PUMA BIOTECHNOLOGY, INC.
Form 10-Q
August 09, 2016

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, 2016

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. 32,493,092 shares of Common Stock, par value $0.0001 per share, were outstanding as of August 2, 2016.

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;
- the anticipated timing of product revenues and the commercial availability 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; derivative lawsuits and a defamation 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, 2015 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, 2016 (unaudited)	December 31, 2015 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,836	$ 31,569
Marketable securities	85,952	184,320
Prepaid expenses and other, current	8,782	7,660
Receivables	1,179	—
Total current assets	153,749	223,549
Property and equipment, net	5,224	2,383
Prepaid expenses and other, long-term	7,604	9,597
Restricted cash	4,315	4,313
Total assets	$ 170,892	$ 239,842
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 24,624	$ 17,803
Accrued expenses	14,344	14,639
Total current liabilities	38,968	32,442
Deferred rent	4,847	1,393
Total liabilities	43,815	33,835
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 32,493,092 shares issued and outstanding at June 30, 2016 and 32,466,842 issued and outstanding at December 31, 2015	3	3
Additional paid-in capital	785,112	726,651
Accumulated other comprehensive income (loss)	31	(147)
Accumulated deficit	(658,069)	(520,500)
Total stockholders' equity	$ 127,077	$ 206,007
Total liabilities and stockholders' equity	$ 170,892	$ 239,842

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
General and administrative	$12,265	$5,532	$23,304	$13,403
Research and development	54,216	59,381	114,423	104,109
Totals	66,481	64,913	137,727	117,512
Loss from operations	(66,481)	(64,913)	(137,727)	(117,512)
Other (expenses) income:				
Interest income	260	213	542	336
Other (expenses) income	(376)	6	(384)	28
Totals	(116)	219	158	364
Net loss	$(66,597)	$(64,694)	$(137,569)	$(117,148)
Net loss applicable to common stock	$(66,597)	$(64,694)	$(137,569)	$(117,148)
Net loss per common share—basic and diluted	$(2.05)	$(2.01)	$(4.23)	$(3.68)
Weighted-average common shares outstanding—basic and diluted	32,493,092	32,158,108	32,485,750	31,874,346

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	$(66,597)	$(64,694)	$(137,569)	$(117,148)
Other comprehensive loss				
Unrealized gain (loss) on available-for-sale securities	2	(92)	178	(86)
Comprehensive loss	$(66,595)	$(64,786)	$(137,391)	$(117,234)

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	Accumulated Other Comprehensive Income	Accumulated	
	Shares	Amount	Capital	(Loss)	Deficit	Total
Balance at December 31, 2015	32,466,842	$ 3	$726,651	$ (147)	$ (520,500)	$206,007
Stock-based compensation	—	—	58,239	—	—	58,239
Exercises of stock options	26,250	—	222	—	—	222
Unrealized gain on available-for-sale securities	—	—	—	178	—	178
Net loss	—	—	—	—	(137,569)	(137,569)
Balance at June 30, 2016	32,493,092	$ 3	$785,112	$ 31	$ (658,069)	$127,077

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	For the Six Months Ended June 30,	
	2016	2015
Operating activities:		
Net loss	$(137,569)	$(117,148)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	455	369
Build-out allowance received from landlord	2,997	179
Stock-based compensation	58,239	48,297
Disposal of leasehold improvements	368	—
Changes in operating assets and liabilities:		
Receivables	(1,179)	1,760
Prepaid expenses and other	871	100
Accounts payable	6,821	(4,553)
Accrued expenses	(295)	(13,789)
Accrual of deferred rent	3,454	215
Net cash used in operating activities	(65,838)	(84,570)
Investing activities:		
Purchase of property and equipment	(3,665)	(791)
Restricted cash	(2)	—
Expenditures for leasehold improvements	(2,997)	(179)
Purchase of available-for-sale securities	(62,727)	(186,720)
Sale/maturity of available-for-sale securities	161,274	66,891
Net cash provided by (used in) investing activities	91,883	(120,799)
Financing activities:		
Net proceeds from issuance of common stock	—	205,133
Net proceeds from exercise of options	222	21,534
Net cash provided by financing activities	222	226,667
Net increase in cash and cash equivalents	26,267	21,298
Cash and cash equivalents, beginning of period	31,569	38,539
Cash and cash equivalents, end of period	$57,836	$59,837

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 with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to three drug candidates—PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the development of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2.

