



Published on *Puma Biotechnology Investor Center* (<https://investor.pumabiotechnology.com>) on 8/10/15 1:07 pm PDT

Puma Biotechnology Reports Second Quarter 2015 Financial Results

Release Date:

Monday, August 10, 2015 1:07 pm PDT

Terms:

Dateline City:

LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced financial results for the second quarter ended June 30, 2015.

Unless otherwise stated, all comparisons are for the second quarter and first half of the year 2015 compared to the second quarter and first half of the year 2014.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$64.7 million, or \$2.01 per share, for the second quarter of 2015, compared to a net loss of \$38.8 million, or \$1.29 per share, for the second quarter of 2014. Net loss applicable to common stock for the first half of 2015 was \$117.1 million, or \$3.68 per share, compared to \$58.6 million, or \$1.96 per share, for the first half of 2014.

Adjusted net loss applicable to common stock was \$36.5 million, or \$1.13 per share, for the second quarter of 2015, compared to adjusted net loss applicable to common stock of \$31.6 million, or \$1.05 per share, for the second quarter of 2014. Adjusted net loss applicable to common stock for the first half of 2015 was \$68.8 million, or \$2.16 per share, compared to \$46.3 million, or \$1.55 per share, for the first half of 2014. Adjusted net loss applicable to common stock excludes stock-based compensation expense, which represents a significant portion of overall expense and has no impact on the cash position of the Company. For a reconciliation of adjusted net loss applicable to common stock to reported net loss applicable to common stock, please see the financial tables at the end of this news release.

Net cash used in operating activities for the second quarter of 2015 was \$34.6 million. Net cash used in operating activities for the first half of 2015 was \$84.6 million. At June 30, 2015, Puma had cash and cash equivalents of \$59.8 million and marketable securities of \$222.5 million, compared to cash and cash equivalents of \$38.5 million and marketable securities of \$102.8 million at December 31, 2014. Puma's current level of cash and cash equivalents and marketable securities includes net proceeds of approximately \$205.0 million from a public offering of the Company's common stock, which was completed in January 2015.

"During the second quarter of 2015 we presented data from the Phase III ExteNET trial at the American Society of Clinical Oncology (ASCO) Annual Meeting," said Alan H. Auerbach, chairman and chief executive officer of Puma. "The positive study demonstrated that treatment with neratinib as extended adjuvant treatment following adjuvant treatment with trastuzumab in women with early-stage HER2 positive breast cancer reduced the risk of disease recurrence by 33%. The two-year disease-free survival rate was 93.9% in the neratinib arm versus 91.6% in the placebo arm. We anticipate our NDA filing for neratinib for the extended adjuvant setting during the first quarter of 2016. Also in the second quarter of 2015, we expanded the second cohort in the Phase II basket trial, which is evaluating the safety and efficacy of neratinib in patients with solid tumors who have an activating HER2 mutation. The second cohort includes patients with metastatic non-small cell lung cancer and whose tumors have a HER2 mutation.

"We expect to continue to execute on our ongoing Phase II and Phase III trials of PB272 in the second half of 2015 and beyond. In addition, during the second half of 2015, we expect to (i) publish Phase III ExteNET trial results in the extended adjuvant treatment of early stage HER2-positive breast cancer (anticipated in the third quarter of 2015); (ii) perform additional presentations of the ExteNET Phase III trial (anticipated in the third and fourth quarters of 2015); (iii) complete our ongoing Phase II FB-7 trial of PB272 as a neoadjuvant treatment for patients with HER2-positive breast cancer (anticipated in the third quarter of 2015); (iv) report data from our Phase II trial of PB272 in HER2 non-amplified breast cancer that has a HER2 mutation (anticipated in the fourth quarter of 2015); (v) report initial data from the Phase II trial of neratinib in extended adjuvant HER2 positive early stage breast cancer using loperamide prophylaxis (anticipated in the fourth quarter of 2015); (vi) complete the ongoing Phase II trial of PB272 in patients with HER2-positive metastatic breast cancer that has metastasized to the brain (anticipated in the second half of 2015); and (vii) expand additional cohorts in our Phase II basket trial of PB272 in patients with solid tumors with activating HER2 mutations (anticipated in the second half of 2015)."

Operating Expenses

Based on GAAP, operating expenses were \$64.9 million for the second quarter of 2015, compared to \$38.9 million for the second quarter of 2014. Operating expenses for the first half of 2015 were \$117.5 million compared to \$58.7 million for the first half of 2014.

General and Administrative Expenses:

Based on GAAP, general and administrative expenses were \$5.5 million in the second quarter of 2015, compared to \$3.9 million in the second quarter of 2014. General and administrative expenses for the first half of 2015 were \$13.4 million

compared to \$7.4 million for the first half of 2014.

