# Puma Biotechnology Reports Third Quarter 2020 Financial Results

November 5, 2020

LOS ANGELES--(BUSINESS WIRE)-- Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2020. Unless otherwise stated, all comparisons are for the third quarter of 2020 compared to the third quarter of 2019.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Net NERLYNX revenue in the third quarter of 2020 was $49.3 million, compared to $53.5 million in the third quarter of 2019. Net NERLYNX revenue in the first nine months of 2020 was $146.7 million, compared to $152.9 million in the first nine months of 2019.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $31.5 million, or $0.79 per share, for the third quarter of 2020, compared to a net loss of $16.9 million, or $0.44 per share, for the third quarter of 2019. Net loss for the first nine months of 2020 was $45.0 million, or $1.14 per share, compared to a net loss of $64.4 million, or $1.67 per share, for the first nine months of 2019.

Non-GAAP adjusted net loss was $23.9 million, or $0.60 per share, for the third quarter of 2020, compared to non-GAAP adjusted net loss of $4.7 million, or $0.12 per share, for the third quarter of 2019. Non-GAAP adjusted net loss for the first nine months of 2020 was $17.9 million, or $0.45 per share, compared to non-GAAP adjusted net loss of $18.6 million, or $0.48 per share, for the first nine months of 2019. Non-GAAP adjusted net loss excludes stock-based compensation expense. For reconciliations of GAAP net loss to non-GAAP adjusted net loss and GAAP net loss per share to non-GAAP adjusted net loss per share, please see the financial tables at the end of this news release.

Net cash provided by operating activities for the third quarter of 2020 was $1.7 million, compared to net cash used in operating activities of $7.3 million in the third quarter of 2019. Net cash provided by operating activities for the first nine months of 2020 was $6.4 million, compared to net cash provided by operating activities of $20.8 million in the first nine months of 2019. At September 30, 2020, Puma had cash, cash equivalents and marketable securities of $109.0 million, compared to cash, cash equivalents and marketable securities of $111.6 million at December 31, 2019.

"During the third quarter Puma continued to be negatively impacted by the challenges presented by COVID-19. Given these challenges, we were pleased that we were able to achieve revenues that were within the previously stated third quarter guidance range of net NERLYNX revenues," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "Although we anticipate that COVID-19 may continue to impact our revenues going forward, we remain focused on and committed to providing support to patients battling breast cancer. Our team has continued to work remotely and continues to respond to any COVID-related challenges, and we are pleased with the accomplishments made by the team during this pandemic. During the third quarter, we announced the publication of updated interim results of the Phase II CONTROL trial in *Annals of Oncology* as well as the publication of overall survival results from the Phase III ExteNET Trial in patients with HER2-positive, hormone receptor-positive, early stage breast cancer in *Clinical Breast Cancer*, which we believe further reinforces the benefits of neratinib."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) reporting Phase II data from the SUMMIT trial of neratinib in hormone receptor positive breast cancer patients with HER2 mutations in the fourth quarter of 2020; (ii) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2020; (iii) reporting Phase II data from the SUMMIT trial of neratinib in bile duct cancer patients with HER2 mutations in the first quarter of 2021; (iv) reporting Phase II data from the SUMMIT trial of neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations in the first half of 2021; (v) conducting a pre-NDA meeting with the FDA to discuss accelerated approval of neratinib in HER2 mutated hormone receptor positive breast cancer and HER2 mutated cervical cancer in the first half of 2021; (vi) reporting data from the Phase II TBCRC-022 trial of the combination of Kadcyla plus neratinib in patients with HER2-positive breast cancer with brain metastases who have previously been treated with Kadcyla in the first half of 2021; (vii) conducting a meeting with the FDA to discuss the potential for an accelerated approval pathway for neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations who have been previously treated with an EGFR tyrosine kinase inhibitor in 2021; and (viii) receiving regulatory decisions for an extended adjuvant HER2-positive early stage breast cancer indication in additional countries in 2021."