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 $66.6 million and $137.6 million for the three and six month ended June 30, 2016, respectively, and negative cash flows from operations of approximately $65.8 million for the six months ended June 30, 2016. 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 unaudited condensed consolidated 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, 2016, 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, 2015. The condensed consolidated balance sheet at December 31, 2015, 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, 2015.

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, 2016, 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 believes that the cash and cash equivalents and marketable securities on hand at June 30, 2016, 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 consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, 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.

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, 2016 and December 31, 2015, 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, 2016	Level 1	Level 2	Level 3	Total
Cash equivalents	$56,220	$—	$ —	$56,220
Commercial paper	—	33,336	—	33,336
Marketable securities - U.S. government	—	6,017	—	6,017
Marketable securities - corporate bonds	—	46,599	—	46,599
	$56,220	$85,952	$ —	$142,172

December 31, 2015	Level 1	Level 2	Level 3	Total
Cash equivalents	$29,166	$—	$ —	$29,166
Commercial paper	—	2,996	—	2,996
Marketable securities - U.S. government	—	11,500	—	11,500
Marketable securities - corporate bonds	—	169,824	—	169,824
	$29,166	$184,320	$ —	$213,486

The Company’s investments in commercial paper, corporate bonds and U.S. government securities are exposed to price fluctuations. The fair value measurements for 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, 2016, were approximately $62.1 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, 2016.

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 common share because the assumed exercise of the Company's outstanding options are anti-dilutive. For the three and six months ended June 30, 2016, potentially dilutive securities excluded from the calculations were 5,765,520 shares issuable upon exercise of options, 9,469 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, 2015, potentially dilutive securities excluded from the earnings per common share calculation were 4,124,009 issuable upon exercise of options, 18,942 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 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 January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in ASU 2016-01 address certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption of some of the amendments included in ASU 2016-01 for financial statements of fiscal years or interim periods that have not yet been issued is permitted as of the beginning of the fiscal year of adoption. The Company is currently evaluating the effect that the adoption of ASU 2016-01 will have on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The amendments in ASU 2016-02 will require organizations that lease assets, with lease terms of more than 12 months, to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with current U.S. Generally Accepted Accounting Principles (“U.S. GAAP”), the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current U.S. GAAP which requires only capital leases to be recognized on the balance sheet, ASU No. 2016-02 will require both types of leases to be recognized on the balance sheet. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the effect that the adoption of ASU 2016-02 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-06, Derivatives and Hedging (Topic 815) Contingent Put and Call Options in Debt Instruments. ASU 2016-06 amends FASB ASC 815-15 to clarify what steps are required when assessing whether the economic characteristics and risks of call (put) options are clearly and closely related to the economic characteristics and risks of their debt hosts, which is one of the criteria for bifurcating an embedded derivative. ASU 2016-06 will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. An entity should apply the amendments in ASU No. 2016-06 on a modified retrospective basis to existing debt instruments as of the beginning of the fiscal year for which the amendments are effective. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the effect that the adoption of ASU 2016-06 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718). ASU 2016-09 will require organizations to recognize all income tax effects of awards in the statement of operations when the awards vest or are settled. ASU 2016-09 will also allow organizations to repurchase more shares from employees than they could previously purchase for tax withholding purposes without triggering liability accounting and to make a policy election to account for forfeitures as they occur. ASU 2016-09 will be effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted in any interim or annual period. The Company is currently evaluating the effect that the adoption of ASU 2016-09 will have on its financial statements.

