News Release

Puma Biotechnology Reports First Quarter 2022 Financial Results

LOS ANGELES, Calif., May 5, 2022 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the first quarter ended March 31, 2022. Unless otherwise stated, all comparisons are for the first quarter of 2022 compared to the first quarter of 2021.

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net in the first quarter of 2022 was $40.7 million, compared to product revenue, net of $45.8 million in the first quarter of 2021.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net loss of $3.4 million, or $0.08 per basic and diluted share, for the first quarter of 2022, compared to net income of $16.5 million, or $0.41 per basic share and $0.40 per diluted share, for the first quarter of 2021.

Non-GAAP adjusted net loss was $0.3 million, or $0.01 per basic and diluted share, for the first quarter of 2022, compared to non-GAAP adjusted net income of $22.4 million, or $0.56 per basic share and $0.55 per diluted share, for the first quarter of 2021. Non-GAAP adjusted net income 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 first quarter of 2022 was $26.9 million, compared to $15.7 million provided by operating activities in the first quarter of 2021. At March 31, 2022, Puma had cash, cash equivalents and marketable securities of $73.9 million, compared to cash, cash equivalents and marketable securities of $82.1 million at December 31, 2021.

"2021 was an important year for Puma as we made operational changes to maximize the efficiency of the Puma team and the environment with which we operate," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "We remain committed to increasing awareness of and access to NERLYNX as an option to reduce the risk of recurrence for patients battling HER2-positive breast cancer; the inclusion of NERLYNX in the updated NCCN guidelines is an important step to expanding the awareness and utilization of neratinib for high-risk patients."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) 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); (ii) reporting Phase II data from the cohort of patients in the SUMMIT basket trial of neratinib in HER2-mutated biliary tract 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 pre-NDA meeting with the FDA to discuss the potential for an accelerated approval pathway of neratinib in HER2-mutated HR-positive breast cancer (H2 2022); (v) 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); (vi) 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 (vii) 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, Puma's first commercial product, license revenue from Puma's sub-licensees and royalty revenue. For the first quarter ended March 31, 2022, total revenue was $45.7 million, of which $40.7 million was net product revenue and $5.0 million was royalty revenue. This compares to total revenue of $98.2 million in the first quarter of 2021, of which $45.8 million was net product revenue, $50.0 million was license revenue and $2.4 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $46.4 million for the first quarter of 2022, compared to $78.0 million for the first quarter of 2021.

Cost of Sales

Cost of sales was $10.8 million for the first quarter of 2022, compared to $29.6 million for the first quarter of 2021. Cost of sales in the first quarter of 2021 included $20.0 million for a termination fee paid to a former sub-licensee for the return of commercial rights to NERLYNX in Greater China, partially offset by higher royalties due on increased non-U.S partner sales.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $20.4 million for the first quarter of 2022, compared to $28.2 million for the first quarter of 2021. The $7.8 million decrease resulted primarily from decreases of approximately $3.1 million in professional fees and expenses, primarily related to a decrease in consulting costs for marketing and commercialization support; $2.9 million in payroll and related costs due to reduced headcount; and $1.4 million in stock-based compensation also due to reduced headcount.

Research and Development Expenses

Research and development expenses were $15.2 million for the first quarter of 2022, compared to $20.2 million for the first quarter of 2021. The $5.0 million decrease resulted primarily from decreases of $2.5 million in internal R&D costs related primarily to reduced payroll costs; $1.3 million in stock-based compensation due to the impact of headcount reductions in 2021; $0.7 million in consultants and contractors due to the close of the CONTROL study and the winding down of the SUMMIT study; and $0.5 million in clinical trial expenses due to reduced study costs as noted above.

Total Other Income (Expenses)

Total other expenses were $2.7 million for the first quarter of 2022, compared to total other expenses of $3.7 million for the first quarter of 2021. The $1.0 million decrease in other expenses resulted primarily from lower interest expense on the milestone installment payments to Pfizer as well as lower costs related to our outstanding debt.

Conference Call

Puma Biotechnology will host a conference call to report its first 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, May 5, 2022. The call may be accessed by dialing (866) 682-6100 (domestic) or (862) 298-0702 (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.

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

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. 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.

Contacts

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

info@pumabiotechnology.com

ir@pumabiotechnology.com

David Schull, Russo Partners, +1 212 845 4200

david.schull@russopartnersllc.com

# # # # #

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	(Unaudited)
Revenues:		
Product revenue, net	$ 40.7	$ 45.8
License revenue	—	50.0
Royalty revenue	5.0	2.4
Total revenue	45.7	98.2
Operating costs and expenses:		
Cost of sales	10.8	29.6
Selling, general and administrative	20.4	28.2
Research and development	15.2	20.2
Total operating costs and expenses	46.4	78.0
Income (loss) from operations	(0.7)	20.2
Other expenses:		
Interest expense	(2.7)	(3.5)
Legal verdict expense	—	(0.2)
Total other expenses	(2.7)	(3.7)
Net income (loss) before income taxes	(3.4)	16.5
Income tax expense	—	—
Net income (loss)	$ (3.4)	$ 16.5
Net income (loss) per share of common stock—basic	$ (0.08)	$ 0.41
Net income (loss) per share of common stock—diluted	$ (0.08)	$ 0.40
Weighted-average shares of common stock outstanding—basic	42,207,709	40,260,864
Weighted-average shares of common stock outstanding—diluted	42,207,709	40,894,868

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

	March 31, 2022 (Unaudited)	December 31, 2021
Cash and cash equivalents	$ 63.9	$ 63.1
Marketable securities	10.0	19.0
Working capital	42.8	30.4
Stockholders' equity (deficit)	7.1	(2.4)

	Three Months Ended March 31, 2022 (Unaudited)	Three Months Ended March 31, 2021 (Unaudited)
Cash provided by (used in):		
Operating activities	$ (26.9)	$ 15.7
Investing activities	9.0	(5.3)
Financing activities	9.8	—
Increase (decrease) in cash and cash equivalents, and restricted cash	$ (8.1)	$ 10.4

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 ended March 31, 2022, stock-based compensation represented approximately 8.8% of operating expenses, and 12.1% for the same period in 2021, 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 March 31,			
	2022		2021	
GAAP net income (loss)	$ (3.4)		$ 16.5	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	2.2		3.6	(1)
Research and development	0.9		2.3	(2)
Non-GAAP adjusted net income (loss)	$ (0.3)		$ 22.4	
GAAP net income (loss) per share—basic	$ (0.08)		$ 0.41	
Adjustment to net income (loss) (as detailed above)	0.07		0.15	
Non-GAAP adjusted basic net income (loss) per share	$ (0.01)		$ 0.56	(3)
GAAP net income (loss) per share—diluted	$ (0.08)		$ 0.40	
Adjustment to net income (loss) (as detailed above)	0.07		0.15	
Non-GAAP adjusted diluted net income (loss) per share	$ (0.01)	(4)	$ 0.55	(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 42,207,709 and 40,260,864 weighted-average shares of common stock outstanding for the three months ended March 31, 2022 and 2021, respectively.

(4) Potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) were not included in this non-GAAP adjusted diluted net loss per share for the three months ended March 31, 2022, as these shares would be considered anti-dilutive.

(5) Non-GAAP adjusted diluted net income per share was calculated based on 40,894,868 weighted-average shares of common stock outstanding for the three months ended March 31, 2021.

# # # # #