**Revenue**

Total revenue consists of product revenue, net from sales of NERLYNX, Puma's first commercial product, license revenue and royalty revenue. For the third quarter of 2020, total revenue was $50.8 million, of which $49.3 million was net product revenue and $1.5 million was royalty revenue from Puma's sub-licensees. This compares to total revenue of $56.4 million in the third quarter of 2019, of which $53.5 million was net NERLYNX revenue, $2.8 million was license revenue, and $0.1 million was royalty revenue from Puma's sub-licensees. For the first nine months of 2020, total revenue was $172.6 million, of which $146.7 million was net product revenue, $22.7 million was license revenue, and $3.2 million was royalty revenue from Puma's sub-licensees. This

compares to total revenue of $209.3 million for the first nine months of 2019, of which $152.9 million was net product revenue, $56.2 million was license revenue, and $0.2 million was royalty revenue from Puma's sub-licensees.

**Operating Costs and Expenses**

Total operating costs and expenses were $62.9 million for the third quarter of 2020, compared to $70.8 million for the third quarter of 2019. Operating costs and expenses in the first nine months of 2020 were $191.8 million, compared to $239.7 million in the first nine months of 2019.

*Cost of Sales*

Cost of sales was $10.0 million for the third quarter of 2020 and $28.4 million for the first nine months of 2020, compared to $9.4 million for the third quarter of 2019 and $26.7 million for the first nine months of 2019.

*Selling, General and Administrative Expenses*

Selling, general and administrative (SG&A) expenses were $29.6 million for the third quarter of 2020, compared to $31.4 million for the third quarter of 2019. SG&A expenses for the first nine months of 2020 were $89.9 million, compared to $110.4 million for the first nine months of 2019. The $20.5 million year-over-year decrease resulted primarily from decreases in stock-based compensation expense of approximately $9.4 million, professional fees and expenses of approximately $7.0 million and travel and meetings expense of approximately $4.4 million.

*Research and Development Expenses*

Research and development (R&D) expenses were $23.3 million for the third quarter of 2020, compared to $30.0 million for the third quarter of 2019. R&D expenses for the first nine months of 2020 were $73.5 million, compared to $102.6 million for the first nine months of 2019. The $29.1 million year-over-year decrease resulted primarily from decreases in clinical trial expense of approximately $16.5 million, stock-based compensation expense of approximately $9.3 million and consultant and contractor expenses of approximately $3.4 million.

**Total Other Income (Expenses)**

Total other expenses were $19.4 million for the third quarter of 2020 and $25.8 million for the first nine months of 2020, compared to total other expenses of $2.5 million for the third quarter of 2019 and $34.0 million for the first nine months of 2019. The $16.9 million increase in total other expenses for the three months ended September 30, 2020, compared to the three months ended September 30, 2019, was largely attributable to a legal verdict expense of $15.9 million. During the third and fourth quarters of 2020, we obtained additional data, previously unavailable, from the claims report relating to our class action lawsuit, which asserted damages in the amount of $50.5 million. While we intend to challenge some of these claims, we have increased our estimate of the legal accrual to $24.8 million. This resulted in the additional $15.7 million legal expense during the third quarter of 2020. The $8.2 million year-over-year decrease in total other expenses resulted primarily from decreases in interest expense of approximately $1.4 million, legal verdict expense of approximately $0.4 million and debt extinguishment loss of approximately $8.1 million and an increase in other income of approximately $0.2 million, partially offset by a decrease in interest income of approximately $1.9 million.

**Conference Call**

Puma Biotechnology will host a conference call to report its third quarter 2020 financial results and provide an update on the Company's business and outlook at 1:30 p.m. PST/4:30 p.m. EST on Thursday, Nov. 5, 2020. The call may be accessed by dialing 1-877-709-8150 (domestic) or 1-201-689-8354 (international). Please dial in at least 10 minutes in advance and inform the operator that you would like to join the "Puma Biotechnology Conference Call." A live webcast of the conference call and presentation slides may be accessed on the Investors section of the Puma Biotechnology website at http://www.pumabiotechnology.com. A replay of the call will be available shortly after completion of the call and will be archived on Puma's website for 90 days.