In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606). ASU 2016-10 amends ASC 606, Revenue from Contracts with Customers, to clarify two aspects of ASC 606, identifying performance obligations and the licensing implementation guidance, while retaining the related principles of those areas. The amendments in ASU 2016-10 do not change the core principle of the guidance in ASC 606. The amendments in ASU No. 2016-10 affect the guidance in ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which is not yet effective. The effective date and transition requirements for the amendments in ASU No. 2016-10 are the same as the effective date and transition requirements in ASC 606 and any other Topic amended by ASU 2014-09. ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, defers the effective date of ASU 2014-09 by one year to annual reporting periods beginning after December 15, 2017,

including interim reporting periods within that reporting period. The Company is currently evaluating the effect that the adoption of ASU 2016-10 will have on its financial statements.

In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606). ASU 2016-12 amends ASC 606 to address certain issues in the guidance on assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. The amendments in ASU 2016-12 do not change the core principle of the guidance in ASC 606. The amendments in ASU No. 2016-12 affect the guidance in ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which is not yet effective. The effective date and transition requirements for the amendments in ASU No. 2016-12 are the same as the effective date and transition requirements in ASC 606 and any other Topic amended by ASU 2014-09. ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, defers the effective date of ASU 2014-09 by one year to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company is currently evaluating the effect that the adoption of ASU 2016-12 will have on its financial statements.

Note 3—Prepaid Expenses and Other:

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

	June 30, 2016	December 31, 2015
Current:		
CRO services	$4,473	$ 2,969
Other clinical development	2,189	2,309
Insurance	560	1,138
Other	1,560	1,244
	8,782	7,660
Long-term:		
CRO services	4,450	5,754
Other clinical development	2,459	3,005
Insurance	72	87
Other	623	751
	7,604	9,597
Totals	$16,386	$ 17,257

Note 4—Property and Equipment:

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

Property and Equipment:	June 30, 2016	December 31, 2015
Leasehold improvements	$3,615	$ 1,502
Computer equipment	1,726	1,646
Telephone equipment	169	169
Furniture and fixtures	2,100	1,167
	7,610	4,484
Less: accumulated depreciation and amortization	(2,386)	(2,101)
Totals	$5,224	$ 2,383

During the six months ended June 30, 2016, the Company disposed of leasehold improvements that were surrendered as a result of the amended lease in its South San Francisco location (see Note 9 – Commitments and Contingencies of the Consolidated Financial Statements section of the Annual Report on Form 10-K for the year ended December 31, 2015). The loss on the disposal of leasehold improvements was approximately $0.4 million.

Note 5—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Accrued CRO services	$6,339	$ 8,436
Accrued other clinical development	3,247	3,618
Accrued legal fees	480	443
Accrued compensation	4,056	1,970
Other	222	172
Totals	$14,344	$ 14,639

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, 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:

Stock-Based Compensation:

The Company's 2011 Incentive Award Plan, or the 2011 Plan, was adopted by the Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. Through June 30, 2016, a total of 10,529,412 shares of the Company's common stock have been reserved for issuance under the 2011 Plan.

Employee stock-based compensation for the three and six months ended June 30, 2016 and 2015 were as follows (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Stock-based compensation:				
Options -				
Research and development, or R&D	$22,494	$25,472	$46,050	$40,726
General and administrative, or G&A	6,168	2,722	12,050	7,426
Performance shares - R&D	67	—	139	145
Total stock-based compensation expense	$28,729	$28,194	$58,239	$48,297
Impact on basic and diluted net loss per share	$0.88	$0.88	$1.79	$1.52
Weighted average shares (basic and diluted)	32,493,092	32,158,108	32,485,750	31,874,346

Performance Shares:

During January 2014, performance share awards that provide for a maximum of 28,411 common stock shares to be issued were granted to certain employees. 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, 2015, the second vesting occurred and the calculations were performed. As a result, 6,530 shares of common stock were issued to the employees and 2,943 performance shares were cancelled. The third and final vesting event will occur on December 15, 2016.

