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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, 2022

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	**77-0683487**
(State or other jurisdiction of incorporation or organization)	**(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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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 issuer's classes of common stock, as of the latest practicable date. 45,555,963 shares of Common Stock, par value $0.0001 per share, were outstanding as of August 1, 2022.

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) tablets ("NERLYNX");
- 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 ability to in-license additional drugs;
- 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, 2021, and this Quarterly Report on Form 10-Q, 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.

Part I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,756	$ 63,131
Marketable securities	7,998	18,975
Accounts receivable	33,987	32,526
Inventory, net	6,665	7,109
Prepaid expenses, current	8,583	8,984
Restricted cash, current	—	8,850
Other current assets	4,291	447
Total current assets	114,280	140,022
Lease right-of-use assets, net	12,723	14,017
Property and equipment, net	1,435	1,756
Intangible assets, net	62,118	66,125
Restricted cash, long-term	2,591	3,311
Prepaid expenses and other, long-term	504	1,354
Total assets	$ 193,651	$ 226,585
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,841	$ 11,174
Accrued expenses, current	41,297	92,575
Post-marketing commitment liability, current	1,856	2,263
Lease liabilities, current	3,840	3,574
Total current liabilities	56,834	109,586
Accrued expenses, long-term	37	915
Lease liabilities, long-term	13,983	15,975
Post-marketing commitment liability, long-term	5,377	5,463
Long-term debt, net	97,682	97,092
Total liabilities	173,913	229,031
Commitments and contingencies (Note 12)		
Stockholders' deficit:		
Common stock - $.0001 par value per share; 100,000,000 shares authorized; 45,274,635 shares issued and outstanding at June 30, 2022 and 41,175,507 issued and outstanding at December 31, 2021	5	4
Additional paid-in capital	1,380,522	1,364,309
Accumulated other comprehensive loss	—	(2)
Accumulated deficit	(1,360,789)	(1,366,757)
Total stockholders' equity (deficit)	19,738	(2,446)
Total liabilities and stockholders' equity (deficit)	$ 193,651	$ 226,585

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,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 51,314	$ 48,856	$ 92,032	$ 94,672
License revenue	—	250	—	50,250
Royalty revenue	8,204	4,278	13,222	6,631
Total revenue	59,518	53,384	105,254	151,553
Operating costs and expenses:				
Cost of sales	14,918	11,969	25,762	41,527
Selling, general and administrative	20,576	39,410	40,978	67,748
Research and development	11,966	18,638	27,203	38,866
Total operating costs and expenses	47,460	70,017	93,943	148,141
Income (loss) from operations	12,058	(16,633)	11,311	3,412
Other income (expenses):				
Interest income	65	121	78	134
Interest expense	(2,702)	(3,518)	(5,366)	(6,968)
Legal verdict (expense) credit	(55)	14,902	(73)	14,717
Other income	62	60	112	102
Total other income (expenses)	(2,630)	11,565	(5,249)	7,985
Net income (loss) before income taxes	$ 9,428	$ (5,068)	$ 6,062	$ 11,397
Income tax expense	(57)	(38)	(94)	(75)
Net income (loss)	$ 9,371	$ (5,106)	$ 5,968	$ 11,322
Net income (loss) per share of common stock—basic	$ 0.21	$ (0.13)	$ 0.14	$ 0.28
Net income (loss) per share of common stock—diluted	$ 0.21	$ (0.13)	$ 0.14	$ 0.28
Weighted-average shares of common stock outstanding—basic	45,058,924	40,479,577	43,641,193	40,370,825
Weighted-average shares of common stock outstanding—diluted	45,358,739	40,479,577	43,889,556	40,939,688

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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Net income (loss)	$ 9,371	$ (5,106)	$ 5,968	$ 11,322
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net of tax of $0 and $0	1	(1)	2	(1)
Comprehensive income (loss)	$ 9,372	$ (5,107)	$ 5,970	$ 11,321

