News Release

Puma Biotechnology Reports Third Quarter 2021 Financial Results

LOS ANGELES, Calif., Nov. 4, 2021 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2021. Unless otherwise stated, all comparisons are for the third quarter of 2021 compared to the third quarter of 2020.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Product revenue, net for the third quarter of 2021 was $43.4 million, compared to product revenue, net of $49.3 million for the third quarter of 2020. Product revenue, net for the first nine months of 2021 was $138.1 million, compared to product revenue, net of $146.7 million for the first nine months of 2020.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $44.7 million, or $1.09 per share, for the third quarter of 2021, compared to a net loss of $31.5 million, or $0.79 per share, for the third quarter of 2020. Net loss for the first nine months of 2021 was $33.4 million, or $0.82 per share, compared to a net loss of $45.0 million, or $1.14 per share, for the first nine months of 2020.

Non-GAAP adjusted net loss was $40.4 million, or $0.99 per share, for the third quarter of 2021, compared to non-GAAP adjusted net loss of $23.9 million, or $0.60 per share, for the third quarter of 2020. Non-GAAP adjusted net loss for the first nine months of 2021 was $5.0 million, or $0.12 per share, compared to non-GAAP adjusted net loss of $17.9 million, or $0.45 per share, for the first nine months of 2020. Non-GAAP adjusted net loss excludes stock-based compensation expense. For a 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, please see the financial tables at the end of this news release.

Net cash provided by operating activities for the third quarter of 2021 was $10.5 million, compared to net cash provided by operating activities of $1.7 million for the third quarter of 2020. Net cash provided by operating activities for the first nine months of 2021 was $26.1 million, compared to net cash provided by operating activities of $6.4 million for the first nine months of 2020. At September 30, 2021, Puma had cash, cash equivalents and marketable securities of $87.5 million, compared to cash, cash equivalents and marketable securities of $93.4 million at December 31, 2020.

"Our operating results continued to be negatively impacted by the effects of COVID-19 and its limitations to our access to healthcare providers during the third quarter," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "Net revenue for the quarter was also negatively impacted by approximately $3.5 million due to inventory reduction at our specialty pharmacies and specialty distributors. We are encouraged with the uptake in the implementation of dose escalation of NERLYNX that was seen in the quarter, which we believe is due to the label expansion that occurred in July. We are also pleased with the continued commercial progress of NERLYNX globally, with the most recent regulatory approval received in the South Korean market by our sub-licensee Bixink Therapeutics. Our team remains committed to providing support to patients battling breast cancer, and we look forward to providing updated neratinib clinical trial data at the San Antonio Breast Cancer Symposium next month."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) reporting top line data from the randomized cohort of the Phase II SUMMIT trial of neratinib in hormone receptor positive breast cancer that has a HER2 mutation (Q4 2021); (ii) reporting data from the Phase II INSIGhT

trial of neratinib in patients with glioblastoma at the Society of NeuroOncology (SNO) Annual Meeting (Q4 2021); (iii) conducting a Type C meeting with the FDA to discuss potential for accelerated approval of neratinib in HER2-mutated hormone receptor positive breast cancer (Q4 2021); (iv) 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 (H1 2022); (v) reporting Phase II data from the SUMMIT trial of neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations (H1 2022); (vi) 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); (vii) reporting Phase II data from the SUMMIT trial of neratinib in cervical cancer patients with HER2 mutations (H1 2022); and (viii) receiving regulatory decisions for the extended adjuvant HER2-positive early stage breast cancer indication in additional countries (Q4 2021/H1 2022)."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, license revenue and royalty revenue. For the third quarter of 2021, total revenue was $46.2 million, of which $43.4 million was product revenue, net and $2.8 million was royalty revenue. This compares to total revenue of $50.8 million for the third quarter of 2020, of which $49.3 million was product revenue, net and $1.5 million was royalty revenue. For the first nine months of 2021, total revenue was $197.8 million, 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. This compares to total revenue of $172.6 million for the first nine months of 2020, of which $146.7 million was product revenue, net, $22.7 million was license revenue from Puma's sub-licensees, and $3.2 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $55.2 million for the third quarter of 2021, compared to $62.9 million for the third quarter of 2020. Operating costs and expenses for the first nine months of 2021 were $203.3 million, compared to $191.8 million for the first nine months of 2020.

Cost of Sales

Cost of sales was $10.3 million for the third quarter of 2021, compared to $10.0 million for the third quarter of 2020. Cost of sales was $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, compared to cost of sales of $28.4 million for the first nine months of 2020.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $26.1 million for the third quarter of 2021, compared to $29.6 million for the third quarter of 2020. SG&A expenses for the first nine months of 2021 were $93.8 million, compared to $89.9 million for the first nine months of 2020.

The $3.9 million increase in SG&A expenses for the first nine months of 2021 compared to the first nine months of 2020 resulted primarily from an increase in stock-based compensation of approximately $9.8 million, partially offset by decreases in payroll and related costs of approximately $1.5 million, professional fees and expenses of approximately $2.2 million, travel and meetings costs of approximately $0.6 million, and other expenses of approximately $1.3 million.

The $9.8 million increase in stock-based compensation expense for the first nine months of 2021 consisted of a $13.6 million incremental expense resulting from a modification to the term of Mr. Auerbach's warrant and

an increase of $3.4 million from new grants, partially offset by decreases of approximately $5.9 million for stock awards that have fully vested and $1.3 million from stock awards forfeited.

Research and Development Expenses

Research and development (R&D) expenses were $18.8 million for the third quarter of 2021, compared to $23.3 million for the third quarter of 2020. R&D expenses for the first nine months of 2021 were $57.7 million, compared to $73.5 million for the first nine months of 2020.

