News Release

Puma Biotechnology Reports Fourth Quarter and Full Year Financial Results

LOS ANGELES, Calif., March 3, 2022 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2021. Unless otherwise stated, all comparisons are for the fourth quarter and full year 2021, compared to the fourth quarter and full year 2020.

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net for the fourth quarter of 2021 was $51.0 million, compared to product revenue, net of $50.0 million in the fourth quarter of 2020. Product revenue, net for the full year 2021 was $189.1 million, compared to product revenue, net of $196.7 million in 2020.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of $4.2 million, or $0.10 per basic and diluted share, for the fourth quarter of 2021, compared to a net loss of $15.0 million, or $0.38 per basic and diluted share, for the fourth quarter of 2020. Net loss for the full year 2021 was $29.1 million, or $0.72 per basic and diluted share, compared to a net loss of $60.0 million, or $1.52 per basic and diluted share, for the full year 2020.

Non-GAAP adjusted net income was $8.4 million, or $0.21 per basic and diluted share, for the fourth quarter of 2021, compared to non-GAAP adjusted net loss of $5.5 million, or $0.14 per basic and diluted share, for the fourth quarter of 2020. Non-GAAP adjusted net income for the full year 2021 was $3.5 million, or $0.09 per basic share and $0.08 per diluted share, compared to non-GAAP adjusted net loss of $23.4 million, or $0.59 per basic and diluted share, for the full year 2020. 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 used in operating activities for the fourth quarter of 2021 was $5.4 million, compared to net cash used in operating activities of $5.6 million for the fourth quarter of 2020. Net cash provided by operating activities for the full year 2021 was $20.7 million, compared to net cash provided by operating activities of $0.8 million for the full year 2020. At December 31, 2021, Puma had cash, cash equivalents, and marketable securities of $82.1 million, compared to cash, cash equivalents, and marketable securities of $93.4 million at December 31, 2020.

"In the fourth quarter of 2021 Puma executed on its key milestones, which included the presentation of data from the SUMMIT trial at the 2021 San Antonio Breast Cancer Symposium," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "We were also pleased to announce the extension of an additional five years to the U.S. patent term of NERLYNX during the quarter as well. We remain committed to providing neratinib to patients with HER2 positive breast cancer and we are grateful to the Puma team members, the physicians and scientists with whom we work, and, most importantly, the patients and caregivers we serve every day."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) conducting a pre-NDA meeting with the FDA to discuss accelerated approval of neratinib in HER2-mutated HR-positive breast cancer (H1 2022); (ii) reporting Phase II data from the cohort of patients in the SUMMIT basket trial of neratinib in HER2-mutated HR-positive breast cancer (H1 2022); (iii) reporting 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 (H2 2022); (iv) 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 previously been treated with an EGFR tyrosine kinase inhibitor (2022); (v) 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); and (vi) reporting Phase II data from the SUMMIT trial of neratinib in cervical cancer patients with HER2 mutations (H2 2022)."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, license revenue and royalty revenue. For the fourth quarter of 2021, total revenue was $55.4 million, 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. This compares to total revenue of $52.6 million for the fourth quarter of 2020, of which $50.0 million was net product revenue and $2.6 million was royalty revenue. For the year ended December 31, 2021, total revenue was $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. This compares to total revenue of $225.1 million for the year ended December 31, 2020, of which $196.7 million was product revenue, net, $22.7 million was license revenue, and $5.7 million was royalty revenue from Puma's sub-licensees.

Operating Costs and Expenses

Total operating costs and expenses were $48.6 million for the fourth quarter of 2021, compared to $63.9 million for the fourth quarter of 2020. Total operating costs and expenses were $251.9 million for the full year 2021 compared to $255.5 million for the full year 2020.

Cost of Sales

Cost of sales was $11.9 million for the fourth quarter of 2021, compared to $10.9 million for the fourth quarter of 2020. Cost of sales was $63.7 million for the 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, compared to cost of sales of $39.4 million for the full year 2020.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $22.5 million for the fourth quarter of 2021, compared to $28.8 million for the fourth quarter of 2020. SG&A expenses for full year 2021 were $116.3 million, compared to $118.4 million for full year 2020, a decrease of $2.1 million. The decrease in SG&A expenses for the full year 2021 compared to 2020 resulted primarily from a decrease in payroll and related costs of $3.2 million due to a reduction in headcount, a decrease of $4.6 million in professional fees related to marketing and commercialization efforts, and a $2.0 million change due to a credit loss recovery related to an outstanding license payment, offset by an increase in stock-based compensation expense of $7.9 million.

Research and Development Expenses

Research and development (R&D) expenses were $14.2 million for the fourth quarter of 2021, compared to $24.2 million for the fourth quarter of 2020. R&D expenses for the full year 2021 were $71.9 million, compared to $97.7 million for the full year 2020. The decrease of $25.8 million in R&D expenses during full year 2021 compared to full year 2020 resulted primarily from a decrease in stock-based compensation expense of $11.9 million, a decrease in internal R&D expense of $5.7 million as a result of lower headcount

and related compensation expense, and a decrease in clinical trial related expenses of $8.3 million due to the close out of certain clinical trials, a reduction in patient enrollments and monitoring cost and a reduction in consulting costs.

