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PUMA BIOTECHNOLOGY, INC. Form 10-Q November 09, 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 September 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 (I.R.S. Employer

incorporation or organization) Identification Number) 10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024

(Address of principal executive offices) (Zip code)

(424) 248-6500

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(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 $\ddot{}$.

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. 32,435,748 shares of Common Stock, par value \$0.0001 per share, were outstanding as of November 2, 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 our Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 and 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)

	•	December 31,
	2015	2014 (Note
	(unaudited)	1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,598	\$ 38,539
Marketable securities	224,177	102,788
Prepaid expenses and other, current	6,888	6,292
Licensor receivable		1,760
Total current assets	254,663	149,379
Property and equipment, net	2,532	2,157
Prepaid expenses and other, long-term	10,117	10,007
Restricted cash	4,312	1,215
Total assets	\$ 271,624	\$ 162,758
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 9,783	\$ 14,997
Accrued expenses	15,548	29,444
Total current liabilities	25,331	44,441
Deferred rent	1,452	1,269
Total liabilities	26,783	45,710
Stockholders' equity:		