UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2017

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 ☒ 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 ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for compying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒ .

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 36,966,278 shares of Common Stock, par value $0.0001 per share, were outstanding as of May 4, 2017.

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, 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;
- 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 and ability to vigorously defend against a 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 statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report on Form 10-Q, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2016 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)
(unaudited)

	March 31, 2017	December 31, 2016 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 105,086	$ 194,494
Marketable securities	88,894	34,982
Prepaid expenses and other, current	10,654	6,998
Total current assets	204,634	236,474
Property and equipment, net	5,000	5,153
Prepaid expenses and other, long-term	2,674	6,846
Restricted cash	4,316	4,317
Total assets	$ 216,624	$ 252,790
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 23,970	$ 20,035
Accrued expenses	19,760	17,426
Total current liabilities	43,730	37,461
Deferred rent	5,502	5,505
Total liabilities	49,232	42,966
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 36,963,278 shares issued and outstanding at March 31, 2017 and 36,826,010 issued and outstanding at December 31, 2016	4	4
Additional paid-in capital	1,036,825	1,006,344
Receivables from the exercise of options	(11)	—
Accumulated other comprehensive loss	(50)	(13)
Accumulated deficit	(869,376)	(796,511)
Total stockholders' equity	167,392	209,824
Total liabilities and stockholders' equity	$ 216,624	$ 252,790

See Accompanying Notes to the Unaudited 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 March 31,	
	2017	**2016**
Operating expenses:		
General and administrative	$ 18,401	$ 11,039
Research and development	54,801	60,207
Total Operating Expense	73,202	71,246
Loss from operations	(73,202)	(71,246)
Other (expenses) income:		
Interest income	350	282
Other (expenses) income	(13)	(8)
Total Other Income	337	274
Net loss	$ (72,865)	$ (70,972)
Net loss applicable to common stock	$ (72,865)	$ (70,972)
Net loss per common share—basic and diluted	$ (1.97)	$ (2.19)
Weighted-average common shares outstanding—basic and diluted	36,931,167	32,478,408

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2017	2016
Net loss	$ (72,865)	$ (70,972)
Other comprehensive loss		
Unrealized gain (loss) on available-for-sale securities	(37)	176
Comprehensive loss	$ (72,902)	$ (70,796)

See Accompanying Notes to the Unaudited 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 Capital	Receivables from the Exercises of Options	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount					
Balance at December 31, 2016	36,826,010	$ 4	$ 1,006,344	$ —	$ (13)	$ (796,511)	$ 209,824
Stock-based compensation	—	—	29,764	—	—	—	29,764
Exercises of stock options/issuances of RSUs	137,268	—	717	(11)	—	—	706
Unrealized gain on available-for-sale securities	—	—	—	—	(37)	—	(37)
Net loss	—	—	—	—	—	(72,865)	(72,865)
Balance at March 31, 2017	36,963,278	$ 4	$ 1,036,825	$ (11)	$ (50)	$ (869,376)	$ 167,392

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	For the Three Months Ended	
	2017	2016
Operating activities:		
Net loss	$ (72,865)	$ (70,972)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	277	208
Stock-based compensation	29,764	29,510
Changes in operating assets and liabilities:		
Prepaid expenses and other	516	(170)
Accounts payable	3,935	7,034
Accrued expenses	2,334	(571)
Accrual of deferred rent	(3)	(67)
Net cash used in operating activities	(36,042)	(35,028)
Investing activities:		
Purchase of property and equipment	(124)	(44)
Restricted cash	1	(1)
Purchase of available-for-sale securities	(79,728)	(36,768)
Sale/maturity of available-for-sale securities	25,779	118,269
Net cash (used in) provided by investing activities	(54,072)	81,456
Financing activities:		
Net proceeds from exercise of options	706	222
Net cash provided by financing activities	706	222
Net increase in cash and cash equivalents	(89,408)	46,650
Cash and cash equivalents, beginning of period	194,494	31,569
Cash and cash equivalents, end of period	$ 105,086	$ 78,219

See Accompanying Notes to the Unaudited 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 $72.9 million for the three months ended March 31, 2017, and negative cash flows from operations of approximately $36.0 million for the three months ended March 31, 2017. 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, 2017, 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, 2016. The condensed consolidated balance sheet at December 31, 2016, 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, 2016.