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, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at March 31, 2022	44,949,360	$ 4	$ 1,377,302	$ (1)	$ (1,370,160)	$ 7,145
Stock-based compensation	—	—	3,220	—	—	3,220
Shares issued or restricted stock units vested under employee stock plans	325,275	—	—	—	—	—
Shares issued under private investments in public equity, net of issuance costs of approximately $0.2M	—	1	—	—	—	1
Unrealized gain on available-for-sale securities	—	—	—	1	—	1
Net income	—	—	—	—	9,371	9,371
Balance at June 30, 2022	45,274,635	$ 5	$ 1,380,522	$ —	$ (1,360,789)	$ 19,738

For the Three Months Ended June 30, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive 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 loss	—	—	—	—	(5,106)	(5,106)
Balance at June 30, 2021	40,733,928	$ 4	$ 1,355,775	$ (1)	$ (1,326,309)	$ 29,469

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, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2021	41,175,507	$ 4	$ 1,364,309	$ (2)	$ (1,366,757)	$ (2,446)
Stock-based compensation	—	—	6,368	—	—	6,368
Shares issued or restricted stock units vested under employee stock plans	514,900	—	—	—	—	—
Shares issued under private investments in public equity, net of issuance costs of approximately $0.2M	3,584,228	1	9,845	—	—	9,846
Unrealized gain on available-for-sale securities	—	—	—	2	—	2
Net income	—	—	—	—	5,968	5,968
Balance at June 30, 2022	45,274,635	$ 5	$ 1,380,522	$ —	$ (1,360,789)	$ 19,738

For the Six Months Ended June 30, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive 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	40,733,928	$ 4	$ 1,355,775	$ (1)	$ (1,326,309)	$ 29,469

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,	
	2022	**2021**
Operating activities:		
Net income	$ 5,968	$ 11,322
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,486	5,886
Stock-based compensation	6,368	24,099
Provision for credit loss recovery	—	(1,000)
Disposal of property and equipment	1	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,461)	(4,006)
Inventory, net	444	(4,166)
Prepaid expenses and other	1,251	271
Other current assets	(3,844)	3,163
Accounts payable	(1,333)	(910)
Accrued expenses and other	(52,156)	(18,503)
Post-marketing commitment liability	(493)	(569)
Net cash provided by (used in) operating activities	(40,769)	15,587
Investing activities:		
Purchase of available-for-sale securities	—	(19,117)
Maturity of available-for-sale securities	10,979	8,085
Net cash provided by (used in) investing activities	10,979	(11,032)
Financing activities:		
Gross proceeds from private investments in public equity	10,000	—
Issuance costs associated with private investments in public equity	(155)	—
Net cash provided by financing activities	9,845	—
Net increase (decrease) in cash, cash equivalents and restricted cash	(19,945)	4,555
Cash, cash equivalents and restricted cash, beginning of period	75,292	97,454
Cash, cash equivalents and restricted cash, end of period	55,347	102,009
Supplemental disclosures of non-cash investing and financing activities:		
Intangibles in accrued expenses	$ —	$ 20,000
Supplemental disclosure of cash flow information:		
Interest paid	$ 4,776	$ 4,550
Income taxes paid	$ 141	$ 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., (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. ("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, such as breast cancer, cervical cancer, lung cancer or other solid tumors.

The Company has one subsidiary, Puma Biotechnology, B.V., a Netherlands company. In March 2022, the Company dissolved its United Kingdom company, Puma Biotechnology Ltd. These two subsidiaries were originally established for the purpose of legal representation in the United Kingdom and the European Union, respectively. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

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 ("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 ("EC") granted marketing authorization for NERLYNX in the European Union ("EU") 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, 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 income of approximately $9.4 million and net income of approximately $6.0 million for the three and six months ended June 30, 2022, respectively, and cash flows used in operations of approximately $40.8 million for the six months ended June 30, 2022. The Company's commercialization, research and development or marketing efforts may require funding in addition to the cash and cash equivalents and marketable securities totaling approximately $60.8 million available at June 30, 2022.