Research and Development Expenses:

Based on GAAP, research and development expenses were \$59.4 million in the second quarter of 2015, compared to \$35.0 million in the second quarter of 2014. Research and development expenses for the first half of 2015 were \$104.1 million, compared to \$51.3 million for the first half of 2014.

About Puma Biotechnology

Puma Biotechnology, Inc. is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. 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. The Company is initially focused on the development of PB272 (oral neratinib), a potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2-positive breast cancer and patients with non-small cell lung cancer, breast cancer and other solid tumors that have a HER2 mutation.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding anticipated timing for regulatory filings and for the commencement and completion of various clinical trials and the announcement of data relative to these trials. All forward-looking statements included in this press release involve risks and uncertainties that could cause the Company's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the fact that the Company has no product revenue and no products approved for marketing; the Company's dependence on PB272, which is still under development and may never receive regulatory approval; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support the Company's drug candidate claims; even if approved, the risk that physicians and patients may not accept or use the Company's products; the Company's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates; the Company's dependence on licensed intellectual property; and the other risk factors disclosed in the periodic reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Annual Report on Form 10-K for the year ended December 31, 2014. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

PUMA BIOTECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30, (Unaudited)		June 30, (Unaudited)	
	2015	2014	2015	2014
Operating expenses:				
General and administrative	\$ 5.5	\$ 3.9	\$ 13.4	\$ 7.4
Research and development	59.4	35.0	104.1	51.3
Totals	<u>64.9</u>	<u>38.9</u>	<u>117.5</u>	<u>58.7</u>
Loss from operations	<u>(64.9)</u>	<u>(38.9)</u>	<u>(117.5)</u>	<u>(58.7)</u>
Other income (expenses):				
Interest income	0.2	0.1	0.3	0.1
Other income (expense)	-	-	0.1	-
Totals	<u>0.2</u>	<u>0.1</u>	<u>0.4</u>	<u>0.1</u>
Net loss	<u>\$ (64.7)</u>	<u>\$ (38.8)</u>	<u>\$ (117.1)</u>	<u>\$ (58.6)</u>
Net loss per common share—basic and diluted	<u>\$ (2.01)</u>	<u>\$ (1.29)</u>	<u>\$ (3.68)</u>	<u>\$ (1.96)</u>
Weighted-average common shares outstanding—basic and diluted	<u>32,158,108</u>	<u>30,117,819</u>	<u>31,874,346</u>	<u>29,843,966</u>

PUMA BIOTECHNOLOGY, INC.
LIQUIDITY AND CAPITAL RESOURCES
(in millions)

	June 30, 2015	December 31, 2014
	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Cash and cash equivalents	\$ 59.8	\$ 38.5
Marketable securities	222.5	102.8
Licensor receivable	-	1.8
Working capital	261.7	104.9
Stockholders' equity	274.8	117.0
Cash provided by (used in):		
Operating activities	\$ (84.6)	\$ (34.4)
Investing activities	(120.8)	(82.7)
Financing activities	226.7	129.4
Increase (decrease) in cash	<u>\$ 21.3</u>	<u>\$ 12.3</u>

Non-GAAP Financial Measures:

In addition to our operating results, as calculated in accordance with GAAP, we use certain non GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net loss and net loss per share, as calculated in accordance with GAAP, as adjusted to remove the impact of employee stock-based compensation. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures. We believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods.

PUMA BIOTECHNOLOGY, INC.

**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 millions except share and per share data)

(Unaudited)

	Three Months Ended June 30,	
	2015	2014
GAAP net loss	\$ (64.7)	\$ (38.8)
Adjustments:		
Stock-based compensation -		
General and administrative	2.7	1.4 (1)
Research and development	25.5	5.8 (2)
Non-GAAP adjusted net loss	<u>\$ (36.5)</u>	<u>\$ (31.6)</u>

GAAP net loss per share - basic and diluted	\$ (2.01)	\$ (1.29)	
Adjustment to net loss (as detailed above)	0.88	0.24	
Non-GAAP adjusted net loss per share	\$ (1.13)	\$ (1.05)	(3)

Six Months Ended June 30,

	2015	2014	
GAAP net loss	\$ (117.1)	\$ (58.6)	
Adjustments:			
Stock-based compensation -			
General and administrative	7.4	2.7	(1)
Research and development	40.9	9.6	(2)
Non-GAAP adjusted net loss	\$ (68.8)	\$ (46.3)	
GAAP net loss per share - basic and diluted	\$ (3.68)	\$ (1.96)	
Adjustment to net loss (as detailed above)	1.52	0.41	
Non-GAAP adjusted net loss per share	\$ (2.16)	\$ (1.55)	(4)

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

Language:

English

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Ticker Slug:

Ticker: PBYI
Exchange: NYSE
ISIN:
 US74587V1070

Source URL: <https://investor.pumabiotechnology.com/press-release/puma-biotechnology-reports-second-quarter-2015-financial-results>