The Company has incurred significant operating losses since its inception, which raises substantial doubt about its ability to continue as a going concern. The Company has not yet launched its first commercial product and is currently exploring methods by which to commercialize its product candidates if approved by the United States Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA. These methods may require funding in addition to the cash and cash equivalents and marketable securities totaling approximately $194.0 million available at March 31, 2017. While the consolidated financial statements have been prepared on a going concern basis, the Company continues to remain dependent on its ability to obtain sufficient funding to sustain operation and successfully commercially launch neratinib if approved by the FDA or EMA. While the Company has been successful in raising financing in the past, there can be no assurance that it will be able to do so in the future. The Company's ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. The Company's continued operations will depend on its ability to raise funds through various potential sources, such as equity and debt financing.

Since its inception through March 31, 2017, the Company's financing was primarily through public offerings of Company common stock and private equity placements. The Company sold shares of its common stock through an underwritten public offering in October 2016 (see Note 6 to the Annual Report on Form 10-K for the year ended December 31, 2016). As a result, the Company received net proceeds of approximately $161.9 million. 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 unaudited condensed consolidated financial statements are as follows:

Use of Estimates:

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the balance sheet, and reported amounts of expenses for the period presented. Accordingly, actual results could differ from those estimates. Significant estimates include 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 unaudited 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) 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.

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 March 31, 2017 and December 31, 2016, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and si gnificant unobservable inputs (Level 3) (in thousands):

March 31, 2017	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 96,932	$ —	$ —	$ 96,932
Commercial paper	—	39,828	—	39,828
Marketable securities - corporate bonds	—	49,066	—	49,066
	$ 96,932	$ 88,894	$ —	$ 185,826

December 31, 2016	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 188,543	$ —	$ —	$ 188,543
Commercial paper	—	5,998	—	5,998
Marketable securities - corporate bonds	—	28,984	—	28,984
	$ 188,543	$ 34,982	$ -	$ 223,525

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.

The Company invests its excess cash in commercial paper and debt instruments of corporations. As of March 31, 2017, the Company's short-term investments had a weighted average maturity of less than one year.

The following tables summarize the Company's short-term investments (in thousands):

March 31, 2017	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 96,932	$ 1	$ —	$ 96,933
Commercial paper	Less than 1	39,828	—	—	39,828
Marketable securities - corporate bonds	Less than 1	49,066	3	(54)	49,015
		$ 185,826	$ 4	$ (54)	$ 185,776

December 31, 2016	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 188,543	$ —	$ —	$ 188,543
Commercial paper	Less than 1	5,998	—	—	5,998
Marketable securities - corporate bonds	Less than 1	28,984	—	(13)	28,971
		$ 223,525	$ —	$ (13)	$ 223,512

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 March 31, 2017, were approximately $109.4 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 March 31, 2017.

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 record expenses in the unaudited condensed consolidated financial statements as the actual services are performed and efforts expended. As actual costs become known, the Company records the actual expenses 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 unaudited 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. The final tranche of performance shares vested in December 2016. All of those performance shares were cancelled because they did not meet the applicable price requirement on the third, and final, vesting date.

Restricted stock units:

The restricted stock units, or RSUs, are valued on the grant date and the fair value of the RSUs is equal to the market price of the Company's common stock on the grant date. The RSU expense is recognized over the requisite service period. When the requisite service period begins prior to the grant date (because the service inception date occurs prior to the grant date), the Company is required to begin recognizing compensation cost before there is a measurement date (i.e., the grant date). The service inception date is the beginning of the requisite service period. If the service inception date precedes the grant date, accrual of compensation cost for periods before the grant date shall be based on the fair value of the award at the reporting date. In the period in which the grant date occurs, cumulative compensation cost shall be adjusted to reflect the cumulative effect of measuring compensation cost based on fair value at the grant date rather than the fair value previously used at the service inception date (or any subsequent reporting date).