The Company believes that its existing cash and cash equivalents and marketable securities as of June 30, 2022 and proceeds that will become available to the Company through product sales and sub-license payments are sufficient to satisfy its operating cash 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 global 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 and cash balance covenants as specified in the agreement.

Since its inception through June 30, 2022 the Company's financing has primarily consisted of proceeds from product, royalty and license revenue, public offerings of its common stock, private equity placements, and various debt instruments.

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 Generally Accepted Accounting Principles ("GAAP") in the United States, 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 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 ("ASC"), ASC, 260, *Earnings per Share*. For purposes of calculating diluted net income 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 ("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 Incentive Award Plan and the 2017 Employment Inducement Incentive Award Plan. 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. The following potentially dilutive outstanding common stock equivalents for the respective periods were excluded from diluted net income (loss) per share because of their anti-dilutive effect:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Options outstanding	4,460,955	5,241,747	4,460,955	4,796,671
Warrant outstanding	2,116,250	2,116,250	2,116,250	2,116,250
Unvested restricted stock units	1,259,700	2,076,079	1,474,112	1,136,005
Totals	7,836,905	9,434,076	8,051,317	8,048,926

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 (see Note 10—Stockholders' Equity).

A reconciliation of the numerators and denominators of the basic and diluted net 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,	
	2022	2021	2022	2021
Numerator:				
Net income (loss)	$ 9,371	$ (5,106)	$ 5,968	$ 11,322
Denominator:				
Weighted average common stock outstanding for basic net income (loss) per share	45,059	40,480	43,641	40,371
Net effect of dilutive common stock equivalents	300	—	248	569
Weighted average common stock outstanding for diluted net income (loss) per share	45,359	40,480	43,890	40,940
Net income (loss) per share of common stock				
Basic	$ 0.21	$ (0.13)	$ 0.14	$ 0.28
Diluted	$ 0.21	$ (0.13)	$ 0.14	$ 0.28

Revenue Recognition:

Under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration 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.

Product revenue also consists of product sales under sub-license agreements to our sub-licensees, who then sell into their respective international territories.

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, 2022 and 2021, respectively.

Reserves for Variable Consideration:

Revenue from product sales is 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 Accounting Standards Update ("ASU") 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, 2022, and, therefore, the transaction price was not reduced further during the quarter ended June 30, 2022. 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 consolidated 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, 2022 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 $579.8 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 $8.2 million and $13.2 million for the three and six months ended June 30, 2022, 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 12—Commitments and Contingencies).

Royalty Expenses:

Royalties incurred in connection with the Company's license agreement with Pfizer, as disclosed in Note 12—Commitments and Contingencies, are expensed to cost of sales as revenue from product sales is recognized.

Research and Development Expenses:

Research and development expenses ("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 ("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* ("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 (see Note 10—Stockholders' Equity) granted to employees and nonemployees are normally valued at the fair value of the instrument on the grant date and are recognized in the condensed 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* ("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, 2022 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 commitments. The lease-related letters of credit will lapse at the end of the respective lease terms through 2026. At each of June 30, 2022 and December 31, 2021, the Company had restricted cash in the amount of approximately $2.6 million and $12.2 million, respectively.

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* ("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, 2022 and December 31, 2021, 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, 2022	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents	$ 37,923	$ —	$ —	$ 37,923
Commercial paper	—	7,998	—	7,998
Totals	$ 37,923	$ 7,998	$ —	$ 45,921

December 31, 2021	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents	$ 50,872	$ —	$ —	$ 50,872
Commercial paper	—	14,589	—	14,589
Corporate bonds	—	4,386	—	4,386
Totals	$ 50,872	$ 18,975	$ —	$ 69,847

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, 2022	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 37,923	$ —	$ —	$ 37,923
Commercial paper	Less than 1	7,999	—	(1)	7,998
Totals		$ 45,922	$ —	$ (1)	$ 45,921

December 31, 2021	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 50,872	$ —	$ —	$ 50,872
Commercial paper	Less than 1	14,590	—	(1)	14,589
Corporate bonds	Less than 1	4,387	—	(1)	4,386
Totals		$ 69,849	$ —	$ (2)	$ 69,847

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, 2022 were approximately $55.2 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'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 cost of sales in the condensed 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.