Performance shares	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2015	9,469	$ 102.46
Granted	—	—
Vested/Issued	—	—
Cancelled	—	—
Nonvested shares at June 30, 2016	9,469	$ 102.46

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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, 2016 and 2015:

	2016	2015
Dividend yield	0.0 %	0.0 %
Expected volatility	67.2%	63.1%
Risk-free interest rate	1.5 %	1.6 %
Expected life in years	5.67	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, 2015	5,542,285	$ 105.59	8.6	$ 87,632
Granted	532,417	$ 46.24	9.4	—
Forfeited	(259,046)	$ 122.88		
Exercised	(26,250)	$ 8.46		$ 920
Expired	(23,886)	$ 106.53		
Outstanding at June 30, 2016	5,765,520	$ 99.77	8.2	$ 17,673
Nonvested at June 30, 2016	3,193,739	$ 105.99	9.1	$ 71
Exercisable at June 30, 2016	2,571,781	$ 92.06	7.1	$ 17,602

At June 30, 2016, total estimated unrecognized employee compensation cost related to nonvested stock options and performance shares granted prior to that date were approximately $170.2 million and $0.3 million, respectively. These unrecognized expenses are expected to be recognized over a weighted-average period of 1.8 years for stock options and 0.5 years for performance shares. The weighted-average grant date fair value of options granted during the six months ended June 30, 2016 and 2015, were $27.42 per share and $115.49 per share, respectively.

	Weighted Average Grant-Date

Stock options	Shares	Fair Value
Nonvested shares at December 31, 2015	3,572,202	$ 73.59
Granted	532,417	27.42
Vested/Issued	(651,834)	95.66
Forfeited	(259,046)	74.49
Nonvested shares at June 30, 2016	3,193,739	63.20

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 $0.5 million and $0.3 million for the six months ended June 30, 2016 and 2015, respectively.

Note 8—Receivables:

On April 1, 2016, the Company took possession of additional office space pursuant to the amendments to the leases entered into in July 2015 (see Note 9 – Commitments and Contingencies of the Consolidated Financial Statements section of the Annual Report on Form 10-K for the year ended December 31, 2015). This office space increased the leased square footage in the Los Angeles and South San Francisco offices by approximately 26,000 square feet and 13,000 square feet, respectively. Pursuant to the terms of these amended leases, the landlords provided tenant improvement allowances. One of the tenant improvement allowances was prepaid by

the Company and will be reimbursed by the landlord prior to December 31, 2016. The total of this landlord receivable is approximately $1.2 million.

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, 2015.

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 with a focus on the development and commercialization of innovative products to enhance cancer care. We in-license the global development and commercialization rights to three drug candidates—PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor, or TKI, that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, we are primarily focused on the development of the oral version of neratinib, and our most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. We believe neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2. 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 2017.

We recently completed a Phase III clinical trial of neratinib for the extended adjuvant treatment of women with early stage HER2-positive breast cancer, which we refer to as the ExteNET trial. Based on the results from the ExteNET trial, we submitted a New Drug Application, or NDA, with the FDA for regulatory approval of neratinib in the extended adjuvant setting in the United States in July 2016 and a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMEA, in June 2016. We are continuing to evaluate potential commercialization options for neratinib in this indication, including developing a direct sales force, contracting with third parties to provide sales and marketing capabilities, some combination of these two options or other strategic options. We expect that our expenses will continue to increase as we continue to evaluate our options with regard to commercialization efforts.

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, 2016, from our accounting policies at December 31, 2015, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

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, preparation for

commercialization and other corporate expenses.

Research and development, or R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for manufacturing of clinical materials and clinical trials. During the six months ended June 30, 2016 and 2015, our R&D expenses consisted primarily of clinical research organization, or CRO fees, fees paid to consultants, salaries and related personnel costs and stock-based compensation. We expense our R&D costs as they are incurred.

Results of Operations

Three Months Ended June 30, 2016 Compared to Three Months Ended June 30, 2015

General and administrative expenses:

For the three months ended June 30, 2016, G&A expenses were approximately $12.3 million, compared to approximately $5.5 million for the three months ended June 30, 2015. G&A expenses for the three months ended June 30, 2016 and 2015 were as follows:

General and administrative expenses (in thousands)	Three Months Ended June 30, 2016	2015	Period to period percentage change	
Payroll and related costs	$1,755	$831	111.2	%
Professional fees and expenses	2,286	755	202.8	%
Facility and equipment costs	1,357	564	140.6	%
Employee stock-based compensation expense	6,168	2,722	126.6	%
Other	699	660	5.9	%
	$12,265	$5,532	121.7	%

