News Release

Puma Biotechnology Reports Second Quarter 2018 Financial Results

LOS ANGELES, Calif., Aug. 9, 2018 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the second quarter ended June 30, 2018. Unless otherwise stated, all comparisons are for the second quarter 2018 compared to the second quarter 2017.

On July 17, 2017, Puma Biotechnology received approval from the U.S. Food and Drug Administration (FDA) for NERLYNX® (neratinib) for the treatment of early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and the Company began shipment to wholesalers at the end of July 2017. Prior to the launch of NERLYNX the Company had no product revenue. Net product revenue from sales of NERLYNX in the second quarter of 2018 amounted to $50.8 million, compared to net product revenue of $36.0 million and $20.1 million in the first quarter of 2018 and fourth quarter of 2017, respectively.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of $44.3 million, or $1.17 per share, for the second quarter of 2018, compared to a net loss applicable to common stock of $77.8 million, or $2.10 per share, for the second quarter of 2017. Net loss applicable to common stock for the first six months of 2018 was $68.7 million, or $1.82 per share, compared to $150.7 million, or $4.08 per share, for the first six months of 2017.

Non-GAAP adjusted net loss was $22.2 million, or $0.59 per share, for the second quarter of 2018, compared to non-GAAP adjusted net loss of $50.9 million, or $1.38 per share, for the second quarter of 2017. Non-GAAP adjusted net loss for the first six months of 2018 was $21.2 million, or $0.56 per share, compared to non-GAAP adjusted net loss of $94.0 million, or $2.54 per share, for the first six months of 2017. Non-GAAP adjusted net loss excludes stock-based compensation expense, which represents a significant portion of overall expense and has no impact on the cash position of the Company. 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 used in operating activities for the second quarter of 2018 was $17.6 million. Net cash used in operating activities for the first six months of 2018 was $23.9 million. At June 30, 2018, Puma had cash and cash equivalents of $95.9 million and marketable securities of $38.6 million, compared to cash and cash equivalents of $81.7 million at December 31, 2017.

“In the second quarter of 2018, we saw strong commercial progress for Puma,” said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. “We continued to grow NERLYNX sales in the United States, with net sales of NERLYNX rising approximately 41% from the 2018 first quarter. We were also pleased that the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization for NERLYNX 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 the completion of prior adjuvant trastuzumab based therapy. The CHMP recommendation will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU).”

Mr. Auerbach added, “We anticipate the following key milestones over the next 12 months: (i) in the third quarter of 2018, a decision by the European Commission (EC) regarding the Marketing

Authorisation Application for neratinib; (ii) in the second half of 2018 or first half of 2019, reporting data from the Phase III NALA trial in third-line metastatic breast cancer patients; (iii) in the second half of 2018 and first half of 2019, submitting for regulatory approval of NERLYNX for the extended adjuvant HER2-positive early stage breast cancer indication in additional countries; (iv) in the fourth quarter of 2018, reporting additional data from the Phase II CONTROL trial; and (v) in the fourth quarter of 2018 and first half of 2019, reporting additional data from the Phase II SUMMIT trial."

Revenue

Total revenue consists of net product revenue from sales of NERLYNX, Puma's first and only commercial product to date, and license revenue. The FDA approved NERLYNX for commercial sale in the United States in July 2017 and Puma commenced shipment to wholesalers in late July. For the second quarter of 2018, total revenue was $50.8 million, all of which was net product revenue. For the first six months of 2018, total revenue was $117.3 million, of which $86.8 million was net product revenue and $30.5 million was license revenue received from Puma's sub-licensees.

Operating Costs and Expenses

Operating costs and expenses were $92.2 million for the second quarter of 2018, compared to $78.2 million for the second quarter of 2017. Operating costs and expenses for the first six months of 2018 were $182.1 million, compared to $151.4 million for the first six months of 2017.

Cost of Sales:

Cost of sales was $8.8 million for the second quarter of 2018 and $15.2 million for the first six months of 2018. The Company had no product sales prior to the third quarter of 2017.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were $40.1 million for the second quarter of 2018, compared to $24.9 million for the second quarter of 2017. SG&A expenses for the first six months of 2018 were $76.7 million, compared to $43.3 million for the first six months of 2017. This approximately $33.4 million increase was attributable to an increase of approximately $8.5 million in external expenses, such as marketing, commercialization support and commercial strategy. Additionally, internal expenses increased approximately $22.0 million, primarily due to the hiring of a salesforce for the commercialization of NERLYNX in the United States. Finally, employee stock-based compensation increased approximately $2.9 million due to the hiring of the salesforce in conjunction with the NERLYNX commercial launch. Puma expects SG&A expenses in 2018 and into 2019 to remain higher than in 2017 as it launches NERLYNX commercially in the United States and other territories.