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, 2022 the Company's inventory balance consisted primarily of raw materials and work-in-process purchased subsequent to FDA approval of NERLYNX.

	June 30, 2022	December 31, 2021
Raw materials	$ 2,903	$ 4,569
Work-in-process (materials, labor and overhead)	3,120	1,385
Finished goods (materials, labor and overhead)	642	1,155
Total Inventories	$ 6,665	$ 7,109

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 (*"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 ("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 5—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 ("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, 2022 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 12—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 approximately $2.0 million and $4.0 million for the three and six months ended June 30, 2022, respectively. As of June 30, 2022 estimated future amortization expense related to the Company's intangible assets was approximately $4.0 million for the remainder of 2022 and $8.0 million for each year starting 2023 through 2029, and $2.0 million for 2030.

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* ("ASU 2019-12"), 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 US 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* ("ASU-2020-10"), which updates various codification topics by clarifying or improving disclosure requirements to align with Securities and Exchange Commission ("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, 2022	December 31, 2021
Trade accounts receivable	$ 25,505	$ 29,646
Royalty revenue receivable	8,482	2,880
Total accounts receivable	$ 33,987	$ 32,526

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 sub-licensees under sub-license agreements. 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, 2022 and December 31, 2021.

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. No credit loss was recorded for the periods ended June 30, 2022 and December 31, 2021.

Note 4—Prepaid Expenses and Other:

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

	June 30, 2022	December 31, 2021
Current:		
CRO services	$ 271	$ 340
Other clinical development	2,824	2,933
Insurance	1,557	3,178
Professional fees	1,064	398
Other	2,867	2,135
	8,583	8,984
Long-term:		
CRO services	160	166
Other clinical development	129	577
Other	215	611
	504	1,354
Totals	$ 9,087	$ 10,338

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—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 $1.5 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 copier lease expense include both fixed and variable lease expenses. Total rent expense for the six months ended June 30, 2022 and June 30, 2021, was approximately $2.5 million and $2.5 million, respectively. 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 six months ended June 30, 2022:		
Operating cash flows used for operating leases (in thousands)	$	2,926
Right-of-use assets obtained in exchange for new operating lease liabilities		—
Weighted average remaining lease term (in years)		3.8
Weighted average discount rate		10.9%

The future minimum lease payments under ASC 842 as of June 30, 2022 were as follows (in thousands):

		Amount
2022 (remaining)	$	2,754
2023		5,631
2024		5,805
2025		5,983
2026		1,508
Total minimum lease payments	$	21,681
Less: imputed interest		(3,858)
Total lease liabilities	$	17,823

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, 2022, respectively, in other income (expenses) in the consolidated statements of operations.

The future minimum lease payments to be received as of June 30, 2022 were as follows (in thousands):

	Amount
2022 (remaining)	$ 243
2023	495
2024	510
2025	525
2026	134
Total	$ 1,907

Note 6—Property and Equipment, Net:

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

	June 30, 2022	December 31, 2021
Leasehold improvements	$ 3,779	$ 3,779
Computer equipment	2,132	2,177
Telephone equipment	302	302
Furniture and fixtures	2,359	2,359
	8,572	8,617
Less: accumulated depreciation	(7,137)	(6,861)
Totals	$ 1,435	$ 1,756

For the three and six months ended June 30, 2022 the Company incurred depreciation expense of $0.1 million and $0.3 million, respectively.

