



## News Release

### **Puma Biotechnology Reports First Quarter 2013 Financial Results**

**LOS ANGELES, Calif., May 9, 2013** – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, reported financial results for the first quarter ended March 31, 2013.

Unless otherwise stated, all comparisons are for the first quarter of 2013 compared to the first quarter of 2012.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$11.8 million, or \$0.41 per share, for the first quarter of 2013, compared to a loss of \$11.9 million, or \$0.59 per share, for the first quarter of 2012.

Adjusted net loss applicable to common stock was \$10.3 million, or \$0.36 per share, for the first quarter of 2013, compared to a net loss of \$3.4 million, or \$0.17 per share, for the first quarter of 2012. The adjusted net loss applicable to common stock and adjusted operating expenses exclude stock-based compensation expense and costs associated with ongoing clinical trials of our lead product candidate, PB272 (neratinib (oral)), that we assumed from the licensor and which we refer to as licensor legacy clinical trials.

Net cash used in operating activities was \$18.5 million during the first quarter of 2013. As of March 31, 2013, Puma reported cash, cash equivalents and marketable securities of \$118.7 million, compared to \$137.4 million at December 31, 2012. Puma's license agreement for PB272 established a limit on the Company's expenses related to the licensor legacy clinical trials. Puma reached this limit, or cap, during the fourth quarter of 2012; therefore, the licensor is responsible for expenses related to the legacy clinical trials until such trials are completed. The license agreement allows the Company to bill the licensor for all external "out of pocket" costs in excess of the cap cost on a quarterly basis. During the first quarter of 2013, Puma billed the licensor for external costs in excess of the cap, and we anticipate receiving payments of approximately \$9.7 million for these outstanding invoices by the end of the second quarter of 2013.

"During the first quarter of 2013, we achieved an important milestone in the global development of PB272 by obtaining agreement with the U.S. Food and Drug Administration under a Special Protocol Assessment for the planned Phase III clinical trial of PB272 in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments," said Alan H. Auerbach, Chairman, Chief Executive Officer and President. "We anticipate initiating this Phase III clinical trial in the second quarter of 2013.

"In addition," noted Mr. Auerbach, "we expect to (i) complete the on-going Phase II trial of PB272 in combination with temsirolimus in fourth line HER2-positive metastatic breast cancer, which we anticipate reporting additional data from later in 2013; (ii) initiate the Phase III trial of the combination of PB272 plus temsirolimus later in 2013; (iii) complete the ongoing Phase II trial of PB272 in patients with HER2-positive metastatic breast cancer that has metastasized to the brain, which we anticipate reporting data from later in 2013; (iv) complete our two ongoing Phase II trials of PB272 as a neoadjuvant treatment for patients with HER2-positive breast cancer, which we expect to report data from in mid-2013 and late 2013, respectively; (v) report data from our Phase II trial of PB272 in patients with HER2 mutated non-small cell lung cancer later in 2013; (vi) continue our Phase II trial of PB272 in HER2-negative breast cancer patients who have a HER2 mutation, which we also have the potential to report initial data from later in 2013."

## **Operating Expenses**

Based on GAAP, operating expenses were \$11.8 million for the first quarter of 2013, compared to \$11.9 million for the first quarter of 2012.

Adjusted operating expenses were \$10.3 million for the first quarter of 2013, compared to \$3.4 million in the first quarter of 2012. Adjusted operating expenses in the first quarter of 2013 exclude stock-based compensation expense of \$1.2 million, of which \$0.5 million was included in general and administrative expenses and \$0.7 million was included in research and development expenses. Licensor legacy clinical trial expenses of \$0.3 million and \$8.4 million for the first quarters of 2013 and 2012, respectively, are also excluded from adjusted operating expenses. Due to Puma reaching the licensor legacy clinical trial cost cap during the fourth quarter of 2012, Puma billed the licensor for all external licensor legacy clinical trials expenses incurred in the first quarter of 2013.

### **General and Administrative Expenses:**

Based on GAAP, general and administrative expenses were \$2.3 million in the first quarter of 2013, compared to \$1.3 million in the first quarter of 2012. Adjusted general and administrative expenses were \$1.8 million for the first quarter of 2013, compared to \$1.4 million in the first quarter of 2012. The increase from the first quarter of 2012 reflects higher professional fees for services such as legal, audit and consulting of approximately \$0.2 million, an increase in payroll and related costs of approximately \$0.1 million, and an increase in facility and equipment costs of approximately \$0.1 million.

### **Research and Development Expenses:**

Based on GAAP, research and development expenses were \$9.5 million in the first quarter of 2013, compared to \$10.6 million in the first quarter of 2012. Adjusted research and development expenses were \$8.5 million in the first quarter of 2013, compared to \$2.0 million in the first quarter of 2012. The increase in adjusted research and development expenses from the first quarter of 2012 was driven primarily by clinical development expenses for Puma-initiated Phase II and Phase III clinical trials of PB272, the hiring of staff and the building out of the Company's corporate infrastructure since the first quarter of 2012.

Excluding the impact of costs associated with legacy clinical trials, clinical development expenses in the first quarter of 2013 included increases in outside clinical research organization and licensor services of \$3.3 million, which are due to Puma reaching the licensor legacy clinical trial cost cap, and increases in other outside clinical development expenses of \$2.1 million. In addition, internal regulatory and internal clinical development expenses increased \$0.4 million and \$0.7 million, respectively, from the first quarter of 2012.

## **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, a potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2-positive metastatic breast cancer and non-small cell lung cancer.

