Puma Biotechnology Reports Fourth Quarter and Full Year Financial Results

March 2, 2023

LOS ANGELES--(BUSINESS WIRE)-- Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2022. Unless otherwise stated, all comparisons are for the fourth quarter and full year 2022, compared to the fourth quarter and full year 2021.

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net for the fourth quarter of 2022 was $53.7 million, compared to $51.0 million in the fourth quarter of 2021. Product revenue, net for the full year 2022 was $200.0 million, compared to $189.1 million in 2021.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $5.6 million, or $0.12 per share, for the fourth quarter of 2022, compared to net income of $4.2 million, or $0.10 per basic and diluted share, for the fourth quarter of 2021. In the fourth quarter of 2022, Puma increased its legal accrual by approximately $12.4 million to reflect the settlement of a lawsuit. Net income for full year 2022 was $0.0 million, or $0.00 per basic and diluted share, compared to a net loss of $29.1 million, or $0.72 per share, for full year 2021.

Non-GAAP adjusted net loss was $3.0 million, or $0.07 per share, for the fourth quarter of 2022, compared to non-GAAP adjusted net income of $8.4 million, or $0.21 per basic and diluted share, for the fourth quarter of 2021. Non-GAAP adjusted net income for full year 2022 was $11.8 million, or $0.26 per basic and diluted share, compared to non-GAAP adjusted net income of $3.5 million, or $0.09 per basic share and $0.08 per diluted share, for full year 2021. Non-GAAP adjusted net income/loss excludes stock-based compensation expense. 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 fourth quarter of 2022 was $7.7 million, compared to net cash used in operating activities of $5.4 million for the fourth quarter of 2021. Net cash used in operating activities for full year 2022 was $15.8 million, compared to net cash provided by operating activities of $20.7 million for full year 2021. At December 31, 2022, Puma had cash, cash equivalents, and marketable securities of $81.1 million, compared to cash, cash equivalents, and marketable securities of $82.1 million at December 31, 2021.

"In the fourth quarter of 2022, we are very pleased to have achieved $53.7 million in NERLYNX revenues," 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 awareness and access to NERLYNX. Puma also continued to execute on its key milestones during the quarter, which included presentation of updated findings from the Phase II SUMMIT basket trial of neratinib for *EGFR* exon 18-mutant non-small cell lung cancer (NSCLC) patients at the EORTC/NCI/AACR Molecular Targets and Cancer Therapeutics Symposium, as well as the presentation of data from the TBCRC-022 trial at the 2022 San Antonio Breast Cancer Symposium," said Mr. Auerbach. "We remain committed to supporting patients with HER2-positive breast cancer with NERLYNX and, with the addition of alisertib to our pipeline, we hope to be able to support more cancer patients in the future."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) publication of the biomarker studies from the randomized trial of alisertib plus fulvestrant versus alisertib alone in hormone receptor positive, HER2-negative breast cancer (H1 2023); (ii) reporting biomarker data from the randomized trial of alisertib plus paclitaxel versus paclitaxel alone in hormone receptor positive, HER2-negative breast cancer (H1 2023); (iii) 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); (iv) conducting a meeting with the FDA to discuss the registration pathway for alisertib in small cell lung cancer (H1 2023); and (v) conducting a meeting with the FDA to discuss the registration pathway for alisertib in hormone receptor positive, HER2-negative breast cancer (H2 2023)."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, license revenue and royalty revenue. For the fourth quarter of 2022, total revenue was $65.7 million, of which $53.7 million was product revenue, net, and $12.0 million was royalty revenue. This compares to total revenue of $55.4 million for the fourth quarter of 2021, of which $51.0 million was product revenue, net, $1.5 million was license revenue received from Puma's sub-licensees, and $2.9 million was royalty revenue. For the year ended December 31, 2022, total revenue was $228.0 million, of which $200.0 million was product revenue, net, and $28.0 million was royalty revenue. This compares to total revenue in 2021 of $253.2 million, of which $189.1 million was product revenue, net, $51.8 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

$12.3 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $55.7 million for the fourth quarter of 2022, compared to $48.6 million for the fourth quarter of 2021. Total operating costs and expenses were $204.3 million for full year 2022, compared to $251.9 million for full year 2021.