**About Puma Biotechnology**

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. Puma in-licenses the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy and is marketed in the United States as NERLYNX® (neratinib) tablets. In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. NERLYNX was granted marketing authorization by the European Commission in 2018 for the extended adjuvant treatment of adult patients with early stage hormone receptor-positive HER2-overexpressed/amplified breast cancer and who are less than one year from completion of prior adjuvant trastuzumab-based therapy. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

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

**IMPORTANT SAFETY INFORMATION**

**NERLYNX® (neratinib) tablets, for oral use**

**INDICATIONS AND USAGE:** NERLYNX is a kinase inhibitor indicated:

- As a single agent, for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy.
- In combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer, who have received two or more prior anti-HER2 based regimens in the metastatic setting.

**CONTRAINDICATIONS:** None

**WARNINGS AND PRECAUTIONS:**

- **Diarrhea:** Aggressively manage diarrhea. If diarrhea occurs despite recommended prophylaxis, treat with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade ≥ 2 diarrhea that occurs after maximal dose reduction.
- **Hepatotoxicity:** Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue NERLYNX in patients experiencing Grade 4 liver abnormalities.
- **Embryo-Fetal Toxicity:** NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

**ADVERSE REACTIONS:**

The most common adverse reactions (reported in ≥ 5% of patients) were as follows:

- NERLYNX as a single agent: Diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increased, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased, and urinary tract infection.
- NERLYNX in combination with capecitabine: Diarrhea, nausea, vomiting, decreased appetite, constipation, fatigue/asthenia, weight decreased, dizziness, back pain, arthralgia, urinary tract infection, upper respiratory tract infection, abdominal distention, renal impairment, and muscle spasms.

**To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.**

**DRUG INTERACTIONS:**

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors. When patients require gastric acid reducing agents, use an $H_2$-receptor antagonist or antacid. Separate NERLYNX by at least 3 hours with antacids. Separate NERLYNX by at least 2 hours before or 10 hours after $H_2$ receptor antagonists.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- Moderate CYP3A4 and P-glycoprotein (P-gp) dual inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

**USE IN SPECIFIC POPULATIONS:**

- **Lactation:** Advise women not to breastfeed.

**Please see Full Prescribing Information for additional safety information.**

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and healthcare providers with reimbursement support and referrals to resources that can help with financial assistance. More information on the Puma Patient Lynx program can be found at www.NERLYNX.com or 1-855-816-5421.

**Forward-Looking Statements**

This news release includes forward-looking statements, including statements regarding Puma's anticipated milestones. All forward-looking statements involve risks and uncertainties that could cause Puma'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, any adverse impact on Puma's business or the global economy and financial markets, generally, from the global COVID-19 pandemic, and the other risk factors disclosed in Puma's Annual Report on Form 10-K for the year ended December 31, 2019, Puma's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 and

subsequent reports filed by Puma 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. Puma assumes no obligation to update these forward-looking statements, except as required by law.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (Unaudited) | (Unaudited) | (Unaudited) | (Unaudited) |
| Revenues: | | | | |
| Product revenue, net | $ 49.3 | $ 53.5 | $ 146.7 | $ 152.9 |
| License revenue | — | 2.8 | 22.7 | 56.2 |
| Royalty revenue | 1.5 | 0.1 | 3.2 | 0.2 |
| Total revenue | 50.8 | 56.4 | 172.6 | 209.3 |
| Operating costs and expenses: | | | | |
| Cost of sales | 10.0 | 9.4 | 28.4 | 26.7 |
| Selling, general and administrative | 29.6 | 31.4 | 89.9 | 110.4 |
| Research and development | 23.3 | 30.0 | 73.5 | 102.6 |
| Total operating costs and expenses | 62.9 | 70.8 | 191.8 | 239.7 |
| Loss from operations | (12.1) | (14.4) | (19.2) | (30.4) |
| Other income (expenses): | | | | |
| Interest income | — | 0.6 | 0.5 | 2.4 |
| Interest expense | (3.6) | (3.1) | (10.5) | (11.9) |
| Legal verdict expense | (15.9) | — | (16.0) | (16.4) |
| Loss on debt extinguishment | — | — | — | (8.1) |
| Other income | 0.1 | — | 0.2 | — |
| Total other expenses | (19.4) | (2.5) | (25.8) | (34.0) |
| Net loss | $ (31.5) | $ (16.9) | $ (45.0) | $ (64.4) |
| Net loss per share of common stock—basic | $ (0.79) | $ (0.44) | $ (1.14) | $ (1.67) |
| Weighted-average shares of common stock outstanding—basic | 39,695,444 | 38,893,757 | 39,473,691 | 38,675,961 |