For the three months ended June 30, 2016, G&A expenses increased approximately $6.8 million compared to the same period in 2015. Approximately $3.5 million of this increase is related to an increase in stock-based compensation expense, attributable to our increased headcount and additional incentive awards to existing employees. The remaining approximately $3.3 million increase in G&A expense for the three months ended June 30, 2016, compared to the same period in 2015, was primarily attributable to:

- an approximately $1.5 million increase in professional fees and expenses, which consist primarily of legal, auditing, consulting and investor relations fees. We expect these fees to increase as we continue to defend against the class action, derivative and defamation lawsuits filed against us and as we support compliance measures related to the Sarbanes Oxley Act of 2002, as amended, or Sarbanes Oxley.
- an approximately $1.0 million increase in payroll and related costs as administrative headcount increased from 15 to 21 to support corporate growth and to prepare for the commercial launch of neratinib. We expect these payroll and related costs to continue to increase as we prepare for commercialization.
- an approximately $0.8 million increase in facility and equipment costs. During 2015, we amended two of our office leases and in April 2016 we took possession of additional office space pursuant to the amended leases; therefore, we expect that our facility and equipment costs will continue at the higher levels similar to the three months ended June 30, 2016.

Research and development expenses:

For the three months ended June 30, 2016, R&D expenses were approximately $54.2 million, compared to approximately $59.4 million for the three months ended June 30, 2015. R&D expenses for the three months ended June 30, 2016 and 2015 were as follows:

Research and development expenses (in thousands)	Three Months Ended June 30, 2016	2015	Period to period percentage change	
Clinical trial expenses	$18,837	$23,716	(20.6	%)
Internal clinical development	6,651	5,169	28.7	%
Internal regulatory affairs and quality assurance	2,484	2,162	14.9	%
Consultants and contractors	3,179	2,610	21.8	%
Internal chemical manufacturing	504	252	100.0	%
Employee stock-based compensation	22,561	25,472	(11.4	%)
	$54,216	$59,381	(8.7	%)

For the three months ended June 30, 2016, R&D expenses decreased approximately $5.2 million compared to the same period in 2015. Approximately $2.9 million of this decrease is related to a decrease in stock-based compensation expense, attributable to a decreased stock price valuation for incentive awards to new and existing employees. The remaining approximately $2.3 million decrease in R&D expense for the three months ended June 30, 2016, compared to the same period in 2015, was primarily attributable to:

- an approximately $4.9 million decrease in clinical trial expenses as a result of a decrease in CRO professional and pass-through costs of approximately $5.1 million and a decrease in drug supply manufacturing and logistics of approximately

$1.1 million as clinical trial activity decreased, offset by an approximately $1.3 million increase in clinical services primarily attributable to our preparation for filing an NDA and MAA, which were submitted in July 2016 and June 2016, respectively.

an approximately $2.0 million increase for internal clinical development, internal regulatory affairs and quality assurance, and internal chemical manufacturing. This increase represents an increase in full-time R&D headcount to 139 from 119 for the three months ended June 30, 2016, compared to the same period in 2015. We expect internal R&D expenses to continue at levels similar to the three months ended June 30, 2016, as we expect headcount will remain at approximately the same level.

an approximately $0.6 million increase in consultants and contractors related expenses due to increased activity in our preparation for filing an NDA and MAA, which were submitted in July 2016 and June 2016, respectively.

Six Months Ended June 30, 2016 Compared to Six Months Ended June 30, 2015

General and administrative expenses:

For the six months ended June 30, 2016, G&A expenses were approximately $23.3 million, compared to approximately $13.4 million for the six months ended June 30, 2015. G&A expenses for the six months ended June 30, 2016 and 2015 were as follows:

General and administrative expenses (in thousands)	Six Months Ended June 30, 2016	2015	Period to period percentage change	
Payroll and related costs	$3,191	$1,864	71.2	%
Professional fees and expenses	4,598	1,729	165.9	%
Facility and equipment costs	2,062	1,115	84.9	%
Employee stock-based compensation expense	12,050	7,426	62.3	%
Other	1,403	1,269	10.6	%
	$23,304	$13,403	73.9	%

