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Puma Biotechnology Reports First Quarter 2015 Financial Results

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced financial results for the first quarter ended March 31, 2015.

Unless otherwise stated, all comparisons are for the first quarter 2015 compared to the first quarter 2014.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$52.5 million, or \$1.66 per share, for the first quarter of 2015, compared to a net loss of \$19.8 million, or \$0.67 per share, for the first quarter of 2014.

Adjusted net loss applicable to common stock was \$32.4 million, or \$1.02 per share, for the first quarter of 2015, compared to adjusted net loss applicable to common stock of \$14.7 million, or \$0.50 per share, for the first quarter 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 first quarter of 2015 was \$50.0 million. At March 31, 2015, Puma had cash and cash equivalents of \$155.5 million and marketable securities of \$154.9 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.

"We have continued to make significant progress with the neratinib clinical program thus far in 2015," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "In addition to continuing all of our ongoing neratinib clinical trials, we also initiated a new Phase II trial of PB272 in early-stage HER2-positive breast cancer patients who have received adjuvant treatment with trastuzumab (a population similar to the Phase III ExteNET trial), where patients will receive primary prophylaxis with high dose loperamide in order to attempt to reduce the neratinib-related diarrhea. We anticipate having initial results from this trial in late 2015, which will allow us to include this data in our NDA filing for neratinib in the extended adjuvant setting that is currently anticipated for the first quarter of 2016. In April 2015, we also expanded the second cohort from our Phase II clinical trial of PB272 in patients with solid tumors who have an activating HER2 mutation (basket trial), where the expanded cohort will include patients with HER2 mutated metastatic non-small cell lung cancer.

"We expect the pace to continue through 2015 and beyond. In 2015, we expect to (i) present and publish Phase III ExteNET trial results in the extended adjuvant treatment of early stage HER2-positive breast cancer (anticipated mid 2015); (ii) present and publish Phase II results from our NEFERTT trial of PB272 as a first-line treatment for HER2-positive metastatic breast cancer (anticipated in mid-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 first half 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 second half of 2015); (v) initiate a Phase III trial of the combination of PB272 plus tamsirolium in fourth-line HER2-positive metastatic breast cancer (anticipated in the second half 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 \$52.6 million for the first quarter of 2015, compared to \$19.8 million for the first quarter of 2014.

General and Administrative Expenses:

Based on GAAP, general and administrative expenses were \$7.9 million for the first quarter of 2015, compared to \$3.5 million for the first quarter of 2014.

Research and Development Expenses:

Based on GAAP, research and development expenses were \$44.7 million for the first quarter of 2015, compared to \$16.3 million for the first quarter 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 | |
|--|--------------------|------------|
| | March 31, | |
| | (Unaudited) | |
| | 2015 | 2014 |
| Operating expenses: | | |
| General and administrative | \$ 7.9 | \$ 3.5 |
| Research and development | 44.7 | 16.3 |
| Totals | 52.6 | 19.8 |
| Loss from operations | (52.6) | (19.8) |
| Other income (expenses): | | |
| Interest income | 0.1 | 0.0 |
| Other income (expense) | 0.0 | (0.0) |
| Totals | 0.1 | 0.0 |
| Net loss | \$ (52.5) | \$ (19.8) |
| Net loss per common share—basic and diluted | \$ (1.66) | \$ (0.67) |
| Weighted-average common shares outstanding—basic and diluted | 31,588,315 | 29,567,071 |

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

| | March 31, 2015 | December 31, 2014 |
|-----------------------------|--|--|
| Cash and cash equivalents | \$ 155.5 | \$ 38.5 |
| Marketable securities | 154.9 | 102.8 |
| Licensor receivable | 1.8 | 1.8 |
| Working capital | 290.6 | 104.9 |
| Stockholders' equity | 304.3 | 117.0 |
| | Three Months Ended March 31, 2015 | Three Months Ended March 31, 2014 |
| Cash provided by (used in): | | |
| Operating activities | \$ (50.0) | \$ (17.0) |
| Investing activities | (52.7) | 7.9 |
| Financing activities | 219.6 | 129.4 |
| Increase (decrease) in cash | <u>\$ 116.9</u> | <u>\$ 120.3</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 March 31, | |
|---|------------------------------|----------------------|
| | 2015 | 2014 |
| GAAP net loss | \$ (52.5) | \$ (19.8) |
| Adjustments: | | |
| Stock-based compensation - | | |
| General and administrative | 4.7 | 1.3 (1) |
| Research and development | 15.4 | 3.8 (2) |
| Non-GAAP adjusted net loss | <u>\$ (32.4)</u> | <u>\$ (14.7)</u> |
| GAAP net loss per share - basic and diluted | \$ (1.66) | \$ (0.67) |
| Adjustment to net loss (as detailed above) | 0.64 | 0.17 |
| Non-GAAP adjusted net loss per share | <u>\$ (1.02)</u> | <u>\$ (0.50) (3)</u> |

(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 31,588,315 and 29,567,071 weighted average common shares outstanding for the three months ended March 31, 2015 and 2014, respectively.

Language:

English

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