News Release

Puma Biotechnology Reports Third Quarter 2022 Financial Results

- ***Raises FY 2022 NERLYNX Net Product Revenue Guidance***

LOS ANGELES, Calif., Nov. 3, 2022 - Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2022. Unless otherwise stated, all comparisons are for the third quarter of 2022 compared to the third quarter of 2021.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Product revenue, net in the third quarter of 2022 was $54.3 million, compared to $43.4 million in the third quarter of 2021. Product revenue, net in the first nine months of 2022 was $146.3 million, compared to $138.1 million in the first nine months of 2021.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $0.4 million, or $0.01 per share, for the third quarter of 2022, compared to a net loss of $44.7 million, or $1.09 per share, for the third quarter of 2021. Net income for the first nine months of 2022 was $5.6 million, or $0.13 per basic and diluted share, compared to a net loss of $33.4 million, or $0.82 per share, for the first nine months of 2021.

Non-GAAP adjusted net income was $2.5 million, or $0.05 per basic and diluted share, for the third quarter of 2022, compared to non-GAAP adjusted net loss of $40.4 million, or $0.99 per share, for the third quarter of 2021. Non-GAAP adjusted net income for the first nine months of 2022 was $14.8 million, or $0.33 per basic and diluted share, compared to non-GAAP adjusted net loss of $5.0 million, or $0.12 per share, for the first nine months of 2021. Non-GAAP adjusted net income (loss) excludes stock-based compensation expenses. For a reconciliation of GAAP net income (loss) to non-GAAP adjusted net income (loss) and GAAP net income (loss) per share to non-GAAP adjusted net income (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 2022 was $17.3 million, compared to net cash provided by operating activities of $10.5 million in the third quarter of 2021. Net cash used in operating activities for the first nine months of 2022 was $23.5 million, compared to net cash provided by operating activities of $26.1 million in the first nine months of 2021. On September 30, 2022, Puma had cash, cash equivalents, and marketable securities of $78.0 million, compared to cash, cash equivalents, and marketable securities of $82.1 million at December 31, 2021.

"We are very pleased to report $54.3 million in NERLYNX revenues in the third quarter of 2022," said Alan H. Auerbach, Chairman, Chief Executive Officer, and President of Puma. "This is being driven by the U.S. commercial revenues from NERLYNX and our commercial execution, which is designed to support increased patient access to NERLYNX. This past quarter we also presented updated results from the Phase II SUMMIT basket trial of neratinib for HER2-mutant, recurrent/metastatic cervical cancer at the 2022 European Society for Medical Oncology (ESMO) Congress and we recently reported Phase II data from the cohort of patients in the SUMMIT basket trial of neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations at the EORTC/NCI/AACR Molecular Targets and Cancer Therapeutics Symposium. Puma remains committed to developing treatments for cancer patients, and in September we were pleased to have in-licensed alisertib, an aurora kinase A inhibitor, which we plan to develop initially for the treatment of hormone receptor-positive breast cancer as well as small cell lung cancer. We will continue evaluating both neratinib and alisertib across a number of cancer indications."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) reporting Phase II TBCRC-022 trial data from Cohort 4B and 4C of the combination of Kadcyla® plus neratinib in patients with HER2-positive breast cancer with brain metastases who have previously been treated with Kadcyla (H2 2022); (ii) publication of the biomarker studies from the randomized trial of alisertib plus fulvestrant versus alisertib alone in hormone receptor positive, HER2 negative breast cancer (Q4 2022); (iii) biomarker data from the randomized trial of alisertib plus paclitaxel versus paclitaxel alone in hormone receptor positive, HER2 negative breast cancer (H1 2023); (iv) reporting data from an ongoing investigator sponsored Phase I/II trial of alisertib plus pembrolizumab for the treatment of patients with Rb-deficient head and neck squamous cell cancer (2023); (v) conducting a meeting with the FDA to discuss the registration pathway of neratinib in HER2-mutated HR-positive breast cancer (H1 2023); (vi) conducting a meeting with the FDA to discuss the registration pathway for neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations who have previously been treated with an EGFR tyrosine kinase inhibitor (H1 2023); and (vii) conducting a meeting with the FDA to discuss the registration pathway for alisertib in hormone receptor positive, HER2 negative breast cancer and small cell lung cancer (H1 2023)."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, Puma's first commercial product, license revenue from Puma's sub-licensees and royalty revenue. For the third quarter of 2022, total revenue was $57.1 million, of which $54.3 million was product revenue, net and $2.8 million was royalty revenue. This compares to total revenue of $46.2 million in the third quarter of 2021, of which $43.4 million was product revenue, net and $2.8 million was royalty revenue. For the first nine months of 2022, total revenue was $162.4 million, of which $146.3 million was product revenue, net and $16.1 million was royalty revenue. This compares to total revenue of $197.8 million for the first nine months of 2021, of which $138.1 million was product revenue, net, $50.3 million was license revenue received from Puma's sub-licensees, which included a $50 million upfront payment for providing development, manufacturing, and commercial rights to NERLYNX in Greater China to Pierre Fabre, and $9.4 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $54.7 million for the third quarter of 2022, compared to $55.2 million for the third quarter of 2021. Operating costs and expenses in the first nine months of 2022 were $148.7 million, compared to $203.3 million in the first nine months of 2021.