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 months ended March 31, 2017, potentially dilutive securities excluded from the calculations were 6,915,865 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 516,961 shares underlying restricted stock units that are subject to vesting and are antidilutive. For the three months ended March 31, 2016, potentially dilutive securities excluded from the earnings per common share calculation were 5,675,393 issuable upon exercise of options, 9,469 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 unaudited 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 shares of common stock from the reserve for the Company's 2011 Incentive Award Plan, as amended, or the 2011 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 unaudited condensed consolidated balance sheet.

Recently Issued Accounting Standards:

In May 2014, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards are effective for interim and annual periods beginning on January 1, 2018, but could have been adopted early beginning January 1, 2017. The new standards are required to be adopted using either a full retrospective or a modified retrospective approach. The Company expects to adopt this standard beginning in 2017 if and when it begins to generate revenue. The Company continues to review the impact that this new standard will have on collaborations and license arrangements, as well as its consolidated financial statements. As the Compay completes its assessment, the Company is also identifying and preparing to implement changes to its accounting policies, business processes, and internal controls to support the new accounting and disclosure requirements.

In February 2016, the FASB issued Accounting Standards Update, or 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 their balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with current 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 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 consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting,* which was intended to simplify various aspects of accounting for share-based payment transactions. The new guidance requires immediate recognition of all excess tax benefits and deficiencies in the income statement; requires classification of excess tax benefits as an operating activity as opposed to a financing activity in the statements of cash flows; requires the classification of cash paid by an employer when directly withholding shares for tax-withholding purposes be classified as a financing activity on the statements of cash flows; and allows the Company to make an accounting policy election to either estimate the number of awards expected to vest or account for forfeitures when they occur. The standard is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual reporting periods. The Company applied this standard in the first quarter of 2017 using the prospective method of adoption. In conjunction with this adoption, the Company applied

an accounting policy election to estimate forfeitures and then true u p actual forfeitures as they occur. Because this treatment was in line with the Company's current treatment of forfeitures, the impact was insignificant as of the three months ended March 31, 2017. Additionally, the Company believes there is no effect on its consolidated financial statements from either the new guidance of immediate recognition of all excess tax benefits and deficiencies in the income statement or the requirement to classify excess tax benefits as an operating activity, as opposed to a fi nancing activity in the statements of cash flows, as the Company currently has a full valuation for any deferred tax asset, therefore, there would be no net effect on the Company's consolidated financial statements. Finally, the Company does not directly withhold shares for tax-withholding purposes, therefore, this change has no net effect on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows* (*Topic 230*) *: Classification of Certain Cash Receipts and Cash Payments* (*a consensus of the Emerging Issues Task Force*), which addresses the diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the impact of adopting ASU 2016-15 on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows* (*Topic 230*): *Restricted Cash* that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This amendment is effective for the Company in the fiscal year beginning December 15, 2017, but early adoption is permissible. The Company is currently evaluating the effect that the adoption of ASU 2016-18 will have on its consolidated financial statements.

In January 2017 , the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* . Public companies should apply these amendments to annual periods beginning after December 15, 2017, including interim periods within those periods. All other entities should apply the amendments to annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. The Company is currently evaluating the effect that the adoption of ASU 2017-01 will have on its consolidated financial statements.

Note 3—Prepaid Expenses and Other:

The Company, from time to time, makes payments to certain vendors for which the service relates to future periods. In these cases, the Company classifies these expenses as prepaid and other and amortizes those payments over the period for which the services relate. In some cases, the vendors require an upfront payment to be applied to the final invoices under the agreements. In those cases, if the contract extends beyond the period of one year, the prepayments are classified as long-term. Prepaid expenses and other consisted of the following (in thousands):

