
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

77-0683487
(I.R.S. Employer
Identification Number)

10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024

(Address of principal executive offices) (Zip code)

(424) 248-6500

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	PBYI	The NASDAQ Stock Market LLC (NASDAQ Global Select Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No .

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No .

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act .

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No .

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 40,779,030 shares of Common Stock, par value \$0.0001 per share, were outstanding as of July 30, 2021.

PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions, future events or performance are not historical facts and may be forward looking. These forward-looking statements include, but are not limited to, statements about:

- the commercialization of NERLYNX® (neratinib);
- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the impact of the global COVID-19 pandemic, and measures to control the spread of COVID-19, on business, financial condition, results of operations and ongoing trials;
- the anticipated timing of regulatory filings;
- the regulatory approval of our drug candidates;
- our use of clinical research organizations and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- efforts of our sub-licensees to obtain regulatory approval and commercialize NERLYNX in areas outside the United States;
- our ability to market any of our products;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our intention and ability to vigorously defend against any litigation to which we are or may become party;
- our estimates for damages that we may be required to pay in connection with the class action lawsuit to which we are a party;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2020 that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)
(unaudited)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 89,848	\$ 85,293
Marketable securities	19,127	8,096
Accounts receivable, net of allowance for credit loss of \$0 and \$1,000	30,549	25,543
Inventory, net	7,620	3,454
Prepaid expenses, current	11,279	11,262
Restricted cash, current	8,850	8,850
Other current assets	478	3,641
Total current assets	167,751	146,139
Lease right-of-use assets, net	15,247	16,404
Property and equipment, net	2,099	2,481
Intangible assets, net	70,133	74,140
Restricted cash, long-term	3,311	3,311
Prepaid expenses and other, long-term	1,457	1,745
Total assets	\$ 259,998	\$ 244,220
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 11,166	\$ 12,076
Accrued expenses, current	66,988	61,325
Accrued in-licensed rights, current	21,613	20,993
Post-marketing commitment liability, current	3,368	2,481
Lease liabilities, current	3,336	3,094
Current portion of long-term debt	31,429	14,286
Total current liabilities	137,900	114,255
Accrued expenses, long-term	1,177	25,963
Lease liabilities, long-term	17,823	19,549
Post-marketing commitment liability, long-term	4,923	6,379
Long-term debt	68,706	84,025
Total liabilities	230,529	250,171
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Common stock - \$.0001 par value per share; 100,000,000 shares authorized; 40,733,928 shares issued and outstanding at June 30, 2021 and 40,086,387 issued and outstanding at December 31, 2020	4	4
Additional paid-in capital	1,355,775	1,331,676
Accumulated other comprehensive loss	(1)	—
Accumulated deficit	(1,326,309)	(1,337,631)
Total stockholders' equity (deficit)	29,469	(5,951)
Total liabilities and stockholders' equity (deficit)	\$ 259,998	\$ 244,220

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue, net	\$ 48,856	\$ 48,771	\$ 94,672	\$ 97,380
License revenue	250	20,700	50,250	22,700
Royalty revenue	4,278	1,111	6,631	1,719
Total revenue	53,384	70,582	151,553	121,799
Operating costs and expenses:				
Cost of sales	11,969	9,415	41,527	18,491
Selling, general and administrative	39,410	29,347	67,748	60,284
Research and development	18,638	24,691	38,866	50,146
Total operating costs and expenses	70,017	63,453	148,141	128,921
Income (loss) from operations	(16,633)	7,129	3,412	(7,122)
Other income (expenses):				
Interest income	121	66	134	452
Interest expense	(3,518)	(3,784)	(6,968)	(6,852)
Legal verdict (expense) credit	14,902	(93)	14,717	(186)
Other income	60	77	102	170
Total other income (expenses)	11,565	(3,734)	7,985	(6,416)
Net income (loss) before income taxes	\$ (5,068)	\$ 3,395	\$ 11,397	\$ (13,538)
Income tax expense	(38)	—	(75)	—
Net income (loss)	\$ (5,106)	\$ 3,395	\$ 11,322	\$ (13,538)
Net income (loss) per share of common stock—basic	\$ (0.13)	\$ 0.09	\$ 0.28	\$ (0.34)
Net income (loss) per share of common stock—diluted	\$ (0.13)	\$ 0.08	\$ 0.28	\$ (0.34)
Weighted-average shares of common stock outstanding—basic				
	40,479,577	39,432,030	40,370,825	39,361,596
Weighted-average shares of common stock outstanding—diluted				
	40,479,577	39,997,571	40,939,688	39,361,596

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)
(unaudited)

	For the Three Months Ended		For the Six Months Ended June 30,	
	June 30,	June 30,	June 30,	June 30,
	2021	2020	2021	2020
Net income (loss)	\$ (5,106)	\$ 3,395	\$ 11,322	\$ (13,538)
Other comprehensive income (loss):				
Unrealized loss on available-for-sale securities, net of tax of \$0 and \$0	(1)	(1)	(1)	(64)
Reclassifications of gain on available-for-sale securities, included in "Other income (expenses)", net of tax of \$0 and \$0	-	-	-	3
Comprehensive income (loss)	<u>\$ (5,107)</u>	<u>\$ 3,394</u>	<u>\$ 11,321</u>	<u>\$ (13,599)</u>

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(unaudited)

For the Three Months Ended June 30, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at March 31, 2021	40,324,263	\$ 4	\$ 1,337,536	\$ -	\$ (1,321,203)	\$ 16,337
Stock-based compensation	—	—	18,239	—	—	18,239
Shares issued or restricted stock units vested under employee stock plans	409,665	—	—	—	—	—
Unrealized loss on available-for- sale securities	—	—	—	(1)	—	(1)
Net income	—	—	—	—	(5,106)	(5,106)
Balance at June 30, 2021	<u>40,733,928</u>	<u>\$ 4</u>	<u>\$ 1,355,775</u>	<u>\$ (1)</u>	<u>\$ (1,326,309)</u>	<u>\$ 29,469</u>

For the Three Months Ended June 30, 2020

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at March 31, 2020	39,317,221	\$ 4	\$ 1,303,940	\$ 2	\$ (1,294,569)	\$ 9,377
Stock-based compensation	—	—	10,630	—	—	10,630
Shares issued or restricted stock units vested under employee stock plans	309,696	—	2	—	—	2
Reclassification of gain on available- for-sale securities	—	—	—	—	—	—
Unrealized loss on available-for- sale securities	—	—	—	(1)	—	(1)
Net income	—	—	—	—	3,395	3,395
Balance at June 30, 2020	<u>39,626,917</u>	<u>\$ 4</u>	<u>\$ 1,314,572</u>	<u>\$ 1</u>	<u>\$ (1,291,174)</u>	<u>\$ 23,403</u>

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(unaudited)

For the Six Months Ended June 30, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2020	40,086,387	\$ 4	\$ 1,331,676	\$ —	\$ (1,337,631)	\$ (5,951)
Stock-based compensation	—	—	24,099	—	—	24,099
Shares issued or restricted stock units vested under employee stock plans	647,541	—	—	—	—	—
Unrealized loss on available-for- sale securities	—	—	—	(1)	—	(1)
Net income	—	—	—	—	11,322	11,322
Balance at June 30, 2021	<u>40,733,928</u>	<u>\$ 4</u>	<u>\$ 1,355,775</u>	<u>\$ (1)</u>	<u>\$ (1,326,309)</u>	<u>\$ 29,469</u>

For the Six Months Ended June 30, 2020

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2019	39,203,304	\$ 4	\$ 1,295,033	\$ 62	\$ (1,277,636)	\$ 17,463
Stock-based compensation	—	—	19,537	—	—	19,537
Shares issued or restricted stock units vested under employee stock plans	423,613	—	2	—	—	2
Reclassification of gain on available-for-sale securities	—	—	—	3	—	3
Unrealized loss on available-for- sale securities	—	—	—	(64)	—	(64)
Net loss	—	—	—	—	(13,538)	(13,538)
Balance at June 30, 2020	<u>39,626,917</u>	<u>\$ 4</u>	<u>\$ 1,314,572</u>	<u>\$ 1</u>	<u>\$ (1,291,174)</u>	<u>\$ 23,403</u>

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	For the Six Months Ended June 30,	
	2021	2020
Operating activities:		
Net income (loss)	\$ 11,322	\$ (13,538)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	5,886	4,153
Stock-based compensation	24,099	19,537
Provision for credit loss expense	(1,000)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(4,006)	4,909
Inventory, net	(4,166)	279
Prepaid expenses and other	271	(119)
Other current assets	3,163	(3,103)
Accounts payable	(910)	(7,416)
Accrued expenses and other	(18,503)	155
Deferred rent	—	(44)
Post-marketing commitment liability	(569)	(125)
Net cash provided by operating activities	<u>15,587</u>	<u>4,688</u>
Investing activities:		
Purchase of property and equipment	—	(12)
Purchase of available-for-sale securities	(19,117)	(16,376)
Maturity of available-for-sale securities	8,085	51,546
Purchase of intangible assets	—	(10,000)
Net cash (used in) provided by investing activities	<u>(11,032)</u>	<u>25,158</u>
Financing activities:		
Net proceeds from shares issued under employee stock plans	—	2
Proceeds from debt	—	8,444
Payment of debt	—	(8,444)
Net cash provided by financing activities	<u>—</u>	<u>2</u>
Net increase in cash, cash equivalents and restricted cash	4,555	29,848
Cash, cash equivalents and restricted cash, beginning of period	97,454	73,210
Cash, cash equivalents and restricted cash, end of period	<u>\$ 102,009</u>	<u>\$ 103,058</u>
Supplemental disclosures of non-cash investing and financing activities:		
Intangibles in accrued expenses	\$ 20,000	\$ 30,000
Supplemental disclosure of cash flow information:		
Interest paid	\$ 4,550	\$ 4,721
Income taxes paid	\$ 84	\$ —

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or the Company, is a biopharmaceutical company based in Los Angeles, California with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses from Pfizer, Inc., or Pfizer, the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357, as well as certain related compounds. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors HER1, HER2 and HER4. Currently, the Company is primarily focused on the development and commercialization of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer and HER2 mutated cancers. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including other tumor types that over-express or have a mutation in HER2 or EGFR, such as breast cancer, cervical cancer, lung cancer or other solid tumors.

The Company has two subsidiaries, Puma Biotechnology Ltd., a United Kingdom company, and Puma Biotechnology, B.V., a Netherlands company. These subsidiaries were established for the purpose of legal representation in the United Kingdom and the European Union.

Basis of Presentation:

The Company has incurred significant operating losses since its inception. The Company believes that it will continue to incur net losses and may incur negative net cash flows from operating activities through the drug development process and global commercialization. In 2017, the Company received U.S. Food and Drug Administration, or FDA, approval for its first product, NERLYNX® (neratinib), formerly known as PB272 (neratinib, oral), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. Following FDA approval in July 2017, NERLYNX became available by prescription in the United States, and the Company commenced commercialization.

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.

In 2018, the European Commission, or EC, granted marketing authorization for NERLYNX in the European Union 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 Company is required to make substantial payments to Pfizer upon the achievement of certain milestones and has contractual obligations for clinical trial contracts.

The Company has entered into other exclusive sub-license agreements with various parties to pursue regulatory approval, if necessary, and commercialize NERLYNX, if approved, in many regions outside the United States, including Europe (excluding Russia and Ukraine), Australia, Canada, China, Southeast Asia, Israel, Mexico, South Korea, and various countries and territories in Central and South America. The Company plans to continue to pursue commercialization of NERLYNX in other countries outside the United States, if approved.

The Company has reported net loss of approximately \$5.1 million and net income of approximately \$11.3 million for the three and six months ended June 30, 2021, respectively, and cash flows from operations of approximately \$15.6 million for the six months ended June 30, 2021. The Company's commercialization, research and development or marketing efforts may require funding in addition to the cash and cash equivalents totaling approximately \$89.8 million and marketable securities totaling approximately \$19.1 million available at June 30, 2021. The Company believes that its existing cash and cash equivalents and marketable securities as of June 30, 2021 and proceeds that will become available to the Company through product sales and sub-license payments are sufficient to satisfy its operating cash and needs for at least one year after the filing of the Quarterly Report on Form 10-Q in which these financial statements are included. The Company continues to remain dependent on its ability to obtain sufficient funding to sustain operations and continue to successfully commercialize neratinib in the United States. While the Company has been successful in raising capital in the past, there can be no assurance that it will be able to do so in the future. The Company's ability to obtain funding may be adversely impacted by uncertain market conditions, including the COVID-19 pandemic, the Company's success in commercializing neratinib, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. Additionally, the terms of the Company's Note Purchase Agreement place

restrictions on the Company’s ability to operate the business and on the Company’s financial flexibility, and the Company may be unable to achieve the revenue necessary to satisfy the minimum revenue covenants as specified in the agreement.

Since its inception through June 30, 2021, the Company’s financing has primarily been proceeds from product and license revenue, public offerings of its common stock, private equity placements, and borrowings under its prior loan and security agreement, which borrowings were paid off in July 2021 using new borrowings from the issuance of notes under the Company’s Note Purchase Agreement.

Note 2—Significant Accounting Policies:

The significant accounting policies followed in the preparation of these unaudited consolidated financial statements are as follows:

Principles of Consolidation:

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Segment Reporting:

Management has determined that the Company operates in one business segment, which is the development and commercialization of innovative products to enhance cancer care.

Use of Estimates:

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the balance sheet, and reported amounts of revenues and expenses for the period presented. Accordingly, actual results could differ from those estimates.

Significant estimates include estimates for variable consideration for which reserves were established. These estimates are included in the calculation of net revenues and include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company’s sale of its products.

Net Income (Loss) per Share of Common Stock:

Basic net income (loss) per share of common stock is computed by dividing net income (loss) available to common stockholders by the weighted-average number of shares of common stock outstanding during the periods presented, as required by Accounting Standards Codification, or ASC, 260, *Earnings per Share*. For purposes of calculating diluted net income (loss) per share of common stock, the denominator includes both the weighted-average number of shares of common stock outstanding and the number of dilutive common stock equivalents, such as stock options, restricted stock units, or RSUs, and warrants. A common stock equivalent is not included in the denominator when calculating diluted earnings per common share if the effect of such common stock equivalent would be anti-dilutive and a net loss is reported.