Further information about Puma Biotechnology can be found at [www.pumabiotechnology.com](http://www.pumabiotechnology.com).

## **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding anticipated timing 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. 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.

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***(Financial Tables Follow)***

**PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
**(in millions except per share data)**

|  | Three Months Ended |                   | Period from      |
|--|--------------------|-------------------|------------------|
|  | March 31,          | March 31,         | September 15,    |
|  | 2013               | 2012              | 2010 (date       |
|  |                    |                   | of inception) to |
|  |                    |                   | March 31, 2013   |
| Operating expenses:  |                    |                   |                  |
| General and administrative   | \$ 2.3             | \$ 1.3            | \$ 36.4          |
| Research and development   | 9.5                | 10.6              | 60.0             |
| Totals   | <u>11.8</u>        | <u>11.9</u>       | <u>96.4</u>      |
| Loss from operations   | <u>(11.8)</u>      | <u>(11.9)</u>     | <u>(96.4)</u>    |
| Other income (expenses):   |                    |                   |                  |
| Interest income  | -                  | -                 | 0.1              |
| Other income (expense)   | -                  | -                 | (0.1)            |
| Totals   | <u>-</u>           | <u>-</u>          | <u>-</u>         |
| Net loss   | <u>\$ (11.8)</u>   | <u>\$ (11.9)</u>  | <u>\$ (96.4)</u> |
| Net loss per common<br>share—basic and diluted                     | <u>\$ (0.41)</u>   | <u>\$ (0.59)</u>  |                  |
| Weighted-average common<br>shares outstanding—basic<br>and diluted | <u>28,676,666</u>  | <u>20,040,000</u> |                  |

**PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY**  
**(A DEVELOPMENT STAGE COMPANY)**  
**LIQUIDITY AND CAPITAL RESOURCES**  
**(in millions except per share data)**

|                             | March 31,                          | December 31,                       |
|-----------------------------|------------------------------------|------------------------------------|
|                             | 2013                               | 2012                               |
| Cash and cash equivalents   | \$ 91.6                            | \$ 137.4                           |
| Marketable securities       | 27.1                               | -                                  |
| Working capital             | 116.6                              | 127.3                              |
| Stockholders' equity        | 118.3                              | 128.9                              |
|                             | Three months<br>ended<br>March 31, | Three months<br>ended<br>March 31, |
|                             | 2013                               | 2012                               |
| Cash provided by (used in): |                                    |                                    |
| Operating activities        | \$ (18.5)                          | \$ (2.8)                           |
| Investing activities        | (27.3)                             | (0.4)                              |
| Financing activities        | <u>-</u>                           | <u>-</u>                           |
| Increase (decrease) in cash | <u>\$ (45.8)</u>                   | <u>\$ (3.2)</u>                    |

**Reconciliation of GAAP and Non-GAAP Financial Information**

**(in millions except share and per share data)**

|  | GAAP               |                     |                 | Non-GAAP           |
|--|--------------------|---------------------|-----------------|--------------------|
|  | Measure            | Expense Adjustments |                 | Measure            |
|  | (Reported)         |                     |                 | (Adjusted)         |
|  | Three Months Ended | Stock-based         | Licensor legacy | Three Months Ended |
|  | March 31, 2013     | compensation        | clinical trials | March 31, 2013     |
| <i>2013 Operating expense:</i>                                 |                    |                     |                 |                    |
| General and administrative                                     | \$ 2.3             | \$ (0.5)            | \$ -            | \$ 1.8             |
| Research and development                                       | 9.5                | (0.7)               | (0.3)           | 8.5                |
| Loss from operations   | (11.8)             | 1.2                 | 0.3             | (10.3)             |
| Other income (expense):  |                    |                     |                 |                    |
| Interest income  | -                  | -                   | -               | -                  |
| Other expense  | -                  | -                   | -               | -                  |
| Totals   | -                  | -                   | -               | -                  |
| Net loss   | \$ (11.8)          | \$ 1.2              | \$ 0.3          | \$ (10.3)          |
| Net loss applicable to common stock                            | \$ (11.8)          | \$ 1.2              | \$ 0.3          | \$ (10.3)          |
| Net loss per common share - basic and diluted                  | \$ (0.41)          | \$ 0.04             | \$ 0.01         | \$ (0.36)          |
| Weighted-average common shares outstanding - basic and diluted | 28,676,666         | 28,676,666          | 28,676,666      | 28,676,666         |
| <i>2012 Operating expense:</i>                                 |                    |                     |                 |                    |
| General and administrative                                     | \$ 1.3             | \$ 0.1              | \$ -            | \$ 1.4             |
| Research and development                                       | 10.6               | (0.2)               | (8.4)           | 2.0                |
| Loss from operations   | (11.9)             | 0.1                 | 8.4             | (3.4)              |
| Other income (expense):  |                    |                     |                 |                    |
| Interest income  | -                  | -                   | -               | -                  |
| Other expense  | -                  | -                   | -               | -                  |
| Totals   | -                  | -                   | -               | -                  |
| Net loss   | \$ (11.9)          | \$ 0.1              | \$ 8.4          | \$ (3.4)           |
| Net loss applicable to common stock                            | \$ (11.9)          | \$ 0.1              | \$ 8.4          | \$ (3.4)           |
| Net loss per common share - basic and diluted                  | \$ (0.59)          | \$ 0.00             | \$ 0.42         | \$ (0.17)          |
| Weighted-average common shares outstanding - basic and diluted | 20,040,000         | 20,040,000          | 20,040,000      | 20,040,000         |