Research and Development Expenses:

Research and development (R&D) expenses were $43.3 million for the second quarter of 2018, compared to $53.3 million for the second quarter of 2017. R&D expenses for the first six months of 2018 were $90.2 million, compared to $108.1 million for the first six months of 2017. The $17.9 million year-to-date decrease resulted primarily from a decrease of approximately $12.1 million for stock-based compensation and a decrease of approximately $9.0 million for clinical trial expenses. This was partially offset by an increase of approximately $3.2 million in other expenses, such as additional personnel needed to support medical affairs and quality assurance. We expect R&D expenses in 2018 to continue to decline slightly when compared with R&D expenses in 2017 based on a decline in clinical trial activities as existing trials continue to wind down.

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. The Company in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in July 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. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

IMPORTANT SAFETY INFORMATION

NERLYNX ® (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early-stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea occurring despite recommended prophylaxis 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 (≥ 5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.

To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) and www.NERLYNX.com 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 (PPI) and H2-receptor antagonists. Separate NERLYNX by 3 hours after antacid dosing.
- Strong or moderate CYP3A4 inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- Lactation: Advise women not to breastfeed.

Please see Full Prescribing Information for additional safety information.

The recommended dose of NERLYNX is 240 mg (six 40 mg tablets) given orally once daily with food, continuously for one year. Antidiarrheal prophylaxis should be initiated with the first dose of NERLYNX and continued during the first 2 months (56 days) of treatment and as needed thereafter.

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.

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

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the benefits of NERLYNX and neratinib, the progress and expected timing of the Company's clinical trials, the announcement of data relative to those trials and the timing for anticipated regulatory approvals. All forward-looking statements involve risks and uncertainties that could cause the Company'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, the risk factors disclosed in the periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

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(*Financial Tables Follow*)

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

	Three Months Ended June 30, (Unaudited)		Six Months Ended June 30, (Unaudited)	
	2018	2017	2018	2017
Product revenue, net	$ 50.8	$ —	$ 86.8	$ —
License revenue	—	—	30.5	—
Total revenue	50.8	—	117.3	—
Operating costs and expenses:				
Cost of sales	8.8	—	15.2	—
Selling, general and administrative	40.1	24.9	76.7	43.3
Research and development	43.3	53.3	90.2	108.1
Totals	92.2	78.2	182.1	151.4
Loss from operations	(41.4)	(78.2)	(64.8)	(151.4)
Other income (expenses):				
Interest income	0.3	0.4	0.5	0.7
Interest expense	(2.6)	—	(3.7)	—
Other expense	(0.6)	—	(0.7)	—
Totals	(2.9)	0.4	(3.9)	0.7
Net loss	$ (44.3)	$ (77.8)	$ (68.7)	$ (150.7)
Net loss per common share—basic and diluted	$ (1.17)	$ (2.10)	$ (1.82)	$ (4.08)
Weighted-average common shares outstanding—basic and diluted	37,819,767	36,992,017	37,759,729	36,961,760

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

	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 95.9	$ 81.7
Marketable securities	38.6	—
Working capital	106.5	48.1
Stockholders' equity	38.3	53.3

	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Cash provided by (used in):		
Operating activities	$ (23.9)	$ (82.0)
Investing activities	(38.8)	(36.0)
Financing activities	76.9	4.3
Increase (decrease) in cash and cash equivalents	$ 14.2	$ (113.7)

Non-GAAP Financial Measures

In addition to operating results as calculated in accordance with GAAP, the Company 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 employee stock-based compensation. For the three and six months ended June 30, 2018, stock-based compensation represented approximately 26.5% and 28.5% of operating expense (which does not include cost of sales), respectively. Although net loss is important to measure financial performance, the Company currently places an emphasis on cash burn and, more specifically, cash used in operations. Stock-based compensation appears in GAAP net loss but is removed from net loss to arrive at cash used in operations on the statement of cash flows. Due to its noncash nature, the Company believes these non-GAAP measures enhance understanding of financial performance, are more indicative of 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 SUBSIDIARY
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 June 30,		
	2018	2017	
GAAP net loss	$ (44.3)	$ (77.8)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	8.5	7.3	(1)
Research and development	13.6	19.6	(2)
Non-GAAP adjusted net loss	$ (22.2)	$ (50.9)	
GAAP net loss per share - basic and diluted	$ (1.17)	$ (2.10)	
Adjustment to net loss (as detailed above)	0.58	0.72	
Non-GAAP adjusted net loss per share	$ (0.59)	$ (1.38)	(3)

	Six Months Ended June 30,		
	2018	2017	
GAAP net loss	$ (68.7)	$ (150.7)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	17.5	14.6	(1)
Research and development	30.0	42.1	(2)
Non-GAAP adjusted net loss	$ (21.2)	$ (94.0)	
GAAP net loss per share - basic and diluted	$ (1.82)	$ (4.08)	
Adjustment to net loss (as detailed above)	1.26	1.54	
Non-GAAP adjusted net loss per share	$ (0.56)	$ (2.54)	(4)

(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 net loss per share was calculated based on 37,819,767 and 36,992,017 weighted average common shares outstanding for the three months ended June 30, 2018 and 2017, respectively.

(4) Non-GAAP adjusted net loss per share was calculated based on 37,759,729 and 36,961,760 weighted average common shares outstanding for the six months ended June 30, 2018 and 2017, respectively.