Note 7—Intangible Assets, Net:

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

	June 30, 2022	December 31, 2021
Acquired and in-licensed rights	$ 90,000	$ 90,000
Less: accumulated amortization	(27,882)	(23,875)
Total intangible asset, net	$ 62,118	$ 66,125

For the three and six months ended June 30, 2022 the Company incurred amortization expense of $2.0 million and $4.0, respectively. The estimated remaining useful life of the intangible assets as of June 30, 2022 is 7.8 years.

Note 8—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Current:		
Accrued legal verdict expense	$ 2,912	$ 57,137
Accrued royalties	11,334	8,829
Accrued CRO services	2,311	2,663
Accrued variable consideration	11,676	11,406
Accrued bonus	3,198	5,083
Accrued compensation	4,152	3,878
Accrued other clinical development	2,573	911
Accrued professional fees	822	672
Accrued legal fees	1,485	674
Accrued manufacturing costs	582	690
Other	252	632
	41,297	92,575
Long-term:		
Accrued CRO services	—	878
Accrued other	37	37
	37	915
Totals	$ 41,334	$ 93,490

On October 29, 2021, the parties to the Company's class action lawsuit, *Hsu v. Puma Biotechnology, Inc. et al*, informed the court that they had reached a settlement in principle, and the court entered judgement in the amount of claimed damages and prejudgment interest totaling approximately $54.2 million. On November 2, 2021, the court dismissed the case in light of the parties' settlement, retaining jurisdiction only for settlement approval. The parties' settlement in principle provides that there will be no judgment for liability entered against the Company or its chief executive officer, Alan Auerbach, and provides for payment by the Company of approximately $54.2 million. On December 29, 2021, the Court issued an order preliminarily approving the parties' settlement. The first payment of $27.1 million was made in January of 2022 with the balance paid in June of 2022. On August 3, 2022, the Court ordered final approval of the parties' settlement.

Also included in accrued legal verdict expense is approximately $2.9 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 $2.9 million which also represents the estimate as the most likely outcome; however, the actual amount of damages payable by the Company is still uncertain and will be ascertained only after the completion of the appeal process and subsequent proceedings on remand, and such amount could be greater than the amount of expense already recognized or high end of the estimate. The Company continues to classify the accrual as a current liability due to the uncertainty of timing and amount of the payment.

Accrued variable consideration represents estimates of adjustments to product revenue, net for which reserves are established. Accrued royalties represent royalties incurred in connection with the Company's license agreement with Pfizer. 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 compensation includes commissions, vacation and restructuring costs.

Restructuring Costs

On November 2, 2021, the Company implemented a restructuring of the organization in part due to the impact of COVID-19 on the Company's sales. The restructuring included a reduction in headcount of approximately 13%, consisting primarily of the commercial and research personnel. The Company incurred approximately $1.2 million in severance related expense which included salary, health insurance and sales commissions. As of June 30, 2022, accrued restructuring amounts had been paid except for an immaterial amount.

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 (the "CARES Act"), and other taxes, insurance and marketing fees.

Note 9—Debt:

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

	June 30, 2022	Maturity Date
Total debt, inclusive of $2.0 million exit payment	$ 102,000	July 23, 2026
Less: debt issuance costs and discounts	(4,318)	
Total long-term debt, net	$ 97,682	

Oxford Loan and Security Agreement:

In October 2017, the Company entered into a loan and security agreement with Silicon Valley Bank ("SVB"), as administrative agent, and the lenders party thereto from time to time, or the Original Lenders, including Oxford Finance, LLC ("Oxford"), and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement ("Original Credit Facility"), the Company borrowed $50.0 million. In May 2018, the Company entered into an amendment to the loan and security agreement, which provided for an amended credit facility ("Amended Credit Facility"). Under the Amended Credit Facility, the Original Lenders agreed to make term loans available to the company 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 outstanding under the Original Credit Facility, and (ii) an aggregate amount of $30.0 million that was drawn in December 2018, which was available under the Amended Credit Facility as a result of achieving a specified minimum revenue milestone.