The $15.8 million decrease in R&D expenses for the first nine months of 2021 compared to the first nine months of 2020 resulted primarily from decreases in stock-based compensation expense of approximately $8.5 million, clinical trial expenses of approximately $2.6 million, internal R&D expenses of approximately $3.3 million, and consultant and contractors' costs of approximately $1.3 million.

Total Other Expenses

Total other expenses were $35.7 million for the third quarter of 2021, compared to $19.4 million for the third quarter of 2020. Total other expenses were $27.7 million for the first nine months of 2021, compared to $25.8 million for the first nine months of 2020. The $1.9 million increase for the first nine months of 2021 compared to the first nine months of 2020 resulted primarily from an increase in debt extinguishment loss of approximately $8.1 million, partially offset by a decrease in legal verdict expense of approximately $6.2 million and other immaterial fluctuations.

Conference Call

Puma Biotechnology will host a conference call to report its third quarter 2021 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 4, 2021. The call may be accessed by dialing 1-888-437-3179 (domestic) or 1-862-298-0702 (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 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 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 dose escalation or loperamide, treat with loperamide, 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 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 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, anticipated obligations arising from the conclusion of the class action lawsuit, 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, 2020. 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,	
	2021 (Unaudited)	2020 (Unaudited)	2021 (Unaudited)	2020 (Unaudited)
Revenues:				
Product revenue, net	$ 43.4	$ 49.3	$ 138.1	$ 146.7
License revenue	—	—	50.3	22.7
Royalty revenue	2.8	1.5	9.4	3.2
Total revenue	46.2	50.8	197.8	172.6
Operating costs and expenses:				
Cost of sales	10.3	10.0	51.8	28.4
Selling, general and administrative	26.1	29.6	93.8	89.9
Research and development	18.8	23.3	57.7	73.5
Total operating costs and expenses	55.2	62.9	203.3	191.8
Loss from operations	(9.0)	(12.1)	(5.5)	(19.2)
Other income (expenses):				
Interest income	—	—	0.1	0.5
Interest expense	(3.1)	(3.6)	(10.1)	(10.5)
Legal verdict expense	(24.5)	(15.9)	(9.8)	(16.0)
Loss on debt extinguishment	(8.1)	—	(8.1)	—
Other income	—	0.1	0.2	0.2
Total other expenses	(35.7)	(19.4)	(27.7)	(25.8)
Net loss before income taxes	$ (44.7)	$ (31.5)	$ (33.2)	$ (45.0)
Income tax expense	—	—	(0.2)	—
Net loss	$ (44.7)	$ (31.5)	$ (33.4)	$ (45.0)
Net loss per share of common stock—basic	$ (1.09)	$ (0.79)	$ (0.82)	$ (1.14)
Net loss per share of common stock—diluted	$ (1.09)	$ (0.79)	$ (0.82)	$ (1.14)
Weighted-average shares of common stock outstanding—basic	40,813,609	39,695,444	40,520,041	39,473,691
Weighted-average shares of common stock outstanding—diluted	40,813,609	39,695,444	40,520,041	39,473,691

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

	September 30, 2021 (Unaudited)	December 31, 2020
Cash and cash equivalents	$ 63.9	$ 85.3
Marketable securities	23.6	8.1
Working capital	20.7	31.9
Stockholders' deficit	(10.9)	(6.0)

	Nine Months Ended September 30, 2021 (Unaudited)	Nine Months Ended September 30, 2020 (Unaudited)
Cash provided by (used in):		
Operating activities	$ 26.1	$ 6.4
Investing activities	(15.5)	22.6
Financing activities	(31.9)	—
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (21.3)	$ 29.0

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 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, 2021, stock-based compensation represented approximately 9.5% and 18.7% of operating expenses, respectively, and 14.3% and 16.6%, 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 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,	
	2021	2020
GAAP net loss	$ (44.7)	$ (31.5)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	3.0	4.1
Research and development (2)	1.3	3.5
Non-GAAP adjusted net loss	$ (40.4)	$ (23.9)
GAAP net loss per share—basic	$ (1.09)	$ (0.79)
Adjustment to net loss (as detailed above)	0.10	0.19
Non-GAAP adjusted basic net loss per share (3) (4)	$ (0.99)	$ (0.60)
GAAP net loss per share—diluted	$ (1.09)	$ (0.79)
Adjustment to net loss (as detailed above)	0.10	0.19
Non-GAAP adjusted diluted net loss per share (5) (6)	$ (0.99)	$ (0.60)

	Nine Months Ended September 30,	
	2021	2020
GAAP net loss	$ (33.4)	$ (45.0)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	23.3	13.5
Research and development (2)	5.1	13.6
Non-GAAP adjusted net loss	$ (5.0)	$ (17.9)
GAAP net loss per share—basic	$ (0.82)	$ (1.14)
Adjustment to net loss (as detailed above)	0.70	0.69
Non-GAAP adjusted basic net loss per share (3) (4)	$ (0.12)	$ (0.45)
GAAP net loss per share—diluted	$ (0.82)	$ (1.14)
Adjustment to net loss (as detailed above)	0.70	0.69
Non-GAAP adjusted diluted net loss per share (5) (6)	$ (0.12)	$ (0.45)

(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 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.
(4) Non-GAAP adjusted basic net loss per share was calculated based on 39,695,444 and 39,473,691 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2020, respectively.
(5) 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.
(6) Non-GAAP adjusted diluted net loss per share was calculated based on 39,695,444 and 39,473,691 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2020, respectively.