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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2015

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	77-0683487
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024

(Address of principal executive offices) (Zip code)

(424) 248-6500

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer	x	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 32,310,605 shares of Common Stock, par value $0.0001 per share, were outstanding as of August 3, 2015.

PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward looking. These forward-looking statements include, but are not limited to, statements about:

the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
the anticipated timing of regulatory filings;
the regulatory approval of our drug candidates;
our use of clinical research organizations and other contractors;
our ability to find collaborative partners for research, development and commercialization of potential products;
our ability to market any of our products;
our history of operating losses;
our expectations regarding our costs and expenses;
our anticipated capital requirements and estimates regarding our needs for additional financing;
our ability to compete against other companies and research institutions;
our ability to secure adequate protection for our intellectual property;
our intention to vigorously defend against a purported securities class action lawsuit;
our ability to attract and retain key personnel; and
our ability to obtain adequate financing.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these state involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report on Form 10-Q, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2014 and Part II, Item 1A. “Risk Factors” of this Quarterly Report on Form 10-Q that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

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

See Accompanying Notes to the Condensed Consolidated Financial Statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands except share and per share data)

(unaudited)

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

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

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

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(in thousands except share data)

(unaudited)

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

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

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

See Accompanying Notes to the Condensed Consolidated Financial Statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or Puma, is a biopharmaceutical company based in Los Angeles, California. References in these Notes to Condensed Consolidated Financial Statements to the "Company" refer to Puma Biotechnology, Inc., a private Delaware company formed on September 15, 2010, or Private Puma, for periods prior to the merger of Private Puma with Public Puma (as defined below), which took place on October 4, 2011, or the Merger, and Puma Biotechnology, Inc., a Delaware company formed on April 27, 2007, and formerly known as Innovative Acquisitions Corp., or Public Puma, for periods following the Merger. The Company is a biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use.

In November 2012, the Company established and incorporated Puma Biotechnology Ltd., a wholly owned subsidiary, for the sole purpose of serving as Puma's legal representative in the United Kingdom and the European Union in connection with Puma's clinical trial activity in those countries.

Basis of Presentation:

The Company is initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive, breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. The Company has reported a net loss of approximately $64.7 million and $117.1 million and negative cash flows from operations of approximately $34.4 million and $84.6 million for the three and six months ended June 30, 2015, respectively. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process.

The accompanying unaudited condensed consolidated interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, for interim financial information. Accordingly, the financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated interim financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the year ending December 31, 2015, or for any subsequent period. These unaudited condensed consolidated interim financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014. The condensed consolidated balance sheet at December 31, 2014, has been derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

The Company's continued operations will depend on its ability to raise funds through various potential sources, such as equity and debt financing. Through June 30, 2015, the Company's financing was primarily through public offerings of

Company common stock and private equity placements. The Company sold additional shares of its common stock through an underwritten public offering in January 2015 (see Note 6). As a result, the Company received net proceeds of approximately $205.1 million. Given the current and desired pace of clinical development of its product candidates, management believes that the cash and cash equivalents and marketable securities on hand at June 30, 2015, are sufficient to fund clinical development through 2016 and into 2017. The Company may need additional financing until it can achieve profitability, if ever. There can be no assurance that additional capital will be available on favorable terms or at all or that any additional capital that the Company is able to obtain will be sufficient to meet its needs. If it is unable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

Note 2—Significant Accounting Policies:

The significant accounting policies followed in the preparation of these condensed consolidated financial statements are as follows:

Use of Estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the balance sheet, and reported amounts of expenses for the period presented. Accordingly, actual results could differ from those estimates. Significant estimates include accrued expenses for the cost of services provided by consultants who manage clinical trials and conduct research and clinical trials on behalf of the Company that are billed on a delayed basis. As the actual costs become known, the Company adjusts its estimated cost in that period. The value of stock-based compensation includes estimates based on future events, which are difficult to predict. It is at least reasonably possible that a change in the estimates used to record accrued expenses and to value the stock-based compensation will occur in the near term.

Principles of Consolidation:

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

Cash and Cash Equivalents:

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

Licensor Receivable:

The Pfizer, Inc., or Licensor, receivable represents the remaining external “out of pocket” clinical trial costs in excess of an agreed upon “cap” for clinical trials that were ongoing at the time the licensing agreement with the Licensor was reached. In July 2014, the license agreement was amended to make the Company solely responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013, and to fix the future royalty rate that must be paid to the Licensor upon commercialization in the low to mid-teens. The balance of licensor receivable at December 31, 2014, of approximately $1.8 million, was fully collected during the three months ended June 30, 2015.

Investment Securities:

The Company classifies all investment securities (short term and long term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management’s strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders’ equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

Assets Measured at Fair Value on a Recurring Basis:

Accounting Standards Codification, or “ASC”, 820, Fair Value Measurement, or ASC 820, provides a single definition of fair value and a common framework for measuring fair value as well as new disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid by a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transaction costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

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

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

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

Following are the major categories of assets measured at fair value on a recurring basis as of June 30, 2015 and December 31, 2014, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

June 30, 2015	Level 1	Level 2	Level 3	Total
Cash equivalents	$54,839	$—	$ —	$54,839
Agency bond	—	5,008	—	5,008
Commercial paper	—			