For the six months ended June 30, 2016, G&A expenses increased approximately $9.9 million compared to the same period in 2015. Approximately $4.6 million of this increase is related to an increase in stock-based compensation expense, attributable to our increased headcount and additional incentive awards to existing employees. The remaining approximately $5.3 million increase in G&A expense for the six months ended June 30, 2016, compared to the same period in 2015, was primarily attributable to:

an approximately $2.9 million increase in professional fees and expenses, which consist primarily of legal, auditing, consulting and investor relations fees. We expect these fees to increase as we continue to defend against the class action, derivative and defamation lawsuits filed against us and as we support compliance measures related to Sarbanes Oxley.

- an approximately $1.3 million increase in payroll and related costs as administrative headcount increased from 15 to 21 to support corporate growth and to prepare for the commercial launch of neratinib. We expect these payroll and related costs to continue to increase as we prepare for commercialization.
- an approximately $1.0 million increase in facility and equipment costs. During 2015, we amended two of our office leases and in April 2016 we took possession of additional office space pursuant to the amended leases; therefore, we expect that our facility and equipment costs will continue at the higher levels similar to the six months ended June 30, 2016.

Research and development expenses:

For the six months ended June 30, 2016, R&D expenses were approximately $114.4 million, compared to approximately $104.1 million for the six months ended June 30, 2015. R&D expenses for the six months ended June 30, 2016 and 2015 were as follows:

Research and development expenses (in thousands)	Six Months Ended June 30, 2016	2015	Period to period percentage change
Clinical trial expenses	$42,454	$43,034	(1.3 %)
Internal clinical development	13,397	10,190	31.5 %
Internal regulatory affairs and quality assurance	5,181	4,130	25.4 %
Consultants and contractors	6,244	5,342	16.9 %
Internal chemical manufacturing	958	542	76.8 %
Employee stock-based compensation	46,189	40,871	13.0 %
	$114,423	$104,109	9.9 %

For the six months ended June 30, 2016, R&D expenses increased approximately $10.3 million compared to the same period in 2015. Approximately $5.3 million of this increase is related to an increase in stock-based compensation expense, attributable to additional incentive awards to new and existing employees. The remaining approximately $5.0 million increase in R&D expense for the six months ended June 30, 2016, compared to the same period in 2015, was primarily attributable to:

- an approximately $4.7 million increase for internal clinical development, internal regulatory affairs and quality assurance, and internal chemical manufacturing. This increase represents an increase in full-time R&D headcount to 139 from 119 for the six months ended June 30, 2016, compared to the same period in 2015. We expect internal R&D expenses to continue at levels similar to the six months ended June 30, 2016, as we expect headcount will remain at approximately the same level.

- an approximately $0.9 million increase in consultants and contractors related expenses due to increased activity in our preparation for filing an NDA and MAA, which were submitted in July 2016 and June 2016, respectively.

- an approximately $0.5 million decrease in clinical trial expenses as a result of a decrease in CRO professional and pass-through costs of approximately $6.4 million, offset by an increase in drug supply manufacturing and logistics of approximately $3.8 million for manufacturing and testing of clinical drug supply and approximately $2.1 million increase in clinical services primarily attributable to our preparation for filing an NDA and MAA, which were submitted in July 2016 and June 2016, respectively.

While expenditures on current and future clinical development programs, particularly our PB272 program, are expected to be substantial, 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, 2016 , we recognized approximately $260,000 and approximately $542,000 in interest income, compared to approximately $213,000 and approximately $336,000 for the same periods in 2015, respectively. The increase in interest income is due to the use of longer-term higher yielding investments.

Other expenses:

During the three and six months ended June 30, 2016, we recognized a loss of approximately $368,000 on the disposal of leasehold improvements due to the relocation of our South San Francisco office space (see Note 9 – Commitments and Contingencies of the Consolidated Financial Statements section of the Annual Report on Form 10-K for the year ended December 31, 2015).