Our potentially dilutive securities include potential common shares related to our stock options and restricted stock units granted in connection with the 2011 and 2017 Plans. Diluted earnings per share (“Diluted EPS”) considers the impact of potentially dilutive securities except in periods in which there is a loss because the inclusion of the potential common shares would have an anti-dilutive effect. Diluted EPS excludes the impact of potential common shares related to our stock options in periods in which the option exercise price is greater than the average market price of our common stock for the period.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Options outstanding	5,241,747	4,930,672	4,796,671	5,172,638
Warrant outstanding	2,116,250	2,116,250	2,116,250	2,116,250
Unvested restricted stock units	2,076,079	1,290,442	1,136,005	2,316,621
Totals	9,434,076	8,337,364	8,048,926	9,605,509

The 2,116,250 shares underlying the warrant will not have an impact on our diluted net income (loss) per share until the average market price of our common stock exceeds the exercise price of \$16 per share. Refer to Note 11 for further details about the warrant.

A reconciliation of the numerators and denominators of the basic and diluted net income (loss) per share of common stock computations is as follows (in thousands, except per share amounts):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net income (loss)	\$ (5,106)	\$ 3,395	\$ 11,322	\$ (13,538)
Denominator:				
Weighted average common stock outstanding for basic net income (loss) per share	40,480	39,432	40,371	39,362
Net effect of dilutive common stock equivalents	-	566	569	-
Weighted average common stock outstanding for diluted net income per share	40,480	39,998	40,940	39,362
Net income (loss) per share of common stock				
Basic	\$ (0.13)	\$ 0.09	\$ 0.28	\$ (0.34)
Diluted	\$ (0.13)	\$ 0.08	\$ 0.28	\$ (0.34)

Revenue Recognition:

Under ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, the Company recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services. The Company had no contracts with customers until the FDA approved NERLYNX on July 17, 2017. Subsequent to receiving FDA approval, the Company entered into a limited number of arrangements with specialty pharmacies and specialty distributors in the United States to distribute NERLYNX. These arrangements are the Company's initial contracts with customers. The Company has determined that these sales channels with customers are similar.

Product Revenue, Net:

The Company sells NERLYNX to a limited number of specialty pharmacies and specialty distributors in the United States. These customers subsequently resell the Company's products to patients and certain medical centers or hospitals. In addition to distribution agreements with these customers, the Company enters into arrangements with health care providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the specialty pharmacy or specialty distributor, as applicable, obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenue is recorded net of applicable reserves for variable consideration, including discounts and allowances. The Company's payment terms range between 10 and 68 days.

Shipping and handling costs for product shipments occur prior to the customer obtaining control of the goods and are recorded in cost of sales.

If taxes should be collected from customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the six months ended June 30, 2021 and 2020.

Reserves for Variable Consideration:

Revenue from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the related sales, and

are classified as reductions of accounts receivable, net when the right of offset exists in accordance with ASU 2013-1, *Balance Sheet (Topic 210): Clarifying the Scope of Disclosures about Offsetting Assets and Liabilities*, or as a current liability. These estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a significant reversal of revenue would not be probable to occur in a future period for the estimates detailed below as of June 30, 2021 and, therefore, the transaction price was not reduced further during the quarter ended June 30, 2021. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances:

The Company generally provides customers with discounts, which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. The reserve for discounts is established in the same period that the related revenue is recognized, together with reductions to accounts receivable, net on the consolidated balance sheets. In addition, the Company compensates its customers for sales order management, data, and distribution services. The Company has determined such services received to date are not distinct from the Company's sale of products to its customers and, therefore, these payments have been recorded as a reduction of revenue within the statements of operations.

Product Returns:

Consistent with industry practice, the Company offers the specialty pharmacies and specialty distributors that are its customers limited product return rights for damaged and expiring product, provided it is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of product revenue, net in the period the related product revenue is recognized, as well as a reduction to accounts receivable, net on the consolidated balance sheets. The Company currently estimates product returns using its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has an insignificant amount of returns to date and believes that returns of its products will continue to be minimal.

Provider Chargebacks and Discounts:

Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to its customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. The reserve for chargebacks is established in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and a reduction to accounts receivable, net on the consolidated balance sheets. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the customer's notification to the Company of the resale. Chargebacks consist of credits the Company expects to issue for units that remain in the distribution channel at each reporting period-end that the Company expects will be sold to qualified healthcare providers and chargebacks that customers have claimed, but for which the Company has not yet issued a payment.

Government Rebates:

The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and the establishment of a current liability, which is included in accrued expenses on the consolidated balance sheets. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimates of future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel at the end of each reporting period.

Payor Rebates:

The Company contracts with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and the establishment of a current liability, which is included in accrued expenses on the consolidated balance sheets.

Other Incentives:

Other incentives the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included as a component of accrued expenses on the consolidated balance sheets.

License Revenue:

The Company also recognizes license revenue under certain of the Company's sub-license agreements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. The Company evaluates these agreements under ASC 606 to determine the distinct performance obligations. Non-refundable, upfront fees that are not contingent on any future performance and require no consequential continuing involvement by the Company, are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. The Company defers recognition of non-refundable upfront license fees if the performance obligations are not satisfied.

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved.

If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on its relative standalone selling price. The standalone selling price is generally determined based on the prices charged to customers or using expected cost-plus margin. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure.

Since 2018, the Company has entered into sub-license agreements with certain sub-licensees in territories outside of the United States. These sub-licensing agreements grant certain intellectual property rights and set forth various respective obligations with respect to actions such as development, pursuit and maintenance of regulatory approvals, commercialization and supply of NERLYNX in the sub-licensees' respective territories.

License fees under the sub-license agreements include one-time upfront payments when each sub-license agreement was executed and potential additional one-time milestone payments due to the Company upon successful completion of certain performance obligations, such as achieving regulatory approvals or sales target thresholds, and potential double-digit royalties on sales of the licensed product, calculated as a percentage of net sales of the licensed product throughout each sub-licensee's respective territory.

As of June 30, 2021, the total potential milestone payments that would be due to the Company upon achievement of all respective performance obligations under the sub-license agreements is approximately \$581.5 million. At this time, the Company cannot estimate if or when these milestone-related performance obligations might be achieved.

Royalty Revenue:

For sub-license agreements that are within the scope of ASC 606, the Company recognizes revenue when the related sales occur in accordance with the sales-based royalty exception under ASC 606-10-55-65.

Royalty revenue consists of consideration earned related to international sales of NERLYNX made by the Company's sub-licensees in their respective territories. The Company recognizes royalty revenue when the performance obligations have been satisfied. Royalty revenue was \$4.3 million and \$6.6 million for the three and six months ended June 30, 2021, respectively.

Legal Contingencies and Expense:

For legal contingencies, the Company accrues a liability for an estimated loss if the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated. Legal fees and expenses are expensed as incurred based on invoices or estimates provided by legal counsel. The Company periodically evaluates available information, both internal and external, relative to such contingencies and adjusts the accrual as necessary. The Company determines whether a contingency should be disclosed by assessing whether a material loss is deemed reasonably possible. In determining whether a loss should be accrued, the Company evaluates, among other factors, the degree of probability of an unfavorable outcome and the ability to make a reasonable estimate of the amount of the loss (see Note 13-Commitments and Contingencies).

Royalty Expenses:

Royalties incurred in connection with the Company's license agreement with Pfizer, as disclosed in Note 13—Commitments and Contingencies, are expensed to cost of sales as revenue from product sales is recognized.

Research and Development Expenses:

Research and development expenses, or R&D Expenses, are charged to operations as incurred. The major components of R&D Expenses include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and clinical research organization, or CRO, costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company's accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. As actual costs become known, the Company adjusts its accruals in that period.

In instances where the Company enters into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded to prepaid expenses and other in the accompanying consolidated balance sheets and expensed as services are performed or as the underlying goods are delivered. If the Company does not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of R&D Expenses.

Stock-Based Compensation:

Stock Option Awards:

ASC Topic 718, *Compensation-Stock Compensation*, or ASC 718, requires the fair value of all share-based payments to employees and nonemployees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee and nonemployee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing Method. As allowed by ASC 718, the Company's estimate of expected volatility is based on its average volatilities using its past eight years of publicly traded history. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. Option forfeitures are estimated when the option is granted to reduce the option expense to be recognized over the life of the award. The estimated forfeiture rate considers historical employee turnover rates stratified into employee pools, actual forfeiture experience and other factors. The option expense is adjusted upon the actual forfeiture of a stock option grant and the Company periodically revises the estimated forfeiture rate in subsequent periods if actual forfeitures differ from those estimates. Due to its limited history of stock option exercises, the Company uses the simplified method to determine the expected life of the option grants. Compensation expense related to modified stock options is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite service period, as appropriate.

Restricted Stock Units:

RSUs are valued on the grant date and the fair value of the RSUs is equal to the market price of the Company's common stock on the grant date. The RSU expense is recognized over the requisite service period. When the requisite service period begins prior to the grant date (because the service inception date occurs prior to the grant date), the Company is required to begin recognizing compensation cost before there is a measurement date (i.e., the grant date). The service inception date is the beginning of the requisite service period. If the service inception date precedes the grant date, accrual of compensation cost for periods before the grant date shall be based on the fair value of the award at the reporting date. In the period in which the grant date occurs, cumulative compensation cost shall be adjusted to reflect the cumulative effect of measuring compensation cost based on fair value at the grant date rather than the fair value previously used at the service inception date (or any subsequent reporting date). RSU forfeitures are estimated when the RSU is granted to reduce the RSU expense to be recognized over the life of the award. The estimated forfeiture rate considers historical employee turnover rates stratified into employee pools, actual forfeiture experience and other factors. The RSU expense is adjusted upon the actual forfeiture of an RSU grant and the Company periodically revises the estimated forfeiture rate in subsequent periods if actual forfeitures differ from those estimates. Compensation expense related to modified restricted stock units is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite service period, as appropriate.

Warrants:

Warrants (refer to Note 11 for further details) granted to employees and nonemployees are normally valued at the fair value of the instrument on the grant date and are recognized in the statement of operations over the requisite service period. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Monte Carlo Simulation Method. When the terms of the warrant become fixed, the Company values the warrant using the Black-Scholes Option Pricing Method. As allowed by ASC 718, the Company's estimate of expected volatility is based on its average volatilities using its publicly traded history. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value of the warrant until the terms are fixed, the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair value of the warrant at the time of issuance as an equity stock-based compensation transaction. The grant date is determined when all pertinent information, such as exercise price and quantity are known. Compensation expense related to warrant modifications is measured based on the fair value of the warrant as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the warrant on the modification date compared to the fair value of the warrant immediately before the modification date is recognized at the modification date or ratably over the requisite service period, as appropriate.

Income Taxes:

The Company follows ASC Topic 740, *Income Taxes*, or ASC 740, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are based on the differences between the consolidated financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of June 30, 2021, the Company's uncertain tax position reserves include a reserve for its R&D credits.

Financial Instruments:

The carrying value of financial instruments, such as cash equivalents, accounts receivable and accounts payable, approximate their fair value because of their short-term nature. The carrying value of long-term debt approximates its fair value as the principal amounts outstanding are subject to variable interest rates that are based on market rates, which are regularly reset.

Cash and Cash Equivalents:

The Company classifies all highly liquid instruments with an original maturity of three months or less as cash equivalents.

Restricted Cash:

Restricted cash represents cash held at financial institutions that is pledged as collateral for stand-by letters of credit for lease and legal verdict commitments. The lease-related letters of credit will lapse at the end of the respective lease terms through 2026. At each of June 30, 2021 and December 31, 2020, the Company had restricted cash in the amount of \$12.2 million.

Investment Securities:

The Company classifies all investment securities (short-term and long-term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management's strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. In accordance with ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, credit losses on available-for-sale securities are reported using an expected loss model and recorded to an allowance. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

Assets Measured at Fair Value on a Recurring Basis:

ASC Topic 820, *Fair Value Measurement*, or ASC 820, provides a single definition of fair value and a common framework for measuring fair value as well as disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid by a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transaction costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.

Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Following are the major categories of assets measured at fair value on a recurring basis as of June 30, 2021 and December 31, 2020, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

June 30, 2021	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 60,703	\$ —	\$ —	\$ 60,703
Commercial paper	—	14,497	—	14,497
Corporate bonds	—	4,630	—	4,630
Totals	<u>\$ 60,703</u>	<u>\$ 19,127</u>	<u>\$ —</u>	<u>\$ 79,830</u>

December 31, 2020	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 59,919	\$ 11,798	\$ —	\$ 71,717
Commercial paper	—	8,096	—	8,096
Totals	<u>\$ 59,919</u>	<u>\$ 19,894</u>	<u>\$ —</u>	<u>\$ 79,813</u>

The Company's investments in commercial paper, corporate bonds and U.S. government securities are exposed to price fluctuations. The fair value measurements for commercial paper, corporate bonds and U.S. government securities are based upon the quoted prices of similar items in active markets multiplied by the number of securities owned.

The following tables summarize the Company's cash equivalents and short-term investments (in thousands):

June 30, 2021	Maturity (in years)	Amortized cost	Unrealized		Estimated fair value
			Gains	Losses	
Cash equivalents		\$ 60,703	\$ —	\$ —	\$ 60,703
Commercial paper	Less than 1	14,497	—	—	14,497
Corporate bonds	Less than 1	4,631	—	(1)	4,630
Totals		\$ 79,831	\$ —	\$ (1)	\$ 79,830

December 31, 2020	Maturity (in years)	Amortized cost	Unrealized		Estimated fair value
			Gains	Losses	
Cash equivalents		\$ 71,717	\$ —	\$ —	\$ 71,717
Commercial paper	Less than 1	8,096	—	—	8,096
Totals	Less than 1	\$ 79,813	\$ —	\$ —	\$ 79,813

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents, marketable securities, and accounts receivable, net. The Company's cash and cash equivalents and restricted cash in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at June 30, 2021, were approximately \$102.0 million. The Company does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held. Pursuant to the Company's internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor's Rating Service and Moody's Investors Service at the time of purchase.