The term loans under the Amended Credit Facility bore interest at an annual rate equal to the greater of (i) 8.25% 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 accrued, plus (b) 3.5%. The Company was required to make monthly interest-only payments on each term loan 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 July 1, 2020. Commencing on July 1, 2020, and continuing on the first calendar day of each calendar month thereafter, the Company would have been required to make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each original lender, calculated pursuant to the Amended Credit Facility. All unpaid principal and accrued and unpaid interest with respect to each term loan would have been due and payable in full on May 1, 2023. Upon repayment of the term loans, the Company was also required to make a final payment to the Original Lenders equal to 7.5% of the original principal amount of term loans funded.

On June 28, 2019 (the "Effective Date"), the Company entered into an amendment and restatement of the loan and security agreement, which provided for a new credit facility ("New Credit Facility"), with Oxford, as collateral agent, and the lenders party thereto from time to time, including Oxford, pursuant to which the Company 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, 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.

The New Credit Facility was secured by substantially all of the Company's personal property other than 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 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 ("Amortization Date"). Commencing on the Amortization Date and continuing on the first calendar day of each calendar month thereafter, the Company was required to make 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 ("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 Company had the option 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.

On July 23, 2021, the Company used proceeds from the Athyrium Note Purchase Agreement to repay the amounts outstanding under the New Credit Facility, together with applicable exit and prepayment fees, and terminated the New Credit Facility.

Athyrium Note Purchase Agreement:

The Company issued senior notes for an aggregate principal amount of $100.0 million pursuant to a note purchase agreement dated July 23, 2021, by the Company, and its subsidiaries, and Athyrium, as Administrative Agent, and certain other investor parties (the “Note Purchase Agreement”), with an initial maturity date of July 23, 2026 (the “Athyrium Notes”). The Athyrium Notes were issued for face amount of $100.0 million net of an original issue discount of $1.5 million. The Athyrium Notes also require a 2.0% exit payment to be made on each payment of principal. The borrowings under the Athyrium Notes, together with cash on hand, were used to repay the Company’s outstanding indebtedness, including the applicable exit and prepayment fees owed to lenders under its Oxford Credit Facility. The Company can borrow up to an additional $25.0 million under the Note Purchase Agreement for general corporate purposes and to further support commercial initiatives. The Athyrium Notes are secured by substantially all of the Company’s assets. The Company incurred $1.9 million of deferred financing costs with the borrowing.

The Athyrium Notes bear interest at an annual rate equal to the sum of (i) 8.0% and (ii) three-month London Interbank Offering Rate ("LIBOR") rate where the three-month LIBOR rate cannot be less than 1.5% or greater than 3.5%. (or a comparable or successor rate that gives due consideration to the then prevailing rate used by commercial banks in the United States, which rate is reasonably determined by Athyrium). Interest is payable quarterly on the last business day of March, June, September and December each year. Beginning June 30, 2024, principal payments are required to be made quarterly at 11.11% of the original face amount with the remaining balance paid at maturity. Each principal payment will also include a 2.0% exit payment. As of December 31, 2021, the effective interest rate for the loan was 10.98%.

At the Company’s option, the Company may prepay the outstanding principal balance of the notes in whole or in part, subject to a prepayment fee of 2.0% of the amount prepaid if the prepayment occurs on or prior to the second anniversary of the issuance date of such notes, plus the present value of remaining interest that would have accrued through and including the second anniversary date, and 2.0% of the amount prepaid if the prepayment occurs after the second anniversary but on or prior to the third anniversary of the issuance date of such notes.

The Athyrium Notes include affirmative and negative covenants applicable to the Company. 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 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 Company is also required to achieve certain minimum product revenue targets, measured as of the last day of each fiscal quarter on a trailing year-to-date basis.