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2016 and December 31, 2015, and is intended to supplement the more detailed discussion that follows:

Operating Activities:

Liquidity and capital resources (in thousands)	June 30, 2016	December 31, 2015
Cash and cash equivalents	$57,836	$ 31,569
Marketable securities	85,952	184,320
Receivable	1,179	—
Working capital	114,781	191,107
Stockholders' equity	127,077	206,007

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Cash provided by (used in):		
Operating activities	$(65,838)	$ (84,570)
Investing activities	91,883	(120,799)
Financing activities	222	226,667
Increase in cash and cash equivalents	$26,267	$ 21,298

For the three and six months ended June 30, 2016, we reported a net loss of approximately $66.6 million and $137.6 million, respectively, compared to approximately $64.7 million and $117.1 million for the same periods in 2015, respectively. Additionally, cash used in operating activities for the three and six months ended June 30, 2016, was approximately $30.8 million and $65.8 million, respectively, compared to approximately $34.6 million and approximately $84.6 million for the same periods in 2015, respectively.

The approximately $65.8 million of net cash used in operating activities for the six months ended June 30, 2016, consisted primarily of approximately $62.1 million of non-cash items such as depreciation and amortization, a build-out allowance from the landlord for our office space, the disposal of leasehold improvements and stock-based compensation; an increase of approximately $3.5 million in the liability for deferred rent; an increase in other receivables of approximately $1.2 million related to the build-out allowance to be received from the landlord; a decrease of approximately $0.9 million in prepaid expenses and other; and an increase of approximately $6.5 million in accrued expenses and accounts payable.

For the six months ended June 30, 2015, the net cash used in operating activities, noted above, consisted primarily of approximately $48.8 million of non-cash items such as depreciation and amortization and stock-based compensation; and a decrease of approximately $18.3 million in accounts payable and accrued expenses, approximately $16.4

million of which represents a payment of taxes for stock option exercises in late December 2014. Cash used in operating activities also included an increase of approximately $0.1 million in prepaid expenses and other and an increase of approximately $0.2 million in deferred rent.

Investing Activities:

During the six months ended June 30, 2016, net cash provided by investing activities was approximately $91.9 million compared to net cash used in investing activities of approximately $120.8 million for the same period in 2015. The approximately $91.9 million of net cash provided by investing activities during the six months ended June 30, 2016 was made up of approximately $161.3 million of sales or maturities of available-for-sale securities, offset by $62.7 million of cash invested in available-for-sale securities, approximately $3.7 million used to purchase property and equipment and approximately $3.0 million of expenditures for leasehold improvements. During the six months ended June 30, 2015, cash used in investing activities was primarily made up of approximately $186.7 million used for the purchase of available-for-sale securities and approximately $1.0 million used to purchase property, equipment, and leasehold improvements, offset by approximately $66.9 million cash provided by the sale or maturities of available-for-sale securities.

Financing Activities:

During the six months ended June 30, 2016, we received approximately $0.2 million of net proceeds from the exercise of stock options. During the same period in 2015, cash provided by financing activities was approximately $226.7 million, comprised of net proceeds of approximately $205.2 million from the closing of the January 2015 public offering of our common stock and approximately $21.5 million of net proceeds from the exercise of stock options.

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, and our preparation for commercialization. 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 $15 million to $20 million over the next 12 months for general and administrative expenses, excluding stock-based compensation. For sales and marketing, which includes costs to prepare for commercialization, we anticipate spending approximately $80 million to $100 million with the majority of these expenses commencing in late 2016 or early 2017. The actual amount of funds we will need to operate is subject to many factors, including the mechanism by which we choose to commercialize and some factors which are beyond our control.

While we believe that the approximately $143.8 million in cash, cash equivalents and marketable securities as of June 30, 2016, 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, 2016, 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:

On April 1, 2016, we took possession of the additional office space pursuant to the amendments to the leases entered into in July 2015 (see Note 9 – Commitments and Contingencies of the Consolidated Financial Statements section of the Annual Report on Form 10-K for the year ended December 31, 2015). This office space increased the leased square footage in the Los Angeles and South San Francisco offices by approximately 26,000 square feet and 13,000 square feet, respectively.