The Company sells its products in the United States primarily through specialty pharmacies and specialty distributors. Therefore, wholesale distributors and large pharmacy chains account for a large portion of its accounts receivables, net and product revenues, net. The creditworthiness of its customers is continuously monitored, and the Company has internal policies regarding customer credit limits. The Company estimates an allowance for doubtful accounts primarily based on the credit worthiness of its customers, historical payment patterns, aging of receivable balances and general economic conditions. The Company recorded a recovery of \$1.0 million credit loss and \$1.0 million as an allowance for credit loss for the periods ended June 30, 2021 and December 31, 2020, respectively.

The Company's success depends on its ability to successfully commercialize NERLYNX. The Company currently has a single product and limited commercial sales experience, which makes it difficult to evaluate its current business, predict its future prospects and forecast financial performance and growth. The Company has invested a significant portion of its efforts and financial resources in the development and commercialization of the lead product, NERLYNX, and expects NERLYNX to constitute the vast majority of product revenue for the foreseeable future.

The Company relies exclusively on third parties to formulate and manufacture NERLYNX and its drug candidates. The commercialization of NERLYNX and any other drug candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide sufficient quantities of product or fail to do so at acceptable quality levels or prices. The Company has no experience in drug formulation or manufacturing and does not intend to establish its own manufacturing facilities. The Company lacks the resources and expertise to formulate or manufacture NERLYNX and other drug candidates. While the drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. The Company is using the same third-party contractors to manufacture, supply, store and distribute drug supplies for clinical trials and the commercialization of NERLYNX. If the Company is unable to continue its relationships with one or more of these third-party contractors, it could experience delays in the development or commercialization efforts as it locates and qualifies new manufacturers. The Company intends to rely on one or more third-party contractors to manufacture the commercial supply of drugs.

Inventory:

The Company values its inventories at the lower of cost and estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment

charges, should they occur, are recorded within the cost of sales in the consolidated statements of operations. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of sales in the consolidated statements of operations.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval, if any, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory that can be used in either the production of clinical or commercial product is recorded as R&D Expenses when selected for use in a clinical trial. Starter kits, provided to patients prior to insurance approval, are expensed by the Company to selling, general and administrative expense as incurred.

As of June 30, 2021, the Company's inventory balance consisted primarily of raw materials purchased subsequent to FDA approval of NERLYNX.

Property and Equipment, Net:

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which is generally three years for computer hardware and software, three years for phone equipment, and seven years for furniture and fixtures. Leasehold improvements are amortized using the straight-line method over the lesser of the useful life or the lease term. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

The Company reviews its long-lived assets used in operations for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, as required by ASC Topic 360, *Property, Plant, and Equipment*, or ASC 360. The Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows over the life of the asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would then determine the fair value of the long-lived asset and recognize an impairment loss for the amount in excess of the carrying value.

Leases:

ASC Topic 842, *Leases*, as adopted in the first quarter of 2019, requires lessees to recognize most leases on the balance sheet with a corresponding right-of-use asset, or ROU asset. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance, as required by ASC 360. A significant indication of impairment of an ROU asset would include a change in the extent or manner in which the asset is being used. The Company must make assumptions which underlie the most significant and subjective estimates in determining whether any impairment exists. Those estimates, and the underlying assumptions, include estimates of future cash flow utilizing market lease rates and determination of fair value. If an ROU asset related to an operating lease is impaired, the carrying value of the ROU asset post-impairment should be amortized on a straight-line basis through the earlier of the end of the useful life of the ROU asset or the end of the lease term. Post impairment, a lessee must calculate the amortization of the ROU asset and interest expense on the lease liability separately, although the sum of the two continues to be presented as a single lease cost. If a lease is planned to be abandoned with no intention of subleasing, the ROU asset should be assessed for impairment.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them. For additional information, see Note 6—Leases.

The Company leases office space and copy machines, all of which are operating leases. Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to extend or terminate a lease are considered in the lease term to the extent that the option is reasonably certain of exercise. The leases do not include options to purchase the leased property. The depreciable life of assets and leasehold improvements is limited by the expected lease term. Covenants imposed by the leases include letters of credit required to be obtained by the lessee.

The incremental borrowing rate, or IBR, represents the rate of interest the Company would expect to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. When determinable, the Company uses the rate implicit in the lease to determine the present value of lease payments. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The Company's average IBR for existing leases as of June 30, 2021 is 10.9%.

License Fees and Intangible Assets:

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale. The Company capitalizes technology licenses upon reaching technological feasibility.

The Company maintains definite-lived intangible assets related to the license agreement with Pfizer. These assets are amortized over their remaining useful lives, which are estimated based on the shorter of the remaining patent life or the estimated useful life of the underlying product. Intangible assets are amortized using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated. Amortization costs are recorded as part of cost of sales.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. In connection with the FDA approval of NERLYNX in July 2017, the Company triggered a one-time milestone payment pursuant to its license agreement with Pfizer. In June 2020, the Company entered into a letter agreement with Pfizer relating to the method of payment associated with a milestone payment under the Company's license agreement with Pfizer (see Note 13-Commitments and Contingencies). The Company capitalized the milestones as intangible assets and is amortizing the assets to cost of sales on a straight-line basis over the estimated useful life of the licensed patent through 2030. The Company recorded amortization expense related to its intangible assets of \$2.0 million and \$4.0 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2021 estimated future amortization expense related to the Company's intangible assets was approximately \$4.0 million for the remainder of 2021 and \$8.0 million for each year starting 2022 through 2029, and \$2.0 million for 2030.

During the six months ended June 30, 2021, the Company agreed to settle its ongoing arbitration proceeding with CANbridge BIOMED Limited, or CANbridge, relating to an agreement in which the Company granted CANbridge an exclusive sub-license to develop and commercialize NERLYNX throughout greater China. The Company and CANbridge agreed to drop their respective claims against one another. At the same time, the Company entered into a separate transaction in which it agreed to pay CANbridge a one-time termination fee of \$20.0 million in exchange for it returning to the Company all rights to NERLYNX in greater China. The Company expensed the \$20.0 million one-time termination fee to cost of sales in the six months ended June 30, 2021.

Recently Issued Accounting Standards:

In December 2019, the Financial Accounting Standards Board, or FASB issued ASU No 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its Simplification Initiative to reduce the cost and complexity in accounting for income taxes. The amendments in ASU 2019-12 remove certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also amends other aspects of the guidance to help simplify and promote consistent application of GAAP. The guidance is effective for interim and annual periods beginning after December 15, 2020, with early adoption permitted. ASU 2019-12 did not have a material effect on the Company's current financial position, results of operations or financial statement disclosures.

In October 2020, the FASB issued *ASU 2020-10, Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with SEC regulations. The Company adopted *ASU 2020-10* as of the reporting period beginning January 1, 2021. ASU 2020-10 did not have a material effect on the Company's current financial position, results of operations or financial statement disclosures.

Note 3—Accounts Receivable, Net:

Accounts receivable, net consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Trade accounts receivable	\$ 26,082	\$ 21,515
License revenue receivable	250	2,500
Royalty revenue receivable	4,217	2,528
Total accounts receivable	\$ 30,549	\$ 26,543
Allowance for credit losses	—	(1,000)
Total accounts receivable, net	<u>\$ 30,549</u>	<u>\$ 25,543</u>

Trade accounts receivable consist entirely of amounts owed from the Company's customers related to product sales. License revenue receivable represents an amount owed from a sub-licensee under a sub-license agreement. Royalty revenue receivable represents amounts owed related to royalty revenue recognized based on the Company's sub-licensees' sales in their respective territories in the periods ended June 30, 2021 and December 31, 2020.

For all accounts receivable, the Company recognized credit losses based on lifetime expected losses to selling, general and administrative expense in the consolidated statements of operations. In determining estimated credit losses, the Company evaluated its historical loss rates, current economic conditions and reasonable and supportable forecasts of future economic conditions. The Company recorded a recovery of \$1.0 million in credit loss and \$1.0 million as a credit loss expense for the periods ended June 30, 2021 and December 31, 2020, respectively. The rollforward of the allowance for credit losses is as follows:

Allowance for credit losses (in thousands):		
Beginning balance at January 1, 2021	\$	(1,000)
Provision for credit loss expense		—
Accounts receivable written-off		—
Recoveries		1,000
Total ending allowance balance as June 30, 2021	<u>\$</u>	<u>—</u>

Note 4—Prepaid Expenses and Other:

Prepaid expenses and other consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Current:		
CRO services	\$ 1,207	\$ 1,550
Other clinical development	3,931	2,718
Insurance	1,723	3,708
Professional fees	1,377	651
Other	3,041	2,635
	<u>11,279</u>	<u>11,262</u>
Long-term:		
CRO services	198	518
Other clinical development	638	437
Other	621	790
	<u>1,457</u>	<u>1,745</u>
Totals	<u>\$ 12,736</u>	<u>\$ 13,007</u>

Other current prepaid amounts consist primarily of deposits, signing bonuses, licenses, subscriptions and software. Other long-term prepaid amounts consist primarily of deposits, signing bonuses, licenses, subscriptions, software, a capitalized sublease commission and a sublease tenant improvement allowance, net of amortization.

Note 5—Other Current Assets:

Other current assets consisted of the following (in thousands):

	June 30, 2021		December 31, 2020
Deposit for manufacturing costs	\$ —	\$	3,376
Deferred rent	197		198
Other	281		67
Totals	<u>\$ 478</u>	<u>\$</u>	<u>3,641</u>

Other current asset amounts consist primarily of a deposit, capitalized sublease commission and a sublease tenant improvement allowance, net of amortization.

Note 6—Leases:

In December 2011, the Company entered into a non-cancelable operating lease for office space in Los Angeles, California, which was subsequently amended in November 2012, December 2013, March 2014, July 2015, and December 2017. The initial term of the lease was for seven years and commenced on December 10, 2011. As amended, the Company rents approximately 65,656 square feet. The term of the lease runs until March 2026, and rent amounts payable by the Company increase approximately 3% per year. Concurrent with the execution of the lease, the Company provided the landlord an automatically renewable stand-by letter of credit in the amount of \$2.0 million. The stand-by letter of credit is collateralized by a high-yield savings account, which is classified as restricted cash, long-term on the accompanying consolidated balance sheets.

In June 2012, the Company entered into a long-term lease agreement for office space in South San Francisco, California, which was subsequently amended in May 2014 and July 2015. As amended, the Company rents approximately 29,470 square feet. The term of this lease runs until March 2026, with the option to extend for an additional five-year term, and rents payable by the Company increase approximately 3% per year. The Company provided the landlord an automatically renewable stand-by letter of credit in the amount of \$1.1 million. The stand-by letter of credit is collateralized by a high-yield savings account, which is classified as restricted cash, long-term on the accompanying consolidated balance sheets. The Company also leases copier equipment for use in the office spaces. Components of lease expense include fixed lease expense and variable lease expense of approximately \$2.3 million and \$0.2 million, respectively, for each of the six months ended June 30, 2021 and June 30, 2020. For purposes of determining straight-line rent expense, the lease term is calculated from the date the Company first takes possession of the facility, including any periods of free rent and any renewal option periods that the Company is reasonably certain of exercising. The Company's office and equipment leases generally have contractually specified minimum rent and annual rent increases that are included in the measurement of the ROU asset and related lease liability. Additionally, under these lease arrangements, the Company may be required to pay directly, or reimburse the lessors, for real estate taxes, insurance, utilities, maintenance and other operating costs. Such amounts are generally variable and therefore not included in the measurement of the ROU asset and related lease liability but are instead recognized as variable lease expense in selling, general and administrative costs in the consolidated statements of operations when they are incurred.

Supplemental cash flow information related to leases for the three months ended June 30, 2021:

Operating cash flows used for operating leases (in thousands)	\$	2,845
Right-of-use assets obtained in exchange for new operating lease liabilities		—
Weighted average remaining lease term (in years)		4.7
Weighted average discount rate		10.9%

The future minimum lease payments under ASC 842 as of June 30, 2021 were as follows (in thousands):

	Amount
2021 (remaining)	\$ 2,704
2022	5,483
2023	5,631
2024	5,805
2025	5,983
Thereafter	1,508
Total minimum lease payments	\$ 27,114
Less: imputed interest	(5,955)
Total lease liabilities	\$ 21,159

In February 2019, the Company entered into a long-term sublease agreement for 12,429 square feet of the office space in Los Angeles, California. The term of the lease runs until March 2026 and rent amounts payable to the Company increase approximately 3% per year. The Company recorded operating sublease income of \$0.1 million and \$0.2 million for the three and six months ended June 30, 2021, respectively, in other income (expenses) in the consolidated statements of operations.

The future minimum lease payments to be received as of June 30, 2021 were as follows (in thousands):

	Amount
2021 (remaining)	\$ 236
2022	481
2023	495
2024	510
2025	525
Thereafter	134
Total	\$ 2,381

Note 7—Property and Equipment, Net:

Property and equipment, net consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Leasehold improvements	\$ 3,779	\$ 3,779
Computer equipment	2,190	2,192
Telephone equipment	302	302
Furniture and fixtures	2,359	2,359
	8,630	8,632
Less: accumulated depreciation	(6,531)	(6,151)
Totals	\$ 2,099	\$ 2,481

For the three and six months ended June 30, 2021, the Company incurred depreciation expense of \$0.2 million and \$0.4 million, respectively.