As of June 30, 2022 the principal balance outstanding under the Athyrium Notes was $100.0 million, representing all of the Company’s long-term debt.

The future minimum principal and exit payments under the Athyrium Notes as of June 30, 2022 are as follows (in thousands):

	Amount
2022 (remaining)	$ —
2023	—
2024	33,997
2025	45,329
2026	22,674
Total	$ 102,000

Debt Issuance Costs and Discounts

Debt issuance costs and discounts consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Debt issuance costs and discounts (Athyrium Notes)	$ 5,410	$ 5,410
Less: accumulated amortization	(1,092)	(502)
Included in long-term debt	$ 4,318	$ 4,908

Debt issuance costs and discounts 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 condensed consolidated statement of operations. For the six months ended June 30, 2022 and 2021 the Company recorded approximately $0.4 million and $1.1 million, respectively, of interest expense related to the amortization of debt issuance costs in the consolidated statements of operations.

Note 10—Stockholders' Equity:

Common Stock:

The Company issued zero shares of common stock upon exercise of stock options during the six months ended June 30, 2022 and 2021 respectively. The Company issued 514,900 and 647,541 shares of common stock upon vesting of RSUs during the six months ended June 30, 2022 and 2021, respectively.

On March 8, 2022, The Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with Alan H. Auerbach, our President, Chief Executive Officer and Chairman of the Board, and Athyrium Opportunities IV Co-Invest 2 LP, an affiliate of the administrative agent and a purchaser under the Company's existing note purchase agreement (together with Mr. Auerbach, the "Purchasers"). Pursuant to the Purchase Agreement, the Company agreed to sell an aggregate of 3,584,228 shares of our common stock, par value $0.0001 per share, to the Purchasers for aggregate gross proceeds of approximately $10.0 million before deducting any offering expenses (the "Private Placement"). The purchase price for each Share was $2.79, which was equal to the closing price of the Company's common stock on NASDAQ on the date of the Purchase Agreement. Each Purchaser agreed to purchase approximately $5.0 million of the shares, which resulted in Mr. Auerbach purchasing 1,792,114 shares of common stock. The Private Placement closed on March 10, 2022.

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, as amended in June 2021, 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, 2026.

Stock Options and Restricted Stock Units:

The Company's 2011 Plan, as amended, 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. As of June 30, 2022 a total of 14,545,860 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, 2022, 5,471,041 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 3,342,958 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—Significant Accounting Policies) with the following weighted-average assumptions used during the six months ended June 30, 2022:

	2022	2021
Dividend yield	0.0%	0.0%
Expected volatility	86.2%	86.7%
Risk-free interest rate	1.8%	0.7%
Expected life in years	5.50	5.82

The Company's 2017 Plan, as amended, 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. 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. As of June 30, 2022 a total of 3,000,000 shares of the Company's common stock have been reserved for issuance under the 2017 Plan. As of June 30, 2022 a total of 898,697 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 1,381,242 shares of the Company's common stock are available for future issuance under the 2017 Plan.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Stock-based compensation:				
Options:				
Selling, general, and administrative	$ 741	$ 964	$ 1,480	$ 1,971
Research and development	138	50	275	279
Restricted stock units:				
Selling, general, and administrative	1,370	2,180	2,830	4,774
Research and development	971	1,458	1,783	3,488
Warrant modification:				
Selling, general, and administrative	—	13,587	—	13,587
Total stock-based compensation expense	$ 3,220	$ 18,239	$ 6,368	$ 24,099

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	4,595,247	$ 62.43	4.5	
Granted	482,353	$ 2.33	9.7	
Expired	(616,645)	$ 33.41		
Outstanding at June 30, 2022	4,460,955	$ 59.94	5.2	$ 251
Nonvested at June 30, 2022	1,055,264	$ 6.74	9.0	$ 251
Exercisable	3,405,691	$ 76.42	3.9	

At June 30, 2022 total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $4.1 million, which is expected to be recognized over a weighted-average period of 1.4 years. At June 30, 2022 the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately $9.1 million, which is expected to be recognized over a weighted-average period of 1.4 years. The weighted-average grant date fair value of options granted during the six months ended June 30, 2022 and 2021 was $1.64 and $8.32 per share, respectively. The weighted average grant date fair value of RSUs awarded during the six months ended June 30, 2022 and 2021 was $2.43 and $11.92 per share, respectively.