Cost of Sales

Cost of sales was $16.8 million for the fourth quarter of 2022, compared to $11.9 million for the fourth quarter of 2021. Cost of sales was $55.1 million for full year 2022, compared to cost of sales of $63.7 million for full year 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 $25.1 million for the fourth quarter of 2022, compared to $22.5 million for the fourth quarter of 2021. SG&A expenses for full year 2022 were $90.0 million, compared to $116.3 million for full year 2021. The $26.3 million decrease in SG&A expenses for full year 2022 compared to 2021 resulted primarily from a decrease in payroll and related costs of approximately $8.2 million, consisting of $7.6 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 $17.7 million, primarily due to $13.6 million of incremental expense in 2021, which resulted from modification to the term of a warrant held by Mr. Auerbach, offset by an increase of commissions and bonuses of $1.2 million.

Research and Development Expenses

Research and development (R&D) expenses were $13.8 million for the fourth quarter of 2022, compared to $14.2 million for the fourth quarter of 2021. R&D expenses for full year 2022 were $52.2 million, compared to $71.9 million for full year 2021. The $19.7 million decrease in R&D expenses during full year 2022 compared to full year 2021 resulted primarily from a decrease in clinical trial expense of approximately $8.7 million, primarily due to the reduction in the number of patients in certain clinical trials; a decrease in internal R&D expenses of approximately $5.6 million; a decrease in consultant and contractors' expense of approximately $2.3 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 $3.2 million, primarily due to the impact of lower headcount combined with the decreased stock price.

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 million during the year ended December 31, 2022.

Total Other Income (Expenses)

Total other expenses were $15.3 million for the fourth quarter of 2022, compared to total other expenses of $2.4 million for the fourth quarter of 2021. Total other expenses were $23.2 million for full year 2022, compared to $30.1 million for full year 2021. The $6.9 million decrease in other expenses in full year 2022 consisted primarily of a net increase in legal verdict expense of $2.9 million, which included a $12.4 million expense related to the legal settlement in the year ended December 31, 2022; $8.1 million in loss on debt extinguishment related to our debt refinancing in July 2021; and a decrease of $1.3 million in lower interest expense related to our outstanding debt.

Full Year 2023 and First Quarter 2023 Financial Outlook

	Full Year 2023	**First Quarter 2023**
Net Product Revenue	$205 - $210 million	$43 -$46 million
Royalty Revenue	$25 - $30 million	$4 - $6 million
Net Income/(Loss)	$20 -$24 million	$(5) - $(2) million
Gross to Net Adjustment	19% - 20%	21% - 21.5%

Conference Call

Puma Biotechnology will host a conference call to report its fourth quarter and full year 2022 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, March 2, 2023. 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 https://www.pumabiotechnology.com. A replay of the call will be available approximately one hour 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-licensed 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 https://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 ≥ 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. Separate NERLYNX by at least 2 hours before or 10 hours after H2-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 and estimates of future financial results for the first quarter and full year 2023. 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, any changes in Puma's product candidates' regulatory approvals, results from Puma's clinical trials, any litigation involving Puma, any changes to Puma's in-licensed intellectual property 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, 2022 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.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)		
Revenues:				
Product revenue, net	$ 53.7	$ 51.0	200.0	$ 189.1
License revenue	—	1.5	-	51.8
Royalty revenue	12.0	2.9	28.0	12.3
Total revenue	65.7	55.4	228.0	253.2
Operating costs and expenses:				
Cost of sales	16.8	11.9	55.1	63.7
Selling, general and administrative	25.1	22.5	90.0	116.3
Research and development	13.8	14.2	52.2	71.9
Acquired in-process research and development	—	—	7.0	—
Total operating costs and expenses	55.7	48.6	204.3	251.9
Income from operations	10.0	6.8	23.7	1.3
Other income (expenses):				
Interest income	0.6	—	0.8	0.1
Interest expense	(3.3)	(2.7)	(11.5)	(12.8)
Legal verdict (expense) credit	(12.4)	0.2	(12.5)	(9.6)
Loss on debt extinguishment	—	—	—	(8.1)
Other income (expense)	(0.2)	0.1	—	0.3
Total other expenses	(15.3)	(2.4)	(23.2)	(30.1)
Net income (loss) before income taxes	(5.3)	4.4	0.5	(28.8)
Income tax expense	(0.3)	(0.2)	(0.5)	(0.3)
Net income (loss)	$ (5.6)	$ 4.2	$ 0.0	$ (29.1)
Net income (loss) per share of common stock—basic	$ (0.12)	$ 0.10	$ 0.00	$ (0.72)
Net income (loss) per share of common stock—diluted	$ (0.12)	$ 0.10	$ 0.00	$ (0.72)
Weighted-average shares of common stock outstanding —basic	45,814,185	40,991,412	44,674,501	40,638,852
Weighted-average shares of common stock outstanding —diluted	45,814,185	41,044,676	44,929,998	40,638,852