	March 31, 2017	December 31, 2016
Current:		
CRO services	$ 7,285	$ 3,471
Other clinical development	1,109	1,069
Insurance	865	1,159
Other	1,395	1,299
	10,654	6,998
Long-term:		
CRO services	1,152	5,077
Other clinical development	1,077	1,243
Insurance	28	40
Other	417	486
	2,674	6,846
Totals	$ 13,328	$ 13,844

Note 4—Property and Equipment:

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

Property and Equipment:	March 31, 2017	December 31, 2016
Leasehold improvements	$ 3,878	$ 3,878
Computer equipment	1,890	1,822
Telephone equipment	262	256
Furniture and fixtures	2,196	2,146
	8,226	8,102
Less: accumulated depreciation and amortization	(3,226)	(2,949)
Totals	$ 5,000	$ 5,153

Note 5—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	March 31, 2017	December 31, 2016
Accrued CRO services	$ 7,864	$ 6,609
Accrued other clinical development	6,225	7,015
Accrued legal fees	1,579	706
Accrued compensation	3,982	3,058
Other	110	38
Totals	$ 19,760	$ 17,426

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 Plan was adopted by the Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options, nonqualified stock options and restricted stock units, 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 and restricted stock units 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 March 31, 2017, 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 months ended March 31, 2017 and 2016 were as follows (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2017	2016
Stock-based compensation:		
Options -		
Research and development, or R&D	$ 20,356	$ 23,556
General and administrative, or G&A	6,189	5,882
Performance shares - R&D	—	72
Restricted stock units -		
R&D	2,124	—
G&A	1,095	—
Total stock-based compensation expense	$ 29,764	$ 29,510

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 three months ended March 31, 2017 and 2016:

	2017	2016
Dividend yield	0.0%	0.0%
Expected volatility	70.1%	66.1%
Risk-free interest rate	2.0%	1.6%
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, 2016	6,578,522	$ 87.52	8.0	$ 18,442
Granted	459,375	$ 36.46		
Forfeited	(60,498)	$ 66.73		
Exercised	(33,468)	$ 21.44		$ 481
Expired	(28,066)	$ 125.43		
Outstanding at March 31, 2017	6,915,865	$ 84.47	7.9	$ 26,584
Nonvested at March 31, 2017	3,136,492	$ 69.39	9.1	$ 2,329
Exercisable at March 31, 2017	3,779,373	$ 97.16	6.9	$ 24,255

At March 31, 2017, total estimated unrecognized employee compensation cost related to nonvested stock options and restricted stock units granted prior to that date were approximately $114.6 million and $23.9 million, respectively. These unrecognized expenses are expected to be recognized over a weighted-average period of 1.7 years for stock options and 2.3 years for restricted stock units. The weighted-average grant date fair value of options granted during the three months ended March 31, 2017 and 2016, were $22.86 per share and $36.28 per share, respectively.

Stock options	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2016	3,106,083	$ 47.78
Granted	459,375	22.86
Vested/Issued	(368,468)	72.27
Forfeited	(60,498)	39.80
Nonvested shares at March 31, 2017	3,136,492	41.50

Restricted stock units:

On October 14, 2016, restricted stock units were awarded to certain employees. These restricted stock units vest over three years in six equal installments on each six month anniversary of the vesting start date, July 19, 2016.

Restricted stock units	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2016	630,508	$ 54.35
Granted	—	—
Vested/Issued	(106,800)	54.35
Forfeited	(6,747)	54.35
Nonvested shares at March 31, 2017	516,961	$ 54.35

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 $0.2 million and $0.3 million for the three months ended March 31, 2017 and 2016, respectively.

Note 8—Commitments and Contingencies:

The Company is involved in various lawsuits, claims and other legal matters from time to time that arise in the ordinary course of conducting business. The Company records a liability when a particular contingency is probable and estimable. The Company has not accrued for any contingency at March 31, 2017, as the Company does not consider any contingency to be probable or estimable. The Company faces contingencies that are reasonably possible to occur; however, they cannot currently be estimated. While complete assurance cannot be given to the outcome of these proceedings, management does not currently believe that any of these matters, individually or in the aggregate, will have a material adverse effect on the Company's financial condition, liquidity or results of operations.