Total Other Income (Expenses)

Total other expenses were $2.4 million for the fourth quarter of 2021, compared to total other expenses of $3.7 million for the fourth quarter of 2020. Total other expenses were $30.1 million for the year ended December 31, 2021, compared to total other expenses of $29.4 million for the year ended December 31, 2020. The $0.7 million increase in other expenses for full year 2021 consisted primarily of an increase of $8.1 million related to a loss on extinguishment of debt, offset by decreases of $6.6 million related to legal verdict expenses and $1.3 million in interest expense.

Conference Call

Puma Biotechnology will host a conference call to report its fourth quarter and full year 2021 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 3, 2022. 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-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.

Important Safety Information Regarding NERLYNX® (neratinib) U.S. Indication

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: 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 https://www.fda.gov/medwatch.

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors. 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. 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.

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 1-855-816-5421.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Puma's anticipated milestones and the outcome of its class action lawsuit. 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. 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 December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
	(Unaudited)	(Unaudited)		
Revenues:				
Product revenue, net	$ 51.0	$ 50.0	$ 189.1	$ 196.7
License revenue	1.5	—	51.8	22.7
Royalty revenue	2.9	2.6	12.3	5.7
Total revenue	55.4	52.6	253.2	225.1
Operating costs and expenses:				
Cost of sales	11.9	10.9	63.7	39.4
Selling, general and administrative	22.5	28.8	116.3	118.4
Research and development	14.2	24.2	71.9	97.7
Total operating costs and expenses	48.6	63.9	251.9	255.5
Income (loss) from operations	6.8	(11.3)	1.3	(30.4)
Other income (expenses):				
Interest income	—	—	0.1	0.5
Interest expense	(2.7)	(3.6)	(12.8)	(14.1)
Legal verdict expense	0.2	(0.2)	(9.6)	(16.2)
Loss on debt extinguishment	—	—	(8.1)	—
Other income	0.1	0.1	0.3	0.4
Total other expenses	(2.4)	(3.7)	(30.1)	(29.4)
Net income (loss) before income taxes	4.4	(15.0)	(28.8)	(59.8)
Income tax expense	(0.2)	-	(0.3)	(0.2)
Net income (loss)	$ 4.2	$ (15.0)	$ (29.1)	$ (60.0)
Net income (loss) per share of common stock—basic	$ 0.10	$ (0.38)	$ (0.72)	$ (1.52)
Net income (loss) per share of common stock—diluted	$ 0.10	$ (0.38)	$ (0.72)	$ (1.52)
Weighted-average shares of common stock outstanding—basic	40,991,412	39,881,131	40,638,852	39,576,107
Weighted-average shares of common stock outstanding—diluted	41,044,676	39,881,131	40,638,852	39,576,107

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

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 63.1	$ 85.3
Marketable securities	19.0	8.1
Working capital	30.4	31.9
Stockholders' deficit	(2.4)	(6.0)

	Twelve Months Ended December 31, 2021	Twelve Months Ended December 31, 2020
Cash provided by (used in):		
Operating activities	$ 20.7	$ 0.8
Investing activities	(10.9)	33.3
Financing activities	(31.9)	(9.9)
Increase (decrease) in cash and cash equivalents, and restricted cash	$ (22.2)	$ 24.2

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, 2021, stock-based compensation represented approximately 11.4% and 17.3% of operating expenses, respectively, and 17.9% and 16.9%, respectively, for the same periods in 2020, 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 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,			
	2021		2020	
GAAP net income (loss)	$ 4.2		$ (15.0)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	2.4		4.3	(1)
Research and development	1.8		5.2	(2)
Non-GAAP adjusted net income (loss)	$ 8.4		$ (5.5)	
GAAP net income (loss) per share—basic	$ 0.10		$ (0.38)	
Adjustment to net income (loss) (as detailed above)	0.11		0.24	
Non-GAAP adjusted basic net income (loss) per share	$ 0.21		$ (0.14)	(3)
GAAP net income (loss) per share—diluted	$ 0.10		$ (0.38)	
Adjustment to net income (loss) (as detailed above)	0.11		0.24	
Non-GAAP adjusted diluted net income (loss) per share	$ 0.21	(4)	$ (0.14)	(5)

	Twelve Months Ended December 31,			
	2021		2020	
GAAP net loss	$ (29.1)		$ (60.0)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	25.7		17.8	(1)
Research and development	6.9		18.8	(2)
Non-GAAP adjusted net income (loss)	$ 3.5		$ (23.4)	
GAAP net loss per share—basic	$ (0.72)		$ (1.52)	
Adjustment to net loss (as detailed above)	0.81		0.93	
Non-GAAP adjusted basic net income (loss) per share	$ 0.09		$ (0.59)	(6)
GAAP net loss per share—diluted	$ (0.70)		$ (1.52)	
Adjustment to net loss (as detailed above)	0.78		0.93	
Non-GAAP adjusted diluted net income (loss) per share	$ 0.08	(7)	$ (0.59)	(5)

(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 40,991,412 and 39,881,131 weighted-average shares of common stock outstanding for the three months ended December 31, 2021 and 2020, respectively.

(4) 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.

(5) 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.

(6) Non-GAAP adjusted net income (loss) per share was calculated based on 40,638,852 and 39.576,107 weighted-average shares of common stock outstanding for the years ended December 31, 2021 and 2020, respectively.

(7) Non-GAAP adjusted diluted net income per share was calculated based on 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, 2021.