld for options exercised.

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 amortization and stock-based compensation, and an increase in accounts payable and accrued expenses of approximately $8.7 million. Cash used in operating activities included an increase in prepaid expenses of approximately $5.1 million. Offsetting that increase was a decrease in licensor receivable of approximately $8.1 million which was paid by the licensor in conjunction with the amended license agreement being signed in July 2014.

Investing Activities:

During the six months ended June 30, 2015, net cash used in investing activities was approximately $120.8 million compared to approximately $82.7 million for the same period in 2014. The approximately $120.8 million net cash invested during the six months ended June 30, 2015 was made up of approximately $186.7 million used for investments of excess cash made in accordance with our investment policy, offset by $66.9 million of cash received from investments that matured and approximately $1.0 million used to purchase property, equipment and leasehold improvements. For the six months ended June 30, 2014, the net cash used in investing activities consisted of approximately $125.5 million used in the purchase of available-for-sale securities, offset by approximately $43.3 million received from the maturity of available-for-sale securities, and $0.5 million used to purchase property, equipment and leasehold improvements.

Financing Activities:

During the six months ended June 30, 2015, we received net proceeds of approximately $205.1 million from the closing of the January 2015 public offering of our common stock, compared to approximately $129.4 million received from the closing of the February 2014 public offering of our common stock during the same period in 2014. During the six months ended June 30, 2015, we received proceeds from the exercise of stock options of approximately $21.5 million.

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 product candidates, over the next 12 months we estimate that our R&D spending will be approximately $115 million to $130 million, excluding stock-based compensation. We anticipate spending approximately $10 million to $12 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 $282.4 million in cash, cash equivalents and marketable securities as of June 30, 2015, will be sufficient to enable us to meet our anticipated expenditures through 2016 and into 2017, 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, 2015, 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.

Contractual Obligations:

In July 2015, we agreed to an amendment to our lease with CA-10880 Wilshire Limited Partnership to expand the rented square feet in our office by approximately 26,000 square feet. We expect that the amendment will be fully executed by the parties in August 2015. The lease will commence on or about April 1, 2016, and increases the monthly rent in the Los Angeles location by approximately $111,000 per month with annual increases of approximately 3% per year for the 10-year lease term.

In addition, in July 2015, we agreed to an amendment to our office lease with PR 701 Gateway, LLC (as successor in interest to DWF III Gateway, LLC) to expand the rented square feet in our South San Francisco location by approximately 13,000 square feet. We expect that the amendment will be fully executed by the parties in August 2015. The lease will commence on or about April 1, 2016, and increases the monthly rent in the South San Francisco location by approximately $45,000 with annual increases of approximately 3% per year for the 10-year lease term.

Non-GAAP Financial Measures:

In addition to our operating results, as calculated in accordance with the accounting principles generally accepted in the United States of America, or GAAP, we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net loss and net loss per share, as calculated in accordance with 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.

For the three and six months ended June 30, 2015, stock-based compensation represented approximately 43.6% and 41.2% of our loss from operations, respectively, compared to 18.5% and 21.0% for the three and six months ended June 30, 2014, respectively. This cost is related to our employee hiring practice and the fair market value of the stock option grants on the day granted.

Reconciliation of GAAP Net Loss to Non-GAAP Adjusted Net Loss and

GAAP Net Loss Per Share to Non-GAAP Adjusted Net Loss Per Share

(in thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014

GAAP net loss	$(64,694)	$(38,844)	$(117,148)	$(58,638)	
Adjustments:					
Stock-based compensation -					
General and administrative	2,722	1,363	7,426	2,704	(1)
Research and development	25,473	5,804	40,871	9,627	(2)
Non-GAAP adjusted net loss	$(36,499)	$(31,677)	$(68,851)	$(46,307)	
GAAP net loss per share—basic and diluted	$(2.01)	$(1.29)	$(3.68)	$(1.96)	
Adjustment to net loss (as detailed above)	0.88	0.24	1.52	0.41	
Non-GAAP adjusted net loss per share	$(1.13)	$(1.05)	$(2.16)	$(1.55)	(3)

(1) To reflect a non-cash charge to operating expense for general and administrative stock-based compensation.
(2) To reflect a non-cash charge to operating expense for research and development stock-based compensation.
(3) Non-GAAP adjusted net loss per share was calculated based on 32,158,108 and 30,117,819 weighted average common shares outstanding for the three months ended June 30, 2015 and 2014, respectively and 31,874,346 and 29,843,966 weighted average common shares outstanding for the six months ended June 30, 2015 and 2014, respectively.

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, 2015, 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 and Treasurer (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 and Treasurer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of June 30, 2015. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer have concluded that these disclosure controls and procedures were effective as of June 30, 2015.

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, 2015, 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

Hsu vs. Puma Biotechnology, Inc., et. al.

On June 3, 2015, Hsingching Hsu, individually and on behalf of all others similarly situated, filed a class action lawsuit against us and certain of our executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). The complaint was filed on behalf of all persons who purchased our securities between July 23, 2014 and May 13, 2015. The complaint alleges that we and certain of our executive officers made false and/or misleading statements and failed to disclose material adverse facts about our business, operations, prospects and performance in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The plaintiff seeks damages, interest, costs, attorneys' fees, and other unspecified equitable relief. We intend to vigorously defend this matter.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on March 2, 2015, 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. Other than the additional risks set forth below, there has been no material change in our risk factors subsequent to the filing of our Annual Report and this Quarterly 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.

We and certain of our executive officers have been named as defendants in a purported securities class action lawsuit, which could cause us to incur substantial costs and divert management's attention, financial resources and other company assets.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. On June 3, 2015, we and certain of our executive officers were named as defendants in a purported securities class action lawsuit on behalf of all persons who purchased our securities between July 23, 2014 and May 13, 2015 that generally alleges that we and such executive officers made false and/or misleading statements and failed to disclose material adverse facts about our business, operations, prospects and performance. This lawsuit and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time-consuming to investigate, defend and resolve, and will divert our management's attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of this and other suits, and we may

not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle this or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial condition, results of operations or stock price. See Item 1. "Legal Proceedings" above for additional information regarding the class action.

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, 2015.

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, 2015.

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	Second Amendment to Puma Biotechnology, Inc. 2011 Incentive Award Plan
10.2	Second Amendment to Lease, dated as of June 10, 2014, by and between DWF III Gateway, LLC and the Company
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, 2015
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, 2015
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 Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy

	Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Linkbase Document

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 10, 2015	By:	/s/ Alan H. Auerbach Alan H. Auerbach President and Chief Executive Officer (Principal Executive Officer)
Date: August 10, 2015	By:	/s/ Charles R. Eyler Charles R. Eyler Senior Vice President, Finance and Administration and Treasurer (Principal Financial and Accounting Officer)