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, 2016.

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 a drug product. Developing drug products, however, is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety issues during the course of developing our drug candidates, we do not expect to receive approval of a product candidate until approximately the second half of 2017, though we cannot assure you that we will receive approval for any of our drug candidates this year or ever.

We recently completed a Phase III clinical trial of neratinib for the extended adjuvant treatment of patients 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 EMA, 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 three months ended March 31, 2017, from our accounting policies at December 31, 2016, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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 three months ended March 31, 2017 and 2016, 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 March 31, 2017 Compared to Three Months Ended March 31, 2016

General and administrative expenses:

For the three months ended March 31, 2017, G&A expenses were approximately $18.4 million, compared to approximately $11.0 million for the three months ended March 31, 2016. G&A expenses for the three months ended March 31, 2017 and 2016 were as follows:

General and administrative expenses (in thousands)	For the Three Months Ended March 31, 2017	2016	Period to period percentage change
Payroll and related costs	$ 2,687	$ 1,436	87.1%
Professional fees and expenses	6,183	2,312	167.4%
Facility and equipment costs	1,245	704	76.8%
Employee stock-based compensation expense	7,284	5,882	23.8%
Other	1,002	705	42.1%
	$ 18,401	$ 11,039	66.7%

For the three months ended March 31, 2017, G&A expenses increased approximately $7.3 million compared to the same period in 2016. Approximately $1.4 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 $5.9 million increase in G&A expense for the three months ended March 31, 2017, compared to the same period in 2016, was primarily attributable to:

- an approximately $1.3 million increase in payroll and related costs as administrative headcount increased from 19 to 33 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 hire a sales force and supporting staff in the second and third quarter 2017 to prepare for commercialization, pending a decision by the FDA on our NDA.

- an approximately $3.9 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, prepare for commercialization and as we support compliance measures related to the Sarbanes Oxley Act of 2002, as amended, or Sarbanes Oxley and various healthcare compliance measures.

- an approximately $0.5 million increase in facility and equipment costs due to higher leasing costs of the larger office spaces. 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; we expect that our facility and equipment costs will continue at the higher levels similar to the three months ended March 31, 2017.

Research and development expenses:

For the three months ended March 31, 2017, R&D expenses were approximately $54.8 million, compared to approximately $60.2 million for the three months ended March 31, 2016. R&D expenses for the three months ended March 31, 2017 and 2016 were as follows:

Research and development expenses (in thousands)	For the Three Months Ended March 31, 2017	2016	Period to period percentage change
Clinical trial expense	$ 18,640	$ 23,617	(21.1%)
Internal clinical development	6,869	6,746	1.8%
Internal regulatory affairs and quality assurance	2,521	2,697	(6.5%)
Consultants and contractors	3,714	3,065	21.2%
Internal chemical manufacturing	577	454	27.1%
Employee stock-based compensation	22,480	23,628	(4.9%)
	$ 54,801	$ 60,207	(9.0%)

For the three months ended March 31, 2017, R&D expenses decreased approximately $5.4 million compared to the same period in 2016. Stock-based compensation expense decreased approximately $1.1 million and reflects a decrease in R&D headcount, offset

by new grants to replacement employees and additional awards to existing employees for the three months ended March 31, 2017. The remaining decrease in R&D expenses was primarily attributable to:

- an approximately $5.0 million decrease in clinical trial expenses primarily attributable to a decrease in drug supply manufacturing and logistics of approximately $5.5 million as contracted manufacturing campaigns were completed during 2016 and not repeated during the three months ended March 31, 2017, offset by an increase in CRO professional and pass-through costs of approximately $0.4 million and an approximately $0.1 million decrease in clinical services both primarily attributable to our preparation for filing the NDA and MAA during the three months ended March 31, 2016, which were submitted in July 2016 and June 2016, respectively.
- internal clinical development, internal regulatory affairs and quality assurance, and internal chemical manufacturing expenses were unchanged, although there was a slight decrease in full-time R&D headcount to 141 from 144 for the three months ended March 31, 2017, compared to the same period in 2016.
- an approximately $0.6 million increase in consultants and contractors related expenses due to increased consulting in support of medical affairs, in support of our NDA with the FDA and MAA with the EMA and overall program management to support commercial launch.