Cost of Sales

Cost of sales was $12.5 million for the third quarter of 2022, compared to $10.3 million for the third quarter of 2021. Cost of sales was $38.3 million for the first nine months of 2022, compared to $51.8 million for the first nine months of 2021, of which $20.0 million was a termination fee paid to a former sub-licensee for the return of commercial rights to NERLYNX in Greater China.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $24.0 million for the third quarter of 2022, compared to $26.1 million for the third quarter of 2021. SG&A expenses for the first nine months of 2022 were $64.9 million, compared to $93.8 million for the first nine months of 2021. The $28.9 million decrease in SG&A expenses for the first nine months of 2022 compared to the first nine months of 2021 resulted primarily from a decrease in payroll and related costs of approximately $8.9 million, consisting of approximately $7.0 million from lower headcount and a $2.0 million payroll tax credit under the CARES Act; and a decrease in stock-based compensation expense of approximately $17.0 million, primarily due to the $13.6 million incremental expense resulting from the modification to the term of Mr. Auerbach's warrant in 2021, as well as approximately $3.4 million due to the impact of lower headcount. Additionally, professional fees and expenses decreased by approximately $2.8 million, due primarily to a decrease of approximately $6.3 million in consultancy efforts related to marketing and commercialization support, partially offset by an

increase of approximately $3.8 million in legal fees.

Research and Development Expenses

Research and development (R&D) expenses were $11.2 million for the third quarter of 2022, compared to $18.8 million for the third quarter of 2021. R&D expenses for the first nine months of 2022 were $38.5 million, compared to $57.7 million for the first nine months of 2021. The $19.2 million decrease in R&D expenses for the first nine months of 2022 compared to the first nine months of 2021 resulted primarily from a decrease in clinical trial expense of approximately $8.5 million, primarily due to the reduction in the number of patients in certain clinical trials; a decrease in internal R&D expenses of approximately $6.3 million; a decrease in consultant and contractor expense of approximately $2.4 million, primarily due to the close of the CONTROL study and a reduction in the number of patients being treated in the SUMMIT study; and a decrease in stock-based compensation expense of approximately $2.1 million, primarily due to the impact of lower headcount.

Acquired In-Process Research and Development Expense

In September 2022, the Company entered into an exclusive license agreement with Takeda Pharmaceutical Company Limited to in-license the worldwide research and development and commercial rights to alisertib. The Company recorded acquired in-process research and development expense related to the up-front payment of $7.0 during the three months ended September 30, 2022.