Note 8—Intangible Assets, Net:

Intangible assets, net consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Acquired and in-licensed rights	\$ 90,000	\$ 90,000
Less: accumulated amortization	(19,867)	(15,860)
Total intangible asset, net	\$ 70,133	\$ 74,140

For the three and six months ended June 30, 2021, the Company incurred amortization expense of \$2.0 million and \$4.0 million, respectively. In June 2020, the Company entered into a letter agreement with Pfizer relating to the method of payment associated with a one-time milestone payment under the Company's license agreement with Pfizer (see Note 13-Commitments and Contingencies). The estimated remaining useful life of the intangible assets as of June 30, 2021 is 8.8 years.

Note 9—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Current:		
Accrued legal verdict expense	\$ 32,829	\$ 22,724
Accrued royalties	9,345	8,604
Accrued CRO services	2,854	3,474
Accrued variable consideration	8,307	9,014
Accrued bonus	3,551	7,788
Accrued compensation	4,704	4,820
Accrued other clinical development	2,037	1,904
Accrued professional fees	1,321	1,420
Accrued legal fees	878	383
Accrued manufacturing costs	429	752
Other	733	442
	66,988	61,325
Long-term:		
Accrued legal verdict expense	—	24,822
Accrued CRO services	971	908
Accrued other	206	233
	1,177	25,963
Totals	\$ 68,165	\$ 87,288

Accrued CRO services, accrued other clinical development expenses, and accrued legal fees represent the Company's estimates of such costs and are recognized as incurred. Accrued royalties represent royalties incurred in connection with the Company's license agreement with Pfizer. Accrued compensation includes accrued commissions and accrued vacation, which is accrued at the rate the employee earns vacation and reduced as vacation is used by the employee. Accrued variable consideration represents estimates of adjustments to product revenue, net for which reserves are established.

Current accrued legal verdict expense includes an estimate of \$2.8 million that may be owed to the plaintiff as a result of the jury verdict in *Eshelman v. Puma Biotechnology, Inc., et al.* The Company estimates the high end of potential damages in the matter could be approximately \$2.8 million; however, the actual amount of damages payable by the Company is still uncertain and will be ascertained only after completion of the appeal process and subsequent proceedings on remand, and such amount could be greater than the amount of expense already recognized or the high end of the estimate. During the quarter ended June 30, 2021, the Company revised its estimate from \$22.9 million to \$2.8 million, a decrease of \$20.1 million, based on changes in the facts and circumstances surrounding this case and recent developments. The Company continues to classify the accrual as a current liability due to the uncertainty of the timing and amount of the payment. See Part II Item 1. "Legal Proceedings" of this Quarterly Report for a more detailed description of recent developments.

Additionally, current accrued legal verdict expense includes the Company's estimate of \$30.0 million that may be owed to class action participants as a result of the jury verdict in *Hsu v. Puma Biotechnology, Inc., et al.* While the final claims report received in *Hsu* reflects a total of \$50.5 million in claimed damages, the Company intends to challenge these claims and estimates that actual claims could be as low as \$30.0 million. The actual amount and timing of payment of damages in *Hsu* is uncertain and will be ascertained only after an extensive claims challenge process, the completion of post-trial proceedings and the exhaustion of any appeals. During the quarter ended June 30, 2021 the Company revised its estimate from \$24.9 million to \$30.0 million, an increase of \$5.1 million, based on changes in the facts and circumstances surrounding this case and recent developments. The Company continues to classify the accrual as a current liability due to the uncertainty of the timing of the payment. Actual damages in the *Hsu* matter may be higher than the Company's estimate. See Part II Item 1. "Legal Proceedings" of this Quarterly Report for a more detailed description of recent developments.

Other current accrued expenses consist primarily of business license fees, one half of the portion of employer Social Security payroll taxes deferred under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, and other taxes, insurance and marketing fees.

Other long-term accrued expenses consist primarily of one half of the portion of employer Social Security payroll taxes deferred under the CARES Act, accrued compensation and deposit from a sublessee.

All accrued expenses are adjusted in the period the actual costs become known.

Note 10—Debt:

Long term debt consisted of the following (in thousands):

	June 30, 2021	Maturity Date
Total debt	\$ 100,000	June 1, 2024
Accretion of final interest payment	4,051	
Less: current portion of long-term debt	(31,429)	
Less: deferred financing costs	(3,916)	
Total long-term debt, net	<u>\$ 68,706</u>	

Loan and Security Agreement:

On June 28, 2019, or the Effective Date, the Company entered into an amendment and restatement of its loan and security agreement, which provided for a new credit facility, or the New Credit Facility, with Oxford Finance, LLC, or Oxford, as collateral agent, and the lenders party thereto from time to time, including Oxford, pursuant to which the Company repaid its outstanding debt, as well as all applicable exit and prepayment fees, owed to the lenders under its prior credit facility, using cash on hand and \$100.0 million in new borrowings from the New Credit Facility. Under the New Credit Facility, the Company issued to Oxford new and/or replacement secured promissory notes in an aggregate principal amount for all such promissory notes of \$100.0 million evidencing the New Credit Facility. No additional money remains available to the Company under the New Credit Facility.

The New Credit Facility was secured by substantially all of the Company’s personal property other than its intellectual property. The Company also pledged 65% of the issued and outstanding capital stock of its subsidiaries, Puma Biotechnology Ltd. and Puma Biotechnology B.V. The New Credit Facility limited the Company’s ability to grant any interest in its intellectual property to certain permitted licenses and permitted encumbrances set forth in the agreement.

The term loans under the New Credit Facility bore interest at an annual rate equal to the greater of (i) 9.0% and (ii) the sum of (a) the “prime rate,” as reported in The Wall Street Journal on the last business day of the month that immediately preceded the month in which the interest will accrue, plus (b) 3.5%. The Company was required to make monthly interest-only payments on each term loan under the New Credit Facility commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through August 1, 2021, or the Amortization Date. Commencing on the Amortization Date, and continuing on the first calendar day of each calendar month thereafter, the Company would have made consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender under the New Credit Facility, calculated pursuant to the New Credit Facility. All unpaid principal and accrued and unpaid interest with respect to each term loan under the New Credit Facility was due and payable in full on June 1, 2024, or the Maturity Date. Upon repayment of such term loans, the Company was also required to make a final payment to the lenders equal to 7.5% of the aggregate principal amount of such term loans outstanding as of the Effective Date. The effective interest rate as of June 30, 2021 was 12.75%.

At the Company’s option, the Company was able to prepay the outstanding principal balance of any term loan in whole but not in part, subject to a prepayment fee of 3.0% of any amount prepaid if the prepayment occurred through and including the first anniversary of the funding date of such term loan, 2.0% of the amount prepaid if the prepayment occurred after the first anniversary of the funding date of such term loan through and including the second anniversary of the funding date of such term loan, and 1.0% of the amount prepaid if the prepayment occurred after the second anniversary of the funding date of such term loan and prior to the Maturity Date.

The New Credit Facility included affirmative and negative covenants applicable to the Company, its current subsidiaries and any subsidiaries the Company would have created in the future. The affirmative covenants included, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. The Company was also required to achieve certain product revenue targets, measured as of the last day of each fiscal quarter on a trailing year-to-date basis. New minimum revenue

levels were to be established for each subsequent fiscal year by mutual agreement of the Company, Oxford, as collateral agent, and the lenders under the New Credit Facility. The negative covenants included, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The New Credit Facility also included events of default, the occurrence and continuation of which could have caused interest to be charged at the rate that would otherwise have been applicable plus 5.0% and would have provided Oxford, as collateral agent, with the right to exercise remedies against the Company and the collateral securing the New Credit Facility, including foreclosure against the property securing the New Credit Facility, including the Company's cash. These events of default included, among other things, the Company's failure to pay principal or interest due under the New Credit Facility, a breach of certain covenants under the New Credit Facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than \$500,000 and one or more judgments against the Company in an amount greater than \$500,000 individually or in the aggregate that remained unsatisfied, unvacated, or unstayed for a period of 10 days after its entry.

On February 27, 2020, the Company and Oxford amended the New Credit Facility to establish the Company's minimum revenue thresholds for the trailing year-to-date periods ending March 31, June 30, September 30 and December 31, 2020 and the fiscal year 2021. On August 5, 2020 the Company and Oxford amended the New Credit Facility to amend the minimum revenue thresholds for the trailing year-to-date periods ending September 30 and December 31, 2020. On February 3, 2021, the Company and Oxford amended the New Credit Facility to establish the Company's minimum revenue thresholds for the trailing year-to-date periods ending March 31, June 30, September 30 and December 31, 2021.

As of June 30, 2021, there were \$100.0 million in term loans outstanding under the New Credit Facility, representing all of the Company's long-term debt outstanding as of that date, and the Company was in compliance with all applicable covenants under the New Credit Facility.

The future minimum principal payments under the New Credit Facility as of June 30, 2021 were as follows (in thousands):

	<u>Amount</u>
2021 (remaining)	\$ 14,286
2022	34,286
2023	34,286
2024	17,142
Thereafter	—
Total	<u>\$ 100,000</u>

Deferred Financing Costs

Deferred financing costs consisted of the following (in thousands):

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Deferred financing costs	\$ 8,668	\$ 8,668
Less: accumulated amortization	(4,752)	(3,666)
Included in long-term debt	<u>\$ 3,916</u>	<u>\$ 5,002</u>

Deferred financing costs are financing costs related to the Company's outstanding debt. Amortization of debt issuance costs is expensed using the effective interest method and is included in interest expense in the consolidated statement of operations. For the six months ended June 30, 2021 and 2020, the Company recorded approximately \$1.1 million and \$0.9 million, respectively, of interest expense related to the amortization of debt issuance costs in the consolidated statements of operations.

In July 2021, the Company entered into a Note Purchase Agreement with a new lender, and used the gross proceeds of \$100.0 million, along with cash on hand, to retire the entire principal balance outstanding, plus related outstanding interest and early payment fees under the New Credit Facility. See Note 14 – Subsequent Events.

Note 11—Stockholders' Equity:

Common Stock:

The Company issued 0 and 500 shares of common stock upon exercise of stock options during the six months ended June 30, 2021 and 2020, respectively. The Company issued 647,541 and 423,113 shares of common stock upon vesting of RSUs during the six months ended June 30, 2021 and 2020, respectively.

Authorized Shares:

The Company has 100,000,000 shares of stock authorized for issuance, all of which are common stock, par value \$0.0001 per share.

Warrants:

In October 2011, the Company issued an anti-dilutive warrant to Alan Auerbach, the Company's founder and Chief Executive Officer. The warrant was issued to provide Mr. Auerbach with the right to maintain ownership of at least 20% of the Company's common stock in the event that the Company raised capital through the sale of its securities in the future.

In connection with the closing of a public offering in October 2012, the exercise price and number of shares underlying the warrant issued to Mr. Auerbach were established and, accordingly, the final value of the warrant became fixed. Pursuant to the terms of the warrant, Mr. Auerbach may exercise the warrant to acquire 2,116,250 shares of the Company's common stock at \$16 per share until October 4, 2021. On April 1, 2021, the Company's Board of Directors approved an amendment to the terms of the warrant by extending the term until October 4, 2026. The amendment was approved by the Company's stockholders on June 15, 2021.

As a result of this amendment, the Company recorded additional stock-based compensation in the amount of \$13.6 million which was included in selling, general and administrative expense for the three and six months ended June 30, 2021. The fair value of the additional stock-based compensation was estimated using the Black-Scholes Option Pricing Method (see Note 2) with the following assumptions as of June 15, 2021, the date of modification:

Dividend yield	0.0%
Expected volatility	87.0%
Risk-free interest rate	0.8%
Expected life in years	5.31

Stock Options and Restricted Stock Units:

The Company's 2011 Incentive Award Plan, as amended, or the 2011 Plan, was adopted by the Company's Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years and the awards generally vest over a three-year period. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. On April 1, 2021, the Board of Directors adopted an amendment to the 2011 Plan to increase the number of shares of the Company's common stock reserved for issuance thereunder by 2,000,000 shares. The amendment was approved by the Company's stockholders on June 15, 2021. As of June 30, 2021, a total of 14,529,412 shares of the Company's common stock have been reserved for issuance under the 2011 Plan.

All of the options awarded by the Company have been "plain vanilla options" as determined by the SEC Staff Accounting Bulletin 107 - *Share Based Payment*. As of June 30, 2021, 6,159,570 shares of the Company's common stock are issuable upon the exercise of outstanding stock options and vesting of RSUs granted under the 2011 Plan and 3,361,888 shares of the Company's common stock are available for future issuance under the 2011 Plan. The fair value of options granted to employees and nonemployees was estimated using the Black-Scholes Option Pricing Method (see Note 2) with the following weighted-average assumptions used during the six months ended June 30:

	2021	2020
Dividend yield	0.0%	0.0%
Expected volatility	86.7%	102.7%
Risk-free interest rate	0.7%	1.0%
Expected life in years	5.82	5.80

The Company's 2017 Employment Inducement Incentive Award Plan, as amended, or the 2017 Plan, was adopted by the Company's Board of Directors on April 27, 2017. Pursuant to the 2017 Plan, the Company may grant stock options and RSUs, as well as other forms of equity-based compensation to employees, as an inducement to join the Company. The maximum term of stock options granted under the 2017 Plan is 10 years and the awards generally vest over a three-year period. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of such shares on the date of grant. As of June 30, 2021, a total of 2,000,000 shares of the Company's common stock have been reserved for issuance under the 2017 Plan. As of June 30, 2021, 1,158,256 shares of the Company's common stock are issuable upon the exercise of outstanding stock options and vesting of RSUs granted under the 2017 Plan and 358,755 shares of the Company's common stock are available for future issuance under the 2017 Plan.

On July 15, 2021, the Board of Directors adopted an amendment to the 2017 Plan to increase the number of shares of the Company's common stock reserved for issuance thereunder by 1,000,000 shares. See Note 14 – Subsequent Events.