We expect R&D expenses, excluding stock-based compensation, to continue to decrease slightly going forward for our existing clinical trials as we conclude the work performed by CRO and related clinical services; however, should we choose to begin additional clinical trials, R&D expenses may increase accordingly.

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 months ended March 31, 2017, we recognized approximately $0.4 million in interest income, compared to approximately $0.3 million for the same period in 2016. The increase in interest income is due to the additional cash, cash equivalents and marketable securities on hand for the three months ended March 2017 from the underwritten public offering in October 2016.

Other expenses:

During both the three months ended March 31, 2017 and 2016, other expenses, consisting primarily of foreign exchange loss, were approximately $0.1 million.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2017 and December 31, 2016, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	March 31, 2017	December 31, 2016
Cash and cash equivalents	$ 105,086	$ 194,494
Marketable securities	88,894	34,982
Working capital	160,904	199,013
Stockholders' equity	167,392	209,824

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Cash provided by (used in):		
Operating activities	$ (36,042)	$ (35,028)
Investing activities	(54,072)	81,456
Financing activities	706	222
(Decrease) increase in cash and cash equivalents	$ (89,408)	$ 46,650

Operating Activities:

For the three months ended March 31, 2017, we reported a net loss of approximately $72.9 million, compared to approximately $71.0 million for the same period in 2016. Additionally, cash used in operating activities for the three months ended March 31, 2017, was approximately $36.0 million, compared to approximately $35.0 million for the same period in 2016.

Cash used in operating activities for the three months ended March 31, 2017 consisted of a net loss of $72.9 million offset, by approximately $30.0 million of non-cash items such as depreciation and amortization and stock-based compensation; an increase of approximately $6.3 million in accrued expenses and accounts payable and an increase of approximately $0.5 million in prepaid expenses and other.

Cash used in operating activities for the three months ended March 31, 2016, consisted of a net loss of $71.0 million, offset by approximately $29.7 million of non-cash items such as depreciation and amortization and stock-based compensation, a decrease in the liability for deferred rent of approximately $0.1 million, an increase in prepaid expenses and other of approximately $0.1 and an increase in accrued expenses and accounts payable of approximately $6.5 million.

Investing Activities:

During the three months ended March 31, 2017, net cash used in investing activities was approximately $54.1 million compared to net cash provided by investing activities of approximately $81.5 million for the same period in 2016. The approximately $54.1 million of net cash used in investing activities during the three months ended March 31, 2017 was made up of approximately $25.8 million of sales or maturities of available-for-sale securities, offset by $79.7 million of cash invested in available-for-sale securities, and approximately $0.1 million used to purchase property and equipment. During the three months ended March 31, 2016, cash provided by investing activities was primarily made up of approximately $36.8 million used for the purchase of available-for-sale securities, offset by approximately $118.3 million cash provided by the sale or maturities of available-for-sale securities.

Financing Activities:

During the three months ended March 31, 2017, cash provided by financing activities consisted of approximately $0.7 million of net proceeds from the exercise of stock options. During the same period in 2016, cash provided by financing activities was approximately $0.2 million, also comprised of net proceeds from the exercise of stock options.

Current and Future Financing Needs:

We have incurred negative cash flows from operations since we started our business, and we do not expect to achieve any product revenues for at least the next 3 to 6 months, if ever. 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, our R&D efforts and the commencement of commercialization 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 $140 million to $150 million, excluding stock-based compensation.

Additionally, we expect increased G&A expenses as we continue to evaluate our options with regard to commercialization efforts.

We are currently exploring methods by which to commercialize our product candidates if approved by the FDA or EMA. These methods may require funding in addition to the cash and cash equivalents and marketable securities totaling approximately $194.0 million available at March 31, 2017. While our unaudited consolidated financial statements have been prepared on a going concern basis, we expect to continue incurring significant losses for the foreseeable future and will continue to remain dependent on our ability to obtain sufficient funding to sustain operations and successfully commercially launch neratinib if approved by the FDA or EMA. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time.