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

| | September 30, 2020 (Unaudited) | December 31, 2019 |
|---|---|---|
| Cash and cash equivalents | $ 90.1 | $ 60.0 |
| Marketable securities | 18.9 | 51.6 |
| Working capital | 41.6 | 75.5 |
| Stockholders' (deficit) equity | (0.5) | 17.5 |

| | Nine Months Ended September 30, 2020 (Unaudited) | Nine Months Ended September 30, 2019 (Unaudited) |
|---|---|---|
| Cash provided by (used in): | | |
| Operating activities | $ 6.4 | $ 20.8 |

| | | |
|---|---|---|
| Investing activities | 22.6 | 5.6 |
| Financing activities | - | (67.1) |
| Increase (decrease) in cash and cash equivalents, and restricted cash | $ 29.0 | $ (40.7) |

**Non-GAAP Financial Measures**

In addition to operating results as calculated in accordance with GAAP, Puma uses certain non-GAAP financial measures when planning, monitoring, and evaluating operational performance. The following table presents the Company's net loss and net loss per share calculated in accordance with GAAP and as adjusted to remove the impact of stock-based compensation. For the three months and nine months ended September 30, 2020, stock-based compensation represented approximately 14.4% and 16.6% of operating expenses, respectively, and 19.9% and 21.5%, respectively, for the same periods in 2019, in each case excluding cost of sales. Puma's management believes that these non-GAAP financial measures are useful to enhance understanding of Puma's financial performance, are more indicative of its operational performance, and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

**PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES**
**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 September 30, | | | |
|---|---|---|---|---|
| | 2020 | | 2019 | |
| GAAP net loss | $ (31.5) | | $ (16.9) | |
| Adjustments: | | | | |
| Stock-based compensation - | | | | |
| Selling, general and administrative | 4.1 | | 5.6 | (1) |
| Research and development | 3.5 | | 6.6 | (2) |
| Non-GAAP adjusted net loss | $ (23.9) | | $ (4.7) | |
| | | | | |
| GAAP net loss per share—basic | $ (0.79) | | $ (0.44) | |
| Adjustment to net loss (as detailed above) | 0.19 | | 0.32 | |
| Non-GAAP adjusted basic net loss per share | $ (0.60) | (3) | $ (0.12) | (4) |

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2020 | | 2019 | |
| GAAP net loss | $ (45.0) | | $ (64.4) | |
| Adjustments: | | | | |
| Stock-based compensation - | | | | |
| Selling, general and administrative | 13.5 | | 22.9 | (1) |
| Research and development | 13.6 | | 22.9 | (2) |
| Non-GAAP adjusted net loss | $ (17.9) | | $ (18.6) | |
| | | | | |
| GAAP net loss per share—basic | $ (1.14) | | $ (1.67) | |
| Adjustment to net loss (as detailed above) | 0.69 | | 1.19 | |
| Non-GAAP adjusted basic net loss per share | $ (0.45) | (3) | $ (0.48) | (4) |

(1) To reflect a non-cash charge to operating expense for selling, 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 basic net loss per share was calculated based on 39,695,444 and 39,437,691 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2020, respectively.

(4) Non-GAAP adjusted basic net loss per share was calculated based on 38,893,757 and 38,675,961 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2019, respectively.

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