Stock-based compensation expense was as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Stock-based compensation:				
Options -				
Selling, general, and administrative	\$ 964	\$ 963	\$ 1,971	\$ 1,883
Research and development	50	731	279	1,572
Restricted stock units -				
Selling, general, and administrative	2,180	3,767	4,774	7,539
Research and development	1,458	5,169	3,488	8,543
Warrant modification				
Selling, general, and administrative	13,587	-	13,587	-
Total stock-based compensation expense	\$ 18,239	\$ 10,630	\$ 24,099	\$ 19,537

Activity with respect to options granted under the 2011 Plan and 2017 Plan is summarized as follows:

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	5,009,342	\$ 71.42	\$ 3,458
Granted	532,027	\$ 11.71	
Forfeited	(110,183)	\$ 12.66	
Exercised	-		
Expired	(189,439)	\$ 117.98	
Outstanding at June 30, 2021	5,241,747	\$ 64.91	\$ 2,528
Nonvested at June 30, 2021	985,497	\$ 10.93	\$ 388
Exercisable	4,256,250	\$ 77.41	\$ 2,140

At June 30, 2021, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately \$7.0 million, which is expected to be recognized over a weighted-average period of 2.0 years. At June 30, 2021, the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately \$21.8 million, which is expected to be recognized over a weighted-average period of 1.84 years. The weighted-average grant date fair value of options granted during the six months ended June 30, 2021 and 2020 was \$8.32 and \$7.86 per share, respectively. The weighted average grant date fair value of RSUs awarded during the six months ended June 30, 2021 and 2020 was \$11.92 and \$10.61 per share, respectively.

Stock Option Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2020	899,672	\$ 8.71
Granted	532,027	8.32
Forfeited	(110,183)	12.66
Vested/Issued	(336,019)	9.65
Nonvested shares at June 30, 2021	985,497	\$ 8.11

Restricted Stock Unit Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2020	1,854,205	\$ 13.51
Granted	1,257,795	11.92
Vested/Issued	(647,541)	15.56
Forfeited	(388,380)	12.95
Nonvested shares at June 30, 2021	2,076,079	\$ 12.02

Note 12—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately \$1.0 million and \$0.7 million for the six months ended June 30, 2021 and 2020, respectively.

Note 13—Commitments and Contingencies:

Contractual Obligations:

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which the Company cannot reasonably predict future payment. The Company's contractual obligations result primarily from obligations for various contract manufacturing organizations and clinical research organizations, which include potential payments we may be required to make under our agreements. The contracts also contain variable costs and milestones that are hard to predict as they are based on such things as patients enrolled and clinical trial sites. The timing of payments and actual amounts paid under contract manufacturing organization, or CMO, and CRO agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations. Also, those agreements are cancelable upon written notice by the Company and, therefore, not long-term liabilities.

License Agreement:

In August 2011, the Company entered into an agreement pursuant to which Pfizer agreed to grant it a worldwide license for the development, manufacture and commercialization of PB272 neratinib (oral), PB272 neratinib (intravenous) and PB357, and certain related compounds. The license is exclusive with respect to certain patent rights owned by or licensed to Pfizer. Under the agreement, the Company is obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and to use commercially reasonable efforts to complete clinical trials and to achieve certain milestones as provided in a development plan. From the closing date of the agreement through December 31, 2011, Pfizer continued to conduct the existing clinical trials on behalf of the Company at Pfizer's sole expense. At the Company's request, Pfizer has agreed to continue to perform certain services in support of the existing clinical trials at the Company's expense. These services will continue through the completion of the transitioned clinical trials. The license agreement "capped" the out of pocket expense the Company would incur to complete the then existing clinical trials. All agreed upon costs incurred by the Company above the "cost cap" would be reimbursed by Pfizer. The Company exceeded the "cost cap" during the fourth quarter of 2012. In accordance with the license agreement, the Company billed Pfizer for agreed upon costs above the "cost cap" until December 31, 2013.

On July 18, 2014, the Company entered into an amendment to the license agreement with Pfizer. The amendment amends the agreement to (1) reduce the royalty rate payable by the Company to Pfizer on sales of licensed products; (2) release Pfizer from its obligation to pay for certain out-of-pocket costs incurred or accrued on or after January 1, 2014 to complete certain ongoing clinical studies; and (3) provide that Pfizer and the Company will continue to cooperate to effect the transfer to the Company of certain records, regulatory filings, materials and inventory controlled by Pfizer as promptly as reasonably practicable.

As consideration for the license, the Company is required to make substantial payments upon the achievement of certain milestones totaling approximately \$187.5 million if all such milestones are achieved. In connection with the FDA approval of NERLYNX in July of 2017, the Company triggered a one-time milestone payment pursuant to the agreement. In June 2020, the Company entered into a letter agreement, or the Letter Agreement, with Pfizer relating to the method of payment associated with a one-time milestone payment under the license agreement with Pfizer. The Letter Agreement permits the Company to make the milestone payment in installments with the remaining amount payable to Pfizer (including interest) to be made in September 2021 for approximately \$21.9 million. Unpaid portions of the milestone payment will accrue interest at 6.25% per annum until paid. The installment payments and accrued interest are included in accrued in-licensed rights on the accompanying consolidated balance sheets. The Company may trigger additional milestone payments in the future. Should the Company commercialize any more of the compounds licensed from Pfizer or any products containing any of these compounds, the Company will be obligated to pay to Pfizer annual royalties at a fixed rate in the low-to-mid teens of net sales of all such products, subject to certain reductions and offsets in some circumstances. The Company's royalty obligation continues, on a product-by-product and country-by-country basis, until the later of (1) the last to expire licensed patent covering the applicable licensed product in such country, or (2) the earlier of generic competition for such licensed product reaching a certain level in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that the Company sublicenses the rights granted to the Company under the license agreement with Pfizer to a third party, the same milestone and royalty payments are required. The Company can terminate the license agreement at will, or for safety concerns, in each case upon specified advance notice.

Legal Proceedings

The Company and certain of its executive officers were named as defendants in the lawsuits detailed in Part II Item 1. "Legal Proceedings" of this Quarterly Report. The Company records a liability in the consolidated financial statements for loss contingencies when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. When determining the estimated loss or range of loss, significant judgment is required to estimate the amount and timing of a loss to be recorded.

Note 14—Subsequent Events:

Note Purchase Agreement

On July 23, 2021, or the NPA Effective Date, the Company repaid the \$100.0 million in term loans outstanding under its prior credit facility, as well as all accrued interest, applicable exit, prepayment and legal fees owed to the lenders under its prior credit facility in an amount of approximately \$9.2 million, using cash on hand and \$100.0 million in new borrowings from the issuance of notes under the note purchase agreement, or the Note Purchase Agreement, that the Company entered into on the NPA Effective Date with Athyrium Opportunities IV Co-Invest I LP, or, together with its affiliates, Athyrium, as administrative agent, and the purchasers party thereto from time to time, or the Purchasers, including Athyrium. Additionally, the Company wrote off approximately \$3.9 million in deferred financing costs associated with its prior credit facility as a result of the transaction in July 2021.

Pursuant to the Note Purchase Agreement, the Purchasers agreed to purchase from the Company, and the Company agreed to issue to such Purchasers, notes payable by the Company. On the NPA Effective Date, the Company issued to the Purchasers notes in an aggregate principal amount for all such notes of \$100.0 million. Subject to satisfaction of certain conditions set forth in the Note Purchase Agreement, \$25.0 million in additional notes remains available to the Company under the Note Purchase Agreement.

The obligations of the Company under the Note Purchase Agreement are secured by substantially all of the Company's assets, including its intellectual property. The Company also pledged 65% of the issued and outstanding capital stock of its subsidiaries, Puma Biotechnology Ltd. and Puma Biotechnology B.V.

The notes issued under the Note Purchase Agreement bear interest at an annual rate equal to the sum of (a) 8.0% and (b) Adjusted Three-Month LIBOR for such Interest Period (as defined in the Note Purchase Agreement). The Company is required to make quarterly interest payments on each note issued under the Note Purchase Agreement commencing on the last business day of September 2021 and continuing on the last business day of each March, June, September and December through June 30, 2024, or the NPA Amortization Date. Commencing on the NPA Amortization Date, and continuing on the last day of each March, June,

September and December thereafter, the Company will make consecutive equal quarterly payments of principal, together with applicable interest, in arrears to each Purchaser, calculated pursuant to the Note Purchase Agreement. All unpaid principal and accrued and unpaid interest with respect to each note issued under the Note Purchase Agreement is due and payable in full on July 23, 2026, or the NPA Maturity Date. At the Company's option, the Company may prepay the outstanding principal balance of all or any portion of the principal amount of the notes, subject to a prepayment fee equal to (i) a make-whole amount if the prepayment occurs on or prior to the second anniversary of the NPA Effective Date and (ii) 2.0% of the amount prepaid if the prepayment occurs after the second anniversary of the NPA Effective Date by on or prior to the third anniversary of the NPA Effective Date. Upon prepayment or repayment of all or any portion of the principal amount of the notes (whether on the NPA Maturity Date or otherwise), the Company is also required to pay an exit fee to the Purchasers equal to 2.00% of the aggregate principal amount of such notes prepaid or repaid.

The Note Purchase Agreement includes affirmative and negative covenants applicable to the Company, its current subsidiaries, and any subsidiaries the Company creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. The Company must also (i) maintain a minimum amount of unrestricted cash in deposit accounts subject to a control agreement in favor of Athyrium at any time and (ii) achieve at least a specified minimum amount of revenue (based on a combination of both sales of NERLYNX in the United States and royalty revenues received by the Company for sales of NERLYNX outside the United States), measured as of the last day of each four consecutive fiscal quarter period. The negative covenants include, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The Note Purchase Agreement also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 2.0% and would provide Athyrium, as administrative agent, with the right to exercise remedies against the Company and the collateral securing the new credit facility, including foreclosure against the property securing the obligations of the Company under the Note Purchase Agreement, including its cash. These events of default include, among other things, the Company's failure to pay principal or interest due under the Note Purchase Agreement, a breach of certain covenants under the Note Purchase Agreement, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than \$750,000 and one or more judgments against the Company in an amount greater than \$750,000 individually or in the aggregate that remains discharged or otherwise satisfied, in each case, as further described in the Note Purchase Agreement.

The foregoing description of the Note Purchase Agreement and the notes is only a summary of the material terms thereof, and does not purport to be complete. The description is qualified in its entirety by reference to the Note Purchase Agreement and the form of note, which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2021.

2017 Plan Amendment

On July 15, 2021, the Company's Board of Directors adopted an amendment to the 2017 Plan to increase the number of shares of the Company's common stock reserved for issuance thereunder by 1,000,000 shares.

Item 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes thereto included in Item 1 in this Quarterly Report on Form 10-Q, or this Quarterly Report. The following discussion should also be read in conjunction with our audited consolidated financial statements and the notes thereto and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Unless otherwise provided in this Quarterly Report, references to the “Company,” “we,” “us,” and “our” refer to Puma Biotechnology, Inc., a Delaware corporation, together with its wholly owned subsidiaries.

Overview

We are a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. We in-license from Pfizer, Inc., or Pfizer, the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor, or TKI, that blocks signal transduction through the human epidermal growth factor receptors, HER1, HER2 and HER4. Currently, we are primarily focused on the development and commercialization of the oral version of neratinib, and our most advanced drug candidates are directed at the treatment of HER2-positive breast cancer and HER2 mutated cancers. We believe neratinib has clinical application in the treatment of several other cancers as well, including other tumor types that over-express or have a mutation in HER2 or EGFR, such as breast cancer, cervical cancer, lung cancer or other solid tumors.

Prior to 2017, our efforts and resources had been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. In 2017, the U.S. Food and Drug Administration, or FDA, approved NERLYNX, formally known as PB272 (neratinib, oral), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. 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. In 2018, the European Commission, or EC, granted marketing authorization for NERLYNX in the European Union 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.

We have entered into exclusive sub-license agreements with various parties to pursue regulatory approval, if necessary, and commercialize NERLYNX, if approved, in numerous regions outside the United States, including Europe (excluding Russia and Ukraine), Australia, Canada, China, Southeast Asia, Israel, Mexico, South Korea, and various countries and territories in Central and South America. We plan to continue to pursue commercialization of NERLYNX in other countries outside the United States, if approved.

During the three months ended June 30, 2021, Puma received FDA approval for an alternate dosing regimen (two-week dose escalation) to be incorporated into the U.S. prescribing information. In addition, the FDA approved the commercial distribution of a new SKU (133 count) to support use of this regimen. In June 2021, the Company’s Canadian partner, Knight Therapeutics, Inc., received Health Canada’s approval of NERLYNX 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.

Our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure and, since 2017, the commercial launch of NERLYNX. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance product development. To date, our major sources of working capital have been proceeds from product and license revenue, public offerings of our common stock, proceeds from our credit facility and sales of our common stock in private placements.

Impact of COVID-19

Our priorities during the COVID-19 pandemic continue to be focused on protecting the health and safety of our employees while delivering on our mission to develop and commercialize innovative products to enhance cancer care. Substantially all geographic regions in which our U.S. sales force operates have imposed restrictions and may in the future change or impose additional restrictions to control or limit the spread of COVID-19 and its variants. These restrictions include, but are not limited to “shelter-in-place” orders, quarantines, testing requirements or similar orders or restrictions. These types of restrictions may deter or prevent cancer patients from traveling to see their doctors and result in a decline in revenue for NERLYNX, our only commercial product. Additionally, the impact of COVID-19 has significantly reduced the ability of our commercial team and our sales force to travel and interact personally with physicians and members of the extended healthcare team. This has reduced our commercial team’s access to

healthcare providers, and a large portion of its promotional activities are now being conducted virtually. Although we have seen some recent easing of local restrictions, these have been inconsistent and have not led to a broad relaxation of requirements. These types of restrictions have adversely impacted our ability to engage with our customers and have adversely impacted sales of NERLYNX, and they may continue to do so. The respective commercial teams affiliated with certain companies to which we sub-license the commercial rights to NERLYNX, and on which we rely for our international sales, have chosen or have been forced to take similar action, and other sub-licensees of NERLYNX may choose or be forced to take similar action in the future. Furthermore, the COVID-19 pandemic has resulted in dramatic increases in unemployment rates, which may result in a substantial number of people becoming uninsured or underinsured. Any of these developments may have an adverse effect on our revenue. We have observed disruptions in patient enrollments in the United States and in our Phase II SUMMIT basket trial. If the COVID-19 pandemic continues to spread in the geographies in which we are conducting clinical trials, we may experience additional disruptions in those clinical trials, which could have a material adverse impact on our clinical trial plans and timelines.