In addition, we have based our estimate of capital needs on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including changes in and progress of our development activities, the impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. 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 will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

Going Concern

Our former independent registered public accounting firm issued a report on our audited consolidated financial statements for the year ended December 31, 2016 that included an explanatory paragraph referring to our significant operating losses and expressing substantial doubt in our ability to continue as a going concern. Our unaudited condensed consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon our ability to generate profitable operations in the future and/ or to obtain the necessary financing to meet our obligations and repay our liabilities arising from normal business operations when they become due. The outcome of these matters cannot be predicted with any certainty at this time and raise substantial doubt that we will be able to continue as a going concern. Our consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

Non-GAAP Financial Measures:

In addition to our operating results, as calculated in accordance with generally accepted accounting principles, 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. For the three months ended March 31, 2017 and 2016, stock-based compensation represented approximately 40.8% and 41.6% of our net loss, respectively. Although net loss is important to measure our financial performance, we currently place an emphasis on cash burn and, more specifically, cash used in operations. Because stock-based compensation appears in the GAAP net loss but is removed from net loss to arrive at cash used in operations on the statement of cash flows due to its non-cash nature, 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. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

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)

	For the Three Months Ended March 31,		
	2017	2016	
GAAP net loss	$ (72,865)	$ (70,972)	
Adjustments:			
Stock-based compensation -			
General and administrative	7,284	5,882	(1)
Research and development	22,480	23,628	(2)
Non-GAAP adjusted net loss	$ (43,101)	$ (41,462)	
GAAP net loss per share ─ basic and diluted	$ (1.97)	$ (2.19)	
Adjustment to net loss (as detailed above)	0.81	0.91	
Non-GAAP adjusted net loss per share	$ (1.16)	$ (1.28)	(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 36,931,167 and 32,478,408 weighted average common shares outstanding for the three months ended March 31, 2017 and 2016, 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 March 31, 2017, 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 po ssible 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 March 31, 2017. 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 March 31, 2017.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended March 31, 2017, 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 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). 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. On September 30, 2016, the court denied our motion to dismiss. The court set a trial for November 6, 2018. We intend to vigorously defend this matter.

Eshelman vs. 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, we 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. On February 6, 2017, the court denied our motion to dismiss. On February 21, 2017, we filed an answer to Dr. Eshelman's complaint and brought counterclaims against Dr. Eshelman for defamatory statements regarding the Company made by him in connection with the proxy contest. The court has set a schedule for discovery to be conducted through September 2017. We intend to vigorously defend against Dr. Eshelman's claims and pursue our claims against him.

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 this matter.

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, 2016, which was filed with the SEC on March 1, 2017, 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 March 31, 2017.

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) promulgated under the Exchange Act made any purchases of our equity securities during the quarter ended March 31, 2017.

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 State 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	Second 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 May 8, 2017 and incorporated herein by reference)
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017
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

SIGNAT URES

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: May 10, 2017

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

Date: May 10, 2017

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

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alan H. Auerbach, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2017;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2017

/s/ Alan H. Auerbach
Alan H. Auerbach
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles R. Eyler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2017;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2017

/s/ Charles R. Eyler
Charles R. Eyler
Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2017, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Executive Officer

I, Alan H. Auerbach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2017, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: May 10, 2017

/s/ Alan H. Auerbach
Alan H. Auerbach
Principal Executive Officer

A signed original of this written statement required by Section 906 has been provided to Puma Biotechnology, Inc. and will be retained by Puma Biotechnology, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2017, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Financial Officer

I, Charles R. Eyler, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2017, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: May 10, 2017

/s/ Charles R. Eyler
Charles R. Eyler
Principal Financial and Accounting Officer

A signed original of this written statement required by Section 906 has been provided to Puma Biotechnology, Inc. and will be retained by Puma Biotechnology, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.