Total Other Income (Expenses)

Total other expenses were $2.7 million for the third quarter of 2022, compared to $35.7 million for the third quarter of 2021. Total other expenses were $7.9 million for the first nine months of 2022, compared to $27.7 million for the first nine months of 2021. The $19.8 million decrease for the first nine months of 2022 compared to the first nine months of 2021 resulted primarily from net reductions in legal verdict expense of $9.8 million, $8.1 million in loss on debt extinguishment related to our debt refinancing in July 2021, and a decrease of $1.8 million in lower interest expense related to our outstanding debt.

Full Year 2022 Financial Outlook

Puma increased its financial guidance for full year 2022 to reflect improvements in U.S. demand for NERLYNX and changes to the timing of shipments to Puma's international partners.

Revised guidance for 2022 is summarized below:

	Current	Previous
Product sales, net (in millions)	$194 - $196	$180 - $190
Royalties (in millions)	$25 - $27	$27 - $30
Net income (in millions)	$7 - $9	$6 - $10
Gross to net adjustment	18% - 19%	20% - 21%

Conference Call

Puma Biotechnology will host a conference call to report its third quarter 2022 financial results and provide an update on the Company's business and outlook at 1:30 p.m. PDT/4:30 p.m. EDT on Thursday, November 3, 2022. The call may be accessed by dialing (877) 709-8150 (domestic) or (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 https://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.

In September 2022, Puma entered into an exclusive license agreement for the development and commercialization of the anti-cancer drug alisertib, a selective, small molecule, orally administered inhibitor of aurora kinase A. Initially, Puma intends to focus the development of alisertib on the treatment of small cell lung cancer and breast cancer.

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 https://www.NERLYNX.com or by dialing 1-855-816-5421.

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

INDICATIONS

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

IMPORTANT SAFETY INFORMATION Regarding NERLYNX® (neratinib) U.S. Indication

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- Diarrhea: Manage diarrhea through either NERLYNX dose escalation or loperamide prophylaxis. 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 $\geq$ 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 https://www.fda.gov/medwatch.

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors. Separate NERLYNX by at least 2 hours before or 10 hours after H_2-receptor antagonists. Or separate NERLYNX by at least 3 hours with antacids.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- P-gp and moderate CYP3A4 dual inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- Certain P-gp substrates: Monitor for adverse reactions of P-gp substrates for which minimal concentration change may lead to serious adverse reactions when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- Lactation: Advise women not to breastfeed.

Please see Full Prescribing Information for additional safety information.

Forward-Looking Statements

This press release contains 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 risk factors disclosed in the periodic and current reports filed by Puma with the Securities and Exchange Commission from time to time, including Puma's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent filings. 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.

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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,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Product revenue, net	$ 54.3	$ 43.4	$ 146.3	$ 138.1
License revenue	—	—	—	50.3
Royalty revenue	2.8	2.8	16.1	9.4
Total revenue	57.1	46.2	162.4	197.8
Operating costs and expenses:				
Cost of sales	12.5	10.3	38.3	51.8
Selling, general and administrative	24.0	26.1	64.9	93.8
Research and development	11.2	18.8	38.5	57.7
Acquired in-process research and development	7.0	—	7.0	—
Total operating costs and expenses	54.7	55.2	148.7	203.3
Income (loss) from operations	2.4	(9.0)	13.7	(5.5)
Other income (expenses):				
Interest income	0.2	—	0.3	0.1
Interest expense	(2.9)	(3.1)	(8.3)	(10.1)
Legal verdict expense	—	(24.5)	(0.1)	(9.8)
Loss on debt extinguishment	—	(8.1)	—	(8.1)
Other income	—	—	0.2	0.2
Total other income (expenses)	(2.7)	(35.7)	(7.9)	(27.7)
Net income (loss) before income taxes	$ (0.3)	$ (44.7)	$ 5.8	$ (33.2)
Income tax expense	(0.1)	—	(0.2)	(0.2)
Net income (loss)	$ (0.4)	$ (44.7)	$ 5.6	$ (33.4)
Net income (loss) per share of common stock—basic	$ (0.01)	$ (1.09)	$ 0.13	$ (0.82)
Net income (loss) per share of common stock—diluted	$ (0.01)	$ (1.09)	$ 0.13	$ (0.82)
Weighted-average shares of common stock outstanding—basic	45,567,739	40,813,609	44,290,432	40,520,041
Weighted-average shares of common stock outstanding—diluted	45,567,739	40,813,609	44,464,682	40,520,041