Our ability to continue to operate without any significant negative impacts will in part depend on the length and severity of the COVID-19 pandemic and our ability to protect our employees and our supply chain. We continue to follow and monitor recommended actions of government and health authorities to protect our employees worldwide. For the six months ended June 30, 2021, we and our key third-party suppliers and manufacturers were able to broadly maintain operations. We rely exclusively on third-party manufacturers to manufacture NERLYNX.

We intend to satisfy our near-term liquidity requirements through a combination of our existing cash and cash equivalents and marketable securities as of June 30, 2021 and proceeds that will become available to us through product sales, royalties and sub-license milestone payments. However, this intention is based on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities, the impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. Some of these developments have had and may continue to have an adverse effect on our revenue and thus could have an adverse effect on our ability to satisfy the minimum revenue covenants in our Note Purchase Agreement.

Critical Accounting Policies

As of the date of the filing of this Quarterly Report, we believe there have been no material changes to our critical accounting policies and estimates during the six months ended June 30, 2021 from our accounting policies at December 31, 2020, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020. We accounted for the following related to sub-license agreements during the six months ended June 30, 2021:

License Revenue:

We recognize license revenue under certain of our sub-license agreements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. We evaluate these agreements under ASC 606 to determine the distinct performance obligations. Non-refundable, up-front fees that are not contingent on any future performance and require no consequential continuing involvement by us, are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. We defer recognition of non-refundable upfront license fees if the performance obligations are not satisfied.

Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include nonrefundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from the collaboration.

If there are multiple distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on its relative standalone selling price. The standalone selling price is generally determined based on the prices charged to customers or using expected cost-plus margin. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations.

Legal Contingencies and Expense:

For legal contingencies, we accrue a liability for an estimated loss if the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated. Legal fees and expenses are expensed as incurred based on invoices or estimates provided by legal counsel. We periodically evaluate available information, both internal and external, relative to such contingencies and adjust the accrual as necessary. We determine whether a contingency should be disclosed by assessing whether a

material loss is deemed reasonably possible. In determining whether a loss should be accrued, we evaluate, among other factors, the degree of probability of an unfavorable outcome and the ability to make a reasonable estimate of the amount of the loss (see Note 13-Commitments and Contingencies in the accompanying notes to the financial statements).

Summary of Income and Expenses

Product revenue, net:

Product revenue, net consists of revenue from sales of NERLYNX. We sell NERLYNX to a limited number of specialty pharmacies and specialty distributors in the United States. We record revenue at the net sales price, which includes an estimate for variable consideration for which reserves are established. Variable consideration consists of trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates and other incentives.

License revenue:

License revenue consists of consideration earned for performance obligations satisfied pursuant to our sub-license agreements.

Royalty revenue:

Royalty revenue consists of consideration earned related to product sales made by our sub-licensees in their respective territories pursuant to our sub-license agreements.

Cost of sales:

Cost of sales consists of third-party manufacturing costs, freight, and indirect overhead costs associated with sales of NERLYNX. Cost of sales also includes period costs related to royalty charges payable to Pfizer, the amortization of milestone payments made to Pfizer, certain inventory manufacturing services, inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Selling, general and administrative expenses:

Selling, general and administrative expenses, or SG&A Expenses, consist primarily of salaries and payroll-related costs, stock-based compensation expense, professional fees, business insurance, rent, general legal activities, credit loss expense and other corporate expenses. We expense SG&A Expenses as they are incurred.

Research and development expenses:

Research and development expenses, or R&D Expenses, include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for the manufacturing of clinical materials and clinical trials. During the three and six months ended June 30, 2021 and 2020, our R&D Expenses consisted primarily of clinical research organization, or CRO, fees; fees paid to consultants; salaries and related personnel costs; and stock-based compensation. We expense our R&D Expenses as they are incurred. Internal R&D Expenses primarily consist of payroll-related costs and also include equipment costs, travel expenses and supplies.

Results of Operations

Three Months Ended June 30, 2021 Compared to Three Months Ended June 30, 2020

Total revenue:

For the three months ended June 30, 2021, total revenue was approximately \$53.4 million, compared to \$70.6 million for the three months ended June 30, 2020.

Product revenue, net:

Product revenue, net was approximately \$48.9 million for the three months ended June 30, 2021, compared to \$48.8 million for the three months ended June 30, 2020. The increase in product revenue, net was primarily attributable to an increase in gross selling price that occurred in the third quarter of 2020 and in the first quarter of 2021; offset by a volume decrease of approximately 10.0% in bottles of NERLYNX sold, and an increase in reserves for variable consideration from approximately 14.4% of product revenue, net for the three months ended June 30, 2020 to approximately 17.7% of product revenue, net for the three months ended

June 30, 2021. The increase in reserves for variable consideration is primarily due to an increase in Medicaid claims and government chargebacks as a percentage of gross revenue.

License revenue:

License revenue was approximately \$0.3 million for the three months ended June 30, 2021, compared to approximately \$20.7 million for the three months ended June 30, 2020. During the three months ended June 30, 2020, the Company recognized one-time license revenue of \$20.7 million for an upfront payment and for satisfaction of two performance-based milestones related to sub-license agreements.

Royalty revenue:

Royalty revenue was approximately \$4.3 million for the three months ended June 30, 2021, compared to \$1.1 million for the three months ended June 30, 2020. The increase was due to increased product sales by our sub-licensees as they continue to commercialize NERLYNX in additional territories.

Cost of sales:

Cost of sales was approximately \$12.0 million for the three months ended June 30, 2021, compared to \$9.4 million for the three months ended June 30, 2020. The increase was primarily attributable to the increase in the amortization of the intangible asset under our license agreement with Pfizer and increased royalty expense due to Pfizer.

Selling, general and administrative expenses:

For the three months ended June 30, 2021, SG&A Expenses were approximately \$39.4 million, compared to approximately \$29.3 million for the three months ended June 30, 2020. SG&A Expenses for the three months ended June 30, 2021 and 2020 were as follows:

(in thousands)	June 30,		\$	%
	2021	2020	2021/2020	2021/2020
Payroll and related costs	\$ 10,088	\$ 10,817	\$ (729)	-6.7%
Professional fees and expenses	9,633	10,551	(918)	-8.7%
Travel and meetings	1,030	517	513	99.2%
Facilities and equipment costs	1,401	1,427	(26)	-1.8%
Stock-based compensation	16,731	4,730	12,001	253.7%
Other	527	1,305	(778)	-59.6%
	\$ 39,410	\$ 29,347	\$ 10,063	34.3%

For the three months ended June 30, 2021, SG&A Expenses increased by approximately \$10.1 million compared to the same period in 2020, primarily attributable to the following:

- an increase in stock-based compensation expense of approximately \$12.0 million primarily due to the \$13.6 million incremental expense resulting from the modification to the term of Mr. Auerbach's warrant and approximately \$1.2 million from new grants, partially offset by the decrease of approximately \$2.2 million for stock awards that have fully vested and a decrease of approximately \$0.6 million from stock awards forfeited; and
- an increase in travel and meetings of approximately \$0.5 million as some travel restrictions due to the COVID-19 pandemic have been lifted.

These increases were partially offset by:

- a decrease in professional fees and expenses of approximately \$0.9 million, consisting primarily of a decrease of approximately \$1.1 million for professional fees, primarily related to decreased consultancy efforts related to marketing and commercialization support, partially offset by an increase of approximately \$0.2 million in insurance premiums and legal fees in connection with various lawsuits;
- a decrease in other expenses of \$0.8 million due to lower bad debt expenses, partially offset by higher sponsorship fees; and
- a decrease in payroll and related costs of approximately \$0.7 million.

Research and development expenses:

For the three months ended June 30, 2021, R&D Expenses were approximately \$18.6 million, compared to approximately \$24.7 million for the three months ended June 30, 2020. R&D Expenses for the three months ended June 30, 2021 and 2020 were as follows:

Research and development expenses (in thousands)	For the Three Months Ended		Change	
	June 30,		\$	%
	2021	2020	2021/2020	2021/2020
Clinical trial expense	\$ 6,982	\$ 7,062	\$ (80)	-1.1%
Internal R&D	8,209	9,894	(1,685)	-17.0%
Consultant and contractors	1,940	1,835	105	5.7%
Stock-based compensation	1,507	5,900	(4,393)	-74.5%
	<u>\$ 18,638</u>	<u>\$ 24,691</u>	<u>\$ (6,053)</u>	<u>-24.5%</u>

For the three months ended June 30, 2021, R&D Expenses decreased by approximately \$6.1 million compared to the same period in 2020, primarily attributable to the following:

- a decrease in stock-based compensation expense of approximately \$4.4 million, primarily due to a decrease of approximately \$3.8 million for stock awards that fully vested and a decrease of approximately \$1.1 million from stock award forfeitures, partially offset by an increase of approximately \$0.5 million from new grants and other immaterial fluctuations; and
- a decrease in Internal R&D of approximately \$1.7 million, primarily due to a decrease in payroll and payroll-related expenses as a result of a reduction in headcount

Other income (expenses):

Other income (expenses) (in thousands)	For the Three Months Ended		Change	
	June 30,		\$	%
	2021	2020	2021/2020	2021/2020
Interest income	\$ 121	\$ 66	\$ 55	83.3%
Interest expense	(3,518)	(3,784)	266	-7.0%
Legal verdict (expense) credit	14,902	(93)	14,995	-16123.7%
Other income	60	77	(17)	-22.1%
	<u>\$ 11,565</u>	<u>\$ (3,734)</u>	<u>\$ 15,299</u>	<u>-409.7%</u>

Interest expense:

For the three months ended June 30, 2021, we recognized approximately \$3.5 million in interest expense, compared to \$3.8 million of interest expense for the three months ended June 30, 2020. The decrease in interest expense was primarily the result of the interest expense for the milestone payments being paid to Pfizer in installments.

Legal verdict (expense) credit:

For the three months ended June 30, 2021, we reduced our legal expense accrual by \$20.0 million with respect to the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment, and we increased our legal expense accrual by \$5.1 million with respect to the *Hsu v. Puma Biotechnology, Inc., et al.* judgment, which resulted in a \$14.9 million net credit in legal verdict expense for the period.

Six Months Ended June 30, 2021 Compared to Six Months Ended June 30, 2020

Total revenue:

For the six months ended June 30, 2021, total revenue was approximately \$151.6 million, compared to \$121.8 million for the six months ended June 30, 2020.

Product revenue, net:

Product revenue, net was approximately \$94.7 million for the six months ended June 30, 2021, compared to \$97.4 million for the six months ended June 30, 2020. The decrease in product revenue, net was attributable to a volume decrease of approximately

15.0% in bottles of NERLYNX sold, and an increase in reserves for variable consideration from approximately 15.3% of product revenue for the six months ended June 30, 2020 to approximately 18.3% of product revenue for the six months ended June 30, 2021. The increase in reserves for variable consideration is primarily due to an increase in Medicaid claims and government chargebacks as a percentage of gross revenue. The decrease in product revenue, net was partially offset by an increase in gross selling price that occurred in the third quarter of 2020 and in the first quarter of 2021.

License revenue:

License revenue was approximately \$50.3 million for the six months ended June 30, 2021, compared to approximately \$22.7 million for the six months ended June 30, 2020. The increase in license revenue is due to a large, upfront payment in connection with an amendment to a sub-license agreement entered into during the six months ended June 30, 2021.

Royalty revenue:

Royalty revenue was approximately \$6.6 million for the six months ended June 30, 2021, compared to \$1.7 million for the six months ended June 30, 2020. The increase was due to increased product sales by our sub-licensees as they continue to commercialize NERLYNX in additional territories.

Cost of sales:

Cost of sales was approximately \$41.5 million for the six months ended June 30, 2021, compared to \$18.5 million for the six months ended June 30, 2020. The increase in cost of sales was primarily attributable to a one-time license termination fee, the increase in the amortization of the intangible asset under our license agreement with Pfizer and increased royalty expense due to Pfizer.

Selling, general and administrative expenses:

For the six months ended June 30, 2021, SG&A Expenses were approximately \$67.7 million, compared to approximately \$60.3 million for the six months ended June 30, 2020. SG&A Expenses for the six months ended June 30, 2021 and 2020 were as follows:

Selling, general, and administrative expenses (in thousands)	For the Six Months Ended		Change	
	June 30,		\$	%
	2021	2020	2021/2020	2021/2020
Payroll and related costs	\$ 20,599	\$ 21,384	\$ (785)	-3.7%
Professional fees and expenses	20,416	20,981	(565)	-2.7%
Travel and meetings	2,042	2,933	(891)	-30.4%
Facilities and equipment costs	2,795	2,864	(69)	-2.4%
Stock-based compensation	20,333	9,422	10,911	115.8%
Other	1,563	2,700	(1,137)	-42.1%
	<u>\$ 67,748</u>	<u>\$ 60,284</u>	<u>\$ 7,464</u>	<u>12.4%</u>

For the six months ended June 30, 2021, SG&A Expenses increased by approximately \$7.5 million compared to the same period in 2020, primarily attributable to the following:

- an increase in stock-based compensation expense of approximately \$10.9 million primarily due to the \$13.6 million incremental expense resulting from the modification to the term of Mr. Auerbach's warrant and an increase of \$2.6 million from new grants, partially offset by a decrease of approximately \$4.2 million for stock awards that have fully vested and a decrease of approximately \$1.1 million from stock awards forfeited.