Non-GAAP Financial Measures:

In addition to our operating results, as calculated in accordance with 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, 2016, stock-based compensation represented approximately 43.1% and 42.3% of our loss from operations, respectively, and approximately 43.6% and 41.2% for the same periods in 2015. 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,		
	2016	2015	2016	2015	
GAAP net loss	$(66,597)	$(64,694)	$(137,569)	$(117,148)	
Adjustments:					
Stock-based compensation - General and administrative	6,168	2,722	12,050	7,426	(1)
Research and development	22,561	25,472	46,189	40,871	(2)
Non-GAAP adjusted net loss	$(37,868)	$(36,500)	$(79,330)	$(68,851)	
GAAP net loss per share—basic and diluted	$(2.05)	$(2.01)	$(4.23)	$(3.68)	
Adjustment to net loss (as detailed above)	0.88	0.88	1.79	1.52	
Non-GAAP adjusted net loss per share	$(1.17)	$(1.13)	$(2.44)	$(2.16)	(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 weighted average common shares outstanding of 32,493,092 and 32,485,750 for the three and six months ended June 30, 2016, and 32,158,108 and 31,874,346 for the three and six months ended June 30, 2015, 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, 2016, 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, 2016. 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, 2016.

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, 2016, 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

Hsu v. 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). On October 16, 2015, lead Plaintiff Norfolk Pension Fund filed an amended complaint on behalf of all persons who purchased our securities between July 22, 2014 and May 29, 2015. The amended 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. On November 30, 2015, we filed a motion to dismiss the amended complaint. The plaintiff opposed this motion, and the court heard oral argument on March 14, 2016. We intend to vigorously defend this matter.

Eshelman v. Puma Biotechnology, Inc., et. al.

On February 2, 2016, Fredric N. Eshelman filed a lawsuit against our Chief Executive Officer and President, Alan H. Auerbach, and us in the United States District Court for the Eastern District of North Carolina (Case No. 7:16-cv-00018-D). The complaint generally alleges that Mr. Auerbach and we made defamatory statements regarding Dr. Eshelman in connection with a proxy contest. Dr. Eshelman seeks compensatory and punitive damages and expenses and costs, including attorneys' fees. On April 4, 2016, the defendants filed a motion to dismiss the complaint. On May 2, 2016, Dr. Eshelman filed a notice of voluntary dismissal of the claims against Mr. Auerbach. We intend to vigorously defend this matter.

Derivative Actions

On April 12 and April 14, 2016, alleged shareholders filed two derivative lawsuits purportedly on behalf of the Company against certain of our officers and directors in the Superior Court of the State of California, Los Angeles, captioned Xing Xie v. Alan H. Auerbach, et al., No. BC616617, and Kevin McKenney v. Auerbach, et al., No. BC617059. The complaints assert claims for breach of fiduciary duty, unjust enrichment, abuse of control, mismanagement and waste of corporate assets arising from substantially similar allegations as those contained in the putative securities class action described above. The complaints seek an unspecified sum of damages and equitable relief. We intend to vigorously defend these matters.

The pending proceedings described in this section involve complex questions of fact and law and will require the expenditure of significant funds and the diversion of other resources to defend. The results of legal proceedings are inherently uncertain, and material adverse outcomes are possible.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the SEC on February 29, 2016, 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, 2016.

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, 2016.

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
3.1	Second Amended and Restated Certificate of Incorporation of the Company, as filed with the Secretary of Sate of the State of Delaware on June 14, 2016 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016 and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on February 16, 2016 and incorporated herein by reference)
10.1+	Letter Agreement, dated April 15, 2016, between

	the Company and Richard B. Phillips
10.2+	Letter Agreement, dated May 24, 2016, between the Company and Robert Charnas
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, 2016
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, 2016
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
	+	Management contract or compensatory plan or arrangement.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: August 9, 2016	By:	/s/ Alan H. Auerbach Alan H. Auerbach President and Chief Executive Officer (Principal Executive Officer)
Date: August 9, 2016	By:	/s/ Charles R. Eyler Charles R. Eyler Senior Vice President, Finance and Administration and Treasurer (Principal Financial and Accounting Officer)