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

	September 30, 2022 (Unaudited)	December 31, 2021
Cash and cash equivalents	$ 78.0	$ 63.1
Marketable securities	—	19.0
Working capital	62.4	30.4
Stockholders' equity (deficit)	22.2	(2.4)

	Nine Months Ended September 30, 2022 (Unaudited)	Nine Months Ended September 30, 2021 (Unaudited)
Cash provided by (used in):		
Operating activities	$ (23.5)	$ 26.1
Investing activities	19.0	(15.5)
Financing activities	9.8	(31.9)
Increase (decrease) in cash and cash equivalents, and restricted cash	$ 5.3	$ (21.3)

Use of Non-GAAP 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 income (loss) and net income (loss) per share calculated in accordance with GAAP and as adjusted to remove the impact of stock-based compensation expense. For the three months and nine months ended September 30, 2022, stock-based compensation represented approximately 8.2% and 8.9% of operating expenses, respectively, and 9.5% and 18.7% for the same period in 2021, in each case excluding cost of sales and acquired in-process research and development. 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 Income (Loss) to Non-GAAP Adjusted Net Income (Loss) and GAAP Net Income (Loss) Per Share to Non-GAAP Adjusted Net Income (Loss) Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended September 30,	
	2022	**2021**
GAAP net loss	$ (0.4)	$ (44.7)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	2.0	3.0
Research and development (2)	0.9	1.3
Non-GAAP adjusted net income (loss)	$ 2.5	$ (40.4)
GAAP net income (loss) per share—basic	$ (0.01)	$ (1.09)
Adjustment to net income (loss) (as detailed above)	0.06	0.10
Non-GAAP adjusted basic net income (loss) per share	$ 0.05 (3)	$ (0.99) (4)
GAAP net income (loss) per share—diluted	$ (0.01)	$ (1.09)
Adjustment to net income (loss) (as detailed above)	0.06	0.10
Non-GAAP adjusted diluted net income (loss) per share	$ 0.05 (5)	$ (0.99) (6)

	Nine Months Ended September 30,	
	2022	**2021**
GAAP net income (loss)	$ 5.6	$ (33.4)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	6.2	23.3
Research and development (2)	3.0	5.1
Non-GAAP adjusted net income (loss)	$ 14.8	$ (5.0)
GAAP net income (loss) per share—basic	$ 0.13	$ (0.82)
Adjustment to net income (loss) (as detailed above)	0.20	0.70
Non-GAAP adjusted basic net income (loss) per share	$ 0.33 (3)	$ (0.12) (4)
GAAP net income per (loss) share—diluted	$ 0.13	$ (0.82)
Adjustment to net income (loss) (as detailed above)	0.20	0.70
Non-GAAP adjusted diluted net income (loss) per share	$ 0.33 (5)	$ (0.12) (6)

(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 income per share was calculated based on 45,567,739 and 44,290,432 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2022, respectively.
(4) Non-GAAP adjusted basic net loss per share was calculated based on 40,813,609 and 40,520,041 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2021, respectively.
(5) Non-GAAP adjusted diluted net income per share was calculated based on 45,797,841 and 44,464,682 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2022, respectively.
(6) Non-GAAP adjusted diluted net loss per share was calculated based on 40,813,609 and 40,520,041 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2021, respectively.