This increase was partially offset by:

- a decrease in other expense of \$1.1 million due to lower sponsorships, software, educational and training costs for the commercial team;
- a decrease in travel and meetings of approximately \$0.9 million related to travel restrictions due to the COVID-19 pandemic;
- a decrease in payroll and related costs of approximately \$0.8 million; and

- a decrease in professional fees and expenses of approximately \$0.6 million, consisting primarily of decreases of approximately \$1.8 million for professional fees, primarily related to decreased consultancy efforts related to marketing and commercialization support and lower audit and IT related expenses of \$0.2 million, partially offset by an increase of approximately \$0.1 million in insurance premiums and an increase of approximately \$1.1 million in legal fees in connection with various lawsuits.

Research and development expenses:

For the six months ended June 30, 2021, R&D expenses were approximately \$38.9 million, compared to approximately \$50.1 million for the six months ended June 30, 2020. R&D expenses for the six months ended June 30, 2021 and 2020 were as follows:

Research and development expenses (in thousands)	For the Six Months Ended		Change	
	June 30,		\$	%
	2021	2020	2021/2020	2021/2020
Clinical trial expense	\$ 13,108	\$ 15,873	\$ (2,765)	-17.4%
Internal R&D	18,469	20,123	(1,654)	-8.2%
Consultant and contractors	3,523	4,035	(512)	-12.7%
Stock-based compensation	3,766	10,115	(6,349)	-62.8%
	<u>\$ 38,866</u>	<u>\$ 50,146</u>	<u>\$ (11,280)</u>	<u>-22.5%</u>

For the six months ended June 30, 2021, R&D Expenses decreased by approximately \$11.3 million compared to the same period in 2020, primarily attributable to the following:

- a decrease in stock-based compensation expense of approximately \$6.3 million, primarily due to a decrease of approximately \$6.3 million for stock awards that fully vested and a decrease of approximately \$1.0 million from stock award forfeitures, partially offset by an increase of approximately \$1.0 million from new grants and other immaterial fluctuations;
- a decrease in clinical trial expenses of approximately \$2.8 million, primarily due to the close out of certain clinical trials, and a reduction in enrollments and patient on studies for open studies;
- a decrease in internal R&D expense of approximately \$1.7 million, primarily due to a decrease in payroll and payroll-related expenses; and
- a decrease in consultant and contractor expenses of approximately \$0.5 million, primarily due to the close out of certain clinical trials.

Other income (expenses):

Other income (expenses) (in thousands)	For the Six Months Ended		Change	
	June 30,		\$	%
	2021	2020	2021/2020	2021/2020
Interest income	\$ 134	\$ 452	\$ (318)	-70.4%
Interest expense	(6,968)	(6,852)	(116)	1.7%
Legal verdict (expense) credit	14,717	(186)	14,903	-8012.4%
Other income	102	170	(68)	-40.0%
	<u>\$ 7,985</u>	<u>\$ (6,416)</u>	<u>\$ 14,401</u>	<u>-224.5%</u>

Interest income:

For the six months ended June 30, 2021, interest income decreased by approximately \$0.3 million compared to the six months ended June 30, 2020. The decrease in interest income reflects less cash invested in money market accounts and high-yield savings accounts in 2021 compared to 2020.

Interest expense:

For the six months ended June 30, 2021, we recognized approximately \$7.0 million in interest expense, compared to \$6.9 million of interest expense for the six months ended June 30, 2020.

Legal verdict (expense) credit:

For the six months ended June 30, 2021, we reduced our legal expense accrual by \$20.0 million with respect to the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment, and we increased our legal expense accrual by \$5.3 million with respect to the *Hsu v. Puma Biotechnology, Inc., et al.* judgment, which resulted in a \$14.7 million net credit in legal verdict expense for the period.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2021 and December 31, 2020, and for the six months ended June 30, 2021 and 2020, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	As of June 30, 2021	As of December 31, 2020
Cash and cash equivalents	\$ 89,848	\$ 85,293
Marketable securities	\$ 19,127	\$ 8,096
Working capital	\$ 29,851	\$ 31,884
Stockholders' equity (deficit)	\$ 29,469	\$ (5,951)

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Cash provided by (used in):		
Operating activities	\$ 15,587	\$ 4,688
Investing activities	(11,032)	25,158
Financing activities	—	2
Net increase in cash, cash equivalents and restricted cash	\$ 4,555	\$ 29,848

Operating Activities:

For the six months ended June 30, 2021, we reported net income of approximately \$11.3 million, compared to a net loss of approximately \$13.5 million for the same period in 2020. Additionally, cash provided by operating activities for the six months ended June 30, 2021 was approximately \$15.6 million compared to approximately \$4.7 million of cash provided by operating activities for the same period in 2020.

Cash provided by operating activities for the six months ended June 30, 2021 consisted of net income of approximately \$11.3 million, an increase in accrued expenses and other of approximately \$18.5 million, an increase in inventory of approximately \$4.2 million, an increase in accounts receivable, net of approximately \$4.0 million, an increase of approximately \$1.2 million in accounts payable and in other immaterial fluctuations, and an increase of \$1.0 million due to a recovery of credit loss expense; partially offset by a decrease of approximately \$30.0 million of non-cash items, such as stock-based compensation and depreciation and amortization, and a decrease in other current assets of approximately \$3.2 million.

Cash provided by operating activities for the six months ended June 30, 2020 consisted of a net loss of approximately \$13.5 million, offset by approximately \$23.7 million of non-cash items, such as stock-based compensation and depreciation and amortization, a decrease in accounts receivable, net of approximately \$4.9 million, and other immaterial changes of \$0.1 million; partially offset by an increase in other current assets of approximately \$3.1 million and a decrease in accounts payable of approximately \$7.4 million.

Investing Activities:

During the six months ended June 30, 2021, cash used in investing activities was approximately \$11.0 million, compared to net cash provided by investing activities of \$25.2 million for the same period in 2020.

Cash used in investing activities during the six months ended June 30, 2021 consisted of approximately \$19.1 million of available-for-sale securities, partially offset by maturities of approximately \$8.1 million of available-for-sale securities.

Net cash provided by investing activities during the six months ended June 30, 2020 consisted of approximately \$51.5 million of maturities of available-for-sale securities, partially offset by the purchase of available for sale securities of approximately \$16.4 million and an increase in intangible assets relating to the milestone achieved under the Company's license agreement with Pfizer of \$10.0 million.

Financing Activities:

During the six months ended June 30, 2021, and the same period in 2020, cash was materially unchanged by financing activities. However, during April 2020, we borrowed and fully repaid approximately \$8.4 million with no penalty or interest from Silicon Valley Bank, or SVB, under the Paycheck Protection Program, or PPP, of the Coronavirus Aid, Relief, and Economic Security Act.

Loan and Security Agreement:

In October 2017, we entered into a loan and security agreement with SVB, as administrative agent, and the lenders party thereto from time to time, or the Original Lenders, including Oxford Finance, LLC, or Oxford, and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement, or the Original Credit Facility, we borrowed \$50.0 million. In May 2018, we entered into an amendment to the loan and security agreement, which provided for an amended credit facility, or the Amended Credit Facility. Under the Amended Credit Facility, the Original Lenders agreed to make term loans available to us in an aggregate amount of \$155.0 million, consisting of (i) an aggregate amount of \$125.0 million, the proceeds of which, in part, were used to repay the \$50.0 million we borrowed under the Original Credit Facility, and (ii) an aggregate amount of \$30.0 million that we drew in December 2018, which was available under the Amended Credit Facility as a result of achieving a specified minimum revenue milestone.

On June 28, 2019, or the Effective Date, we entered into an amendment and restatement of the loan and security agreement, which provided for a new credit facility, or the New Credit Facility, with Oxford, as collateral agent, and the lenders party thereto from time to time, including Oxford, pursuant to which we repaid the \$155.0 million outstanding under the Amended Credit Facility, as well as all applicable exit and prepayment fees, owed to the Original Lenders under the Amended Credit Facility, using cash on hand and \$100.0 million in new borrowings from the New Credit Facility. Under the New Credit Facility, we issued to Oxford new and/or replacement secured promissory notes in an aggregate principal amount for all such promissory notes of \$100.0 million evidencing the New Credit Facility. No additional money remains available to us under the New Credit Facility.

The New Credit Facility was secured by substantially all of our personal property other than our intellectual property. We also pledged 65% of the issued and outstanding capital stock of our subsidiaries, Puma Biotechnology Ltd. and Puma Biotechnology B.V. The New Credit Facility limited our ability to grant any interest in our intellectual property to certain permitted licenses and permitted encumbrances set forth in the agreement.

The term loans under the New Credit Facility bore interest at an annual rate equal to the greater of (i) 9.0% and (ii) the sum of (a) the “prime rate,” as reported in The Wall Street Journal on the last business day of the month that immediately preceded the month in which the interest will accrue, plus (b) 3.5%. We were required to make monthly interest-only payments on each term loan under the New Credit Facility commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through August 1, 2021, or the Amortization Date. Commencing on the Amortization Date, and continuing on the first calendar day of each calendar month thereafter, we would have made consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender under the New Credit Facility, calculated pursuant to the New Credit Facility. All unpaid principal and accrued and unpaid interest with respect to each term loan under the New Credit Facility was due and payable in full on June 1, 2024, or the Maturity Date. Upon repayment of such term loans, we were also required to make a final payment to the lenders equal to 7.5% of the aggregate principal amount of such term loans outstanding as of the Effective Date. The effective interest rate as of June 30, 2021 was 12.75%.

At our option, we were able to prepay the outstanding principal balance of any term loan in whole but not in part, subject to a prepayment fee of 3.0% of any amount prepaid if the prepayment occurred through and including the first anniversary of the funding date of such term loan, 2.0% of the amount prepaid if the prepayment occurred after the first anniversary of the funding date of such term loan through and including the second anniversary of the funding date of such term loan, and 1.0% of the amount prepaid if the prepayment occurred after the second anniversary of the funding date of such term loan and prior to the Maturity Date.

The New Credit Facility included affirmative and negative covenants applicable to us, our current subsidiaries and any subsidiaries we would have created in the future. The affirmative covenants included, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. We were also required to achieve certain product revenue targets, measured as of the last day of each fiscal quarter on a trailing year-to-date basis. New minimum revenue levels were to be established for each subsequent fiscal year by mutual agreement of us, Oxford, as collateral agent, and the lenders under the New Credit Facility. The negative covenants included, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The New Credit Facility also included events of default, the occurrence and continuation of which could have caused interest to be charged at the rate that would otherwise have been applicable plus 5.0% and would have provided Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the New Credit Facility, including foreclosure against the property securing the New Credit Facility, including our cash. These events of default included, among other things, our failure to pay principal or interest due under the New Credit Facility, a breach of certain covenants under the New Credit Facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than \$500,000 and one or more judgments against us in an amount greater than \$500,000 individually or in the aggregate that remained unsatisfied, unvacated, or unstayed for a period of 10 days after its entry.

On February 27, 2020, we entered into an amendment of the New Credit Facility with Oxford to establish our minimum revenue thresholds for the trailing year to date periods ending March 31, June 30, September 30, and December 31, 2020 and the fiscal year 2021. On August 5, 2020, we entered into an amendment of the New Credit Facility with Oxford to amend the minimum revenue thresholds for the trailing year to date periods ending September 30 and December 31, 2020. On February 3, 2021, we entered into an amendment of the New Credit Facility with Oxford to establish our minimum revenue thresholds for the trailing year to date periods ending March 31, June 30, September 30 and December 31, 2021.

As of June 30, 2021, there were \$100.0 million in term loans outstanding under the New Credit Facility, representing all of our long-term debt outstanding as of that date, and we were in compliance with all applicable covenants under the New Credit Facility.

Note Purchase Agreement:

On July 23, 2021, or the NPA Effective Date, we repaid the \$100.0 million in term loans outstanding under the New Credit Facility, as well as all accrued interest, applicable exit, prepayment and legal fees owed to the lenders under the New Credit Facility in an amount of approximately \$9.2 million, using cash on hand and \$100.0 million in new borrowings from the issuance of notes under the note purchase agreement, or the Note Purchase Agreement, that we entered into on the NPA Effective Date with Athyrium Opportunities IV Co-Invest 1 LP, or, together with its affiliates, Athyrium, as administrative agent, and the purchasers party thereto from time to time, or the Purchasers, including Athyrium.

Pursuant to the Note Purchase Agreement, the Purchasers agreed to purchase from us, and we agreed to issue to such Purchasers, notes payable by us. On the NPA Effective Date, we issued to the Purchasers notes in an aggregate principal amount for all such notes of \$100.0 million. Subject to satisfaction of certain conditions set forth in the Note Purchase Agreement, \$25.0 million in additional notes remains available to us under the Note Purchase Agreement.

The obligations of us under the Note Purchase Agreement are secured by substantially all of our assets, including our intellectual property. We also pledged 65% of the issued and outstanding capital stock of our subsidiaries, Puma Biotechnology Ltd. and Puma Biotechnology B.V.

The notes issued under the Note Purchase Agreement bear interest at an annual rate equal to the sum of (a) 8.0% and (b) Adjusted Three-Month LIBOR for such Interest Period (as defined in the Note Purchase Agreement). We are required to make quarterly interest payments on each note issued under the Note Purchase Agreement commencing on the last business day of September 2021, and continuing on the last business day of each March, June, September and December through June 30, 2024, or the NPA Amortization Date. Commencing on the NPA Amortization Date, and continuing on the last day of each March, June, September and December thereafter, we will make consecutive equal quarterly payments of principal, together with applicable interest, in arrears to each Purchaser, calculated pursuant to the Note Purchase Agreement. All unpaid principal and accrued and unpaid interest with respect to each note issued under the Note Purchase Agreement is due and payable in full on July 23, 2026, or the NPA Maturity Date. At our option, we may prepay the outstanding principal balance of all or any portion of the principal amount of the notes, subject to a prepayment fee equal to (i) a make-whole amount if the prepayment occurs on or prior to the second anniversary of the NPA Effective Date and (ii) 2.0% of the amount prepaid if the prepayment occurs after the second anniversary of the NPA Effective Date by on or prior to the third anniversary of the NPA Effective Date. Upon prepayment or repayment of all or any portion of the principal amount of the notes (whether on the NPA Maturity Date or otherwise), we are also required to pay an exit fee to the Purchasers equal to 2.00% of the aggregate principal amount of such notes prepaid or repaid.