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
LIQUIDITY AND CAPITAL RESOURCES

(in millions)

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 76.2	$ 63.1
Marketable securities	4.9	19.0
Working capital	56.8	30.4
Stockholders' deficit	21.6	(2.4)

	Twelve Months Ended December 31, 2022	Twelve Months Ended December 31, 2021
Cash provided by (used in):		
Operating activities	$ (15.8)	$ 20.7
Investing activities	7.1	(10.9)
Financing activities	12.2	(31.9)
Increase (decrease) in cash and cash equivalents, and restricted cash	$ 3.5	$ (22.2)

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 twelve months ended December 31, 2022, stock-based compensation represented approximately 6.8% and 8.3% of operating expenses, respectively, and 11.4% and 17.3% for the same periods 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 December 31,			
	2022		2021	
GAAP net income (loss)	$ (5.6)		$ 4.2	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	1.8		2.4	(1)
Research and development	0.8		1.8	(2)
Non-GAAP adjusted net income (loss)	$ (3.0)		$ 8.4	
GAAP net income (loss) per share—basic	$ (0.12)		$ 0.10	
Adjustment to net income (loss) (as detailed above)	0.05		0.11	
Non-GAAP adjusted basic net income (loss) per share	$ (0.07)	(3)	$ 0.21	(3)
GAAP net income (loss) per share—diluted	$ (0.12)		$ 0.10	
Adjustment to net income (loss) (as detailed above)	0.05		0.11	
Non-GAAP adjusted diluted net income (loss) per share	$ (0.07)	(4)	$ 0.21	(5)

	Twelve Months Ended December 31,

	2022		2021	
GAAP net income (loss)	$ 0.0		$ (29.1)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	8.0		25.7	(1)
Research and development	3.8		6.9	(2)
Non-GAAP adjusted net income	$ 11.8		$ 3.5	
GAAP net income (loss) per share—basic	$ 0.00		$ (0.72)	
Adjustment to net income (loss) (as detailed above)	0.26		0.81	
Non-GAAP adjusted basic net income per share	$ 0.26	(6)	$ 0.09	(6)
GAAP net income (loss) per share—diluted	$ 0.00		$ (0.70)	
Adjustment to net income (loss) (as detailed above)	0.26		0.78	
Non-GAAP adjusted diluted net income per share	$ 0.26	(7)	$ 0.08	(7)

(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 (loss) per share was calculated based on 44,814,185 and 40,991 412 weighted-average shares of common stock outstanding for the three months ended December 31, 2022 and 2021, respectively.

(4) Potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) were not included in the non-GAAP adjusted diluted net loss as these shares would be considered anti-dilutive.

(5) Non-GAAP adjusted diluted net income per share was calculated based on 41,044,676 weighted average common shares outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the three months ended December 31, 2021.

(6) Non-GAAP adjusted net income per share was calculated based on 44,674,501 and 40,638,852 weighted-average shares of common stock outstanding for the years ended December 31, 2022 and 2021, respectively.

(7) Non-GAAP adjusted diluted net income per share was calculated based on 44,929,998 and 41,558,838 weighted average common shares outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the twelve months ended December 31, 2022 and 2021, respectively.

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