The Note Purchase Agreement includes affirmative and negative covenants applicable to us, our current subsidiaries and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. We must also (i) maintain a minimum amount of unrestricted cash in deposit accounts subject to a control agreement in favor of Athyrium at any time and (ii) achieve at least a specified minimum amount of revenue (based on a combination of both sales of NERLYNX in the United States and royalty revenues received by us for sales of NERLYNX outside the United States), measured as of the last day of each four consecutive fiscal quarter period. The negative covenants include, among others,

restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The Note Purchase Agreement also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 2.0% and would provide Athyrium, as administrative agent, with the right to exercise remedies against us and the collateral securing the new credit facility, including foreclosure against the property securing the obligations of us under the Note Purchase Agreement, including our cash. These events of default include, among other things, our failure to pay principal or interest due under the Note Purchase Agreement, a breach of certain covenants under the Note Purchase Agreement, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than \$750,000 and one or more judgments against us in an amount greater than \$750,000 individually or in the aggregate that remains discharged or otherwise satisfied, in each case, as further described in the Note Purchase Agreement.

The foregoing description of the Note Purchase Agreement and the notes is only a summary of the material terms thereof, and does not purport to be complete. The description is qualified in its entirety by reference to the Note Purchase Agreement and the form of note, which will be filed as exhibits to our Quarterly Report on Form 10-Q for the quarter ending September 30, 2021.

Current and Future Financing Needs:

We did not receive or record any product revenues until the third quarter of 2017. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, our research and development efforts and our commercialization efforts.

We may choose to begin new research and development efforts or we may choose to launch additional marketing efforts. These efforts may require funding in addition to the cash and cash equivalents totaling approximately \$89.8 million and \$19.1 million in marketable securities available at June 30, 2021. While our consolidated financial statements have been prepared on a going concern basis, we expect to continue incurring significant losses for the foreseeable future and will need to generate significant revenue to sustain operations and successfully commercialize neratinib. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, including the global COVID-19 pandemic, our success in commercializing neratinib, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time.

In addition, we have based our estimate of capital needs on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities, the impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

Non-GAAP Financial Measures

In addition to our operating results, as calculated in accordance with generally accepted accounting principles, or GAAP, we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net loss and net loss per share, as calculated in accordance with GAAP, as adjusted to remove the impact of stock-based compensation. For the three and six months ended June 30, 2021, stock-based compensation represented approximately 31.4% and 22.6% of our operating expenses, respectively, compared to 19.7% and 17.7% for the same respective period in 2020, in each case excluding cost of sales. Our management believes that these non-GAAP financial measures are useful to enhance understanding of our financial performance, are more indicative of our 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.

**Reconciliation of GAAP Net Income (Loss) to Non-GAAP Adjusted Net Income and
GAAP Net Income (Loss) Per Share to Non-GAAP Adjusted Net Income Per Share
(in thousands except share and per share data)**

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP net income (loss)	\$ (5,106)	\$ 3,395	\$ 11,322	\$ (13,538)
Adjustments:				
Stock-based compensation -				
Selling, general and administrative (1)	16,731	4,730	20,332	9,422
Research and development (2)	1,508	5,900	3,767	10,115
Non-GAAP adjusted net income	<u>\$ 13,133</u>	<u>\$ 14,025</u>	<u>\$ 35,421</u>	<u>\$ 5,999</u>
GAAP net income (loss) per share—basic	\$ (0.13)	\$ 0.09	\$ 0.28	\$ (0.34)
Adjustment to net income (loss) (as detailed above)	0.45	0.27	0.60	0.49
Non-GAAP adjusted basic net income per share	<u>\$ 0.32 (3)</u>	<u>\$ 0.36 (4)</u>	<u>\$ 0.88 (3)</u>	<u>\$ 0.15 (4)</u>
GAAP net income (loss) per share—diluted	\$ (0.13)	\$ 0.08	\$ 0.28	\$ (0.34)
Adjustment to net income (loss) (as detailed above)	0.45	0.27	0.59	0.49
Non-GAAP adjusted diluted net income per share	<u>\$ 0.32 (5)</u>	<u>\$ 0.35 (6)</u>	<u>\$ 0.87 (5)</u>	<u>\$ 0.15 (6)</u>

(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 per share was calculated based on 40,479,577 and 40,370,825 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2021, respectively.

(4) Non-GAAP adjusted basic net income per share was calculated based on 39,432,030 and 39,361,596 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2020, respectively.

(5) Non-GAAP adjusted diluted net income per share was calculated based on 40,986,716 and 40,939,688 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2021, respectively.

(6) Non-GAAP adjusted diluted net income per share was calculated based on 39,997,571 and 39,815,867 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2020, respectively.

Off-Balance Sheet Arrangements

We do not have any “off-balance sheet agreements,” as defined by SEC regulations.

Contractual Obligations

In June 2020, we entered into a letter agreement, or the Letter Agreement, with Pfizer relating to the method of payment associated with our achievement of a milestone that triggered a \$40.0 million payment under our license agreement with Pfizer. The Letter Agreement permits us to make the milestone payment in installments with the majority of the amount payable to Pfizer (including interest) to be made in 2021 and the final payment occurring by September 30, 2021. Unpaid portions of the milestone payment will accrue interest at 6.25% per annum until paid.

Other than as described in the preceding paragraph, there have been no material changes outside the ordinary course of business to our contractual obligations and commitments as described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2020.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the cash equivalents to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. We invested our excess cash primarily in cash equivalents such as money market investments as of June 30, 2021. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our cash and cash equivalents without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Because of the short-term maturities of our cash equivalents, we do not believe that a 10% increase in interest rates would have a material effect on the realized value of our cash equivalents.

We also have interest rate exposure as a result of borrowings outstanding under our Note Purchase Agreement. As of June 30, 2021, the outstanding principal amount of our borrowings under our prior loan and security agreement was \$100.0 million, which has since been repaid in full. As of July 23, 2021, the outstanding principal amount of our borrowings under our Note Purchase Agreement was \$100.0 million. Our borrowings under the Note Purchase Agreement bear interest at an annual rate equal to the sum of (a) 8.0% and (b) Adjusted Three-Month LIBOR for such Interest Period (as defined in the Note Purchase Agreement). Changes in LIBOR may therefore affect our interest expense associated with our borrowings under the Note Purchase Agreement.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of June 30, 2021. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective as of June 30, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Hsu v. Puma Biotechnology, Inc., et al.

On June 3, 2015, Hsingching Hsu, individually and on behalf of all others similarly situated, filed a class action lawsuit against us and certain of our executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased our securities between July 22, 2014 and May 29, 2015. A trial on the claims relating to four statements alleged to have been false or misleading was held from January 15 to January 29, 2019. At trial, the jury found that three of the four challenged statements were not false or misleading, and thus found in the defendants' favor on those claims. The jury found liability as to one statement and awarded a maximum of \$4.50 per share in damages, which represents approximately 5% of the total claimed damages of \$87.20 per share. On September 9, 2019, the Court entered an order specifying the rate of prejudgment interest to be awarded on any valid claims at the 52-week Treasury Bill rate. On September 8, 2020, the claims administrator submitted its final claims report to the Court and, on October 9, 2020, the claims administrator submitted its supplemental claims report. The claims report reflects approximately \$50.5 million in claimed damages. We disagree with the amount of claimed damages. On November 27, 2020, the Court issued an order setting out the process for challenging claims. That process remains on-going. On June 28, 2021, plaintiffs filed a proposed judgment on certain claims totaling approximately \$41.99 million in damages plus interest in the amount of approximately \$2.95 million. Defendants dispute the entry of judgment and the proposed amount of prejudgment interest. Defendants objected to plaintiffs' proposed judgment on July 19, 2021 and intend to file a motion to exclude certain disputed claims from any judgment. Based on a review of specific claims and subject to the outcome of the claims challenge process, we believe that total claimed damages after all claims challenges have been adjudicated could range from \$30.0 million to \$51.4 million. The total amount of aggregate class-wide damages still remains uncertain and will be ascertained only after the claims challenge process and the exhaustion of any appeals. It is reasonably possible that the final total damages awarded will differ from these estimates; however, the amount is not estimable at this time. A final judgment has not been entered.

Eshelman v. Puma Biotechnology, Inc., et al.

In February 2016, Fredric N. Eshelman filed a lawsuit against our Chief Executive Officer and President, Alan H. Auerbach, and us in the United States District Court for the Eastern District of North Carolina (Case No. 7:16-cv-00018-D). The complaint generally alleged that we and Mr. Auerbach made defamatory statements regarding Dr. Eshelman in connection with a proxy contest. In May 2016, Dr. Eshelman filed a notice of voluntary dismissal of the claims against Mr. Auerbach. A trial on the remaining defamation claims against us took place from March 11 to March 15, 2019. At trial, the jury found us liable and awarded Dr. Eshelman \$15.9 million in compensatory damages and \$6.5 million in punitive damages. We strongly disagree with the verdict and, on April 22, 2019, filed a motion for a new trial or, in the alternative, a reduced damages award. The Court denied that motion on March 2, 2020. We have appealed that ruling and the verdict. Additionally, after trial, the plaintiff filed a motion seeking approximately \$3.0 million in attorneys' fees, as well as pre-judgment interest. In the Court's March 2 ruling, it denied the motion for attorneys' fees but granted the request for pre-judgment interest, bringing the total judgment to \$26.3 million. On March 30, 2020, the plaintiff filed a notice of cross-appeal and conditional cross-appeal, appealing the Court's order denying the plaintiff's request for attorneys' fees and conditionally cross-appealing a Court ruling that certain communications between Mr. Auerbach and his attorneys were protected by attorney-client privilege and a related evidentiary ruling. On June 23, 2021, the United States Court of Appeals for the Fourth Circuit affirmed the liability verdict in the *Eshelman v. Puma Biotechnology, Inc., et al.* matter but found the \$22.35 million damages award, payable by us, to be excessive in light of the evidence at trial. The Court vacated this award and remanded for a new trial on damages. The Court's judgment will eliminate the damages award, including interest on the judgment, pending further proceedings on remand. On July 7, 2021, the plaintiff filed a petition for panel or *en banc* rehearing, which was denied on July 20, 2021. On July 26, 2021, the plaintiff filed a motion to stay issuance of the Fourth Circuit's mandate pending the filing and resolution of a petition for certiorari in the Supreme Court. The Fourth Circuit denied that motion on July 29, 2021. We estimate the high end of potential damages in the matter could be approximately \$2.8 million.

Legal Malpractice Suit

On September 17, 2020, we filed a lawsuit against Hedrick Gardner Kincheloe & Garofalo, L.L.P. and David L. Levy, the attorneys who previously represented us in *Eshelman v. Puma Biotechnology, Inc., et al.* in the Superior Court of Mecklenburg County, North Carolina. We are alleging legal malpractice based on the defendants' negligent handling of the defense of us in *Eshelman v. Puma Biotechnology, Inc., et al.* as detailed above. We are seeking recovery of the entire amount awarded in *Eshelman v. Puma Biotechnology, Inc., et al.* On November 23, 2020, the defendant filed an answer to the complaint denying the allegations of negligence.

On June 23, 2021, the United States Court of Appeals for the Fourth Circuit set aside the damages award in the *Eshelman v. Puma Biotechnology, Inc., et al.* matter and remanded the case to the District Court for a new trial on damages. As a result, the amount of potential damages that may be recovered in the legal malpractice case is uncertain at this time.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020, we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report. There has been no material change in our risk factors subsequent to the filing of our prior reports referenced above. However, the risks described in our reports are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

We did not sell any of our equity securities without registration under the Securities Act of 1933, as amended, during the three months ended June 30, 2021.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any “affiliated purchasers” within the definition of Rule 10b-18(a)(3) promulgated under the Exchange Act made any purchases of our equity securities during the quarter ended June 30, 2021.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit Number	Description
3.1	<u>Second Amended and Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 14, 2016 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016 and incorporated herein by reference)</u>
3.2	<u>Third Amended and Restated Bylaws of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 28, 2019 and incorporated herein by reference)</u>
4.1#	<u>Amendment to Warrant to Purchase Shares of Common Stock of Puma Biotechnology, Inc. (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 17, 2021 and incorporated herein by reference)</u>
10.1#	<u>Fifth Amendment to Puma Biotechnology, Inc. 2011 Incentive Award Plan (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 17, 2021, and incorporated herein by reference)</u>
31.1+	<u>Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021</u>
31.2+	<u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021</u>
32.1++	<u>Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2++	<u>Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS+	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH+	Inline XBRL Taxonomy Extension Schema Document
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	Inline XBRL Taxonomy Extension Linkbase Document
104+	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
+	Filed herewith
++	Furnished herewith
#	Management contract or compensatory plan or arrangement

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: August 5, 2021

By: /s/ Alan H. Auerbach
Alan H. Auerbach
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2021

By: /s/ Maximo F. Nougues
Maximo Nougues
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Alan H. Auerbach, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended June 30, 2021;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2021

/s/ Alan H. Auerbach

Alan H. Auerbach
Principal Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Maximo F. Nougues, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended June 30, 2021;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2021

/s/ Maximo F. Nougues

Maximo F. Nougues
Chief Financial Officer

**CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended June 30, 2021, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Executive Officer

I, Alan H. Auerbach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended June 30, 2021, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: August 5, 2021

/s/ Alan H. Auerbach

Alan H. Auerbach

Principal Executive Officer

A signed original of this written statement required by Section 906 has been provided to Puma Biotechnology, Inc. and will be retained by Puma Biotechnology, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended June 30, 2021, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Financial Officer

I, Maximo F. Nougues, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended June 30, 2021, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: August 5, 2021

/s/ Maximo F. Nougues

Maximo F. Nougues

Principal Financial and Accounting Officer

A signed original of this written statement required by Section 906 has been provided to Puma Biotechnology, Inc. and will be retained by Puma Biotechnology, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.