Stock Option Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2021	835,297	$ 7.76
Granted	482,353	1.64
Vested/Issued	(262,386)	8.14
Nonvested shares at June 30, 2022	1,055,264	$ 4.87

Restricted Stock Unit Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2021	1,399,317	$ 11.03
Granted	1,244,936	2.43
Vested/Issued	(514,900)	11.67
Forfeited	(220,570)	7.54
Nonvested shares at June 30, 2022	1,908,783	$ 5.66

Note 11—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 $1.0 million for the six months ended June 30, 2022 and 2021, respectively.

Note 12—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 ("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 (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 permitted the Company to make the milestone payment in installments with the remaining amount payable to Pfizer (including interest). The milestone payment accrued interest at 6.25% per annum. The milestone payment including accrued interest of $1.8 million was paid in full in September 2021. The installment payments and accrued interest were 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. During the three months ended June 30, 2022, the Company paid the amount due of $27.1 million related to *Hsu v. Puma Biotechnology, Inc., et al.,* and no amount was recorded as payable at June 30, 2022. Also, there remained an accrual amount of $2.9 million at June 30, 2022 on the accompanying consolidated balance sheets related to *Eshelman v. Puma Biotechnology, Inc., et al.* as detailed below. For certain legal expenses related to the verdicts listed below, the Company has received reimbursements from its insurers.

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

On October 29, 2021, the parties informed the court that they had reach a settlement in principle, and the court entered judgment in the amount of claimed damages and prejudgment interest totaling approximately $54.2 million. On November 2, 2021, the court dismissed the case in light of the parties' settlement, retaining jurisdiction only for settlement approval. The parties' settlement provides that there will be no judgment for liability entered against the Company or its Chief Executive Officer, Alan Auerbach, and provides for two installment payments by the Company of approximately $27.1 million each, which were paid in January 2022 and June 2022. On December 29, 2021, the Court issued an order preliminarily approving the parties' settlement. On August 3, 2022, the Court ordered final approval of the parties' settlement.

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

In February 2016, Fredric N. Eshelman filed a lawsuit against the Company's Chief Executive Officer and President, Alan H. Auerbach, and the Company 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 Mr. Auerbach and the Company 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 the Company took place from March 11 to March 15, 2019. At trial, the jury found the Company liable and awarded Dr. Eshelman $15.9 million in compensatory damages and $6.5 million in punitive damages. The Company strongly disagreed 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. The Company has 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 prejudgment interest. In the Court's March 2020 ruling, it denied the motion for attorneys' fees but granted the request for prejudgment 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, et al* matter but found the $22.4 million damages award, payable by the Company, 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 eliminates 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. On October 18, 2021, the plaintiff filed a petition of certiorari with the Supreme Court seeking review of the Fourth Circuit's ruling, which was denied on December 13, 2021. On remand, the District Court set a trial date for the new trial on damages for November 7, 2022. We estimate the high end of potential damages in the matter could be approximately $2.9 million which also represents our estimate as the most likely outcome.

Due to the appeal, the Company secured a bond for the potential damages, which was collateralized by an automatically renewable stand-by letter of credit in the amount of $8.9 million, which was classified as restricted cash, current, as of December 31, 2021. In the six months ended June 30, 2022, the bond was cancelled and the stand-by letter of credit was released, which increased our cash by $8.9 million on the accompanying consolidated balance sheets.

Legal Malpractice Suits

On September 17, 2020, the Company filed a lawsuit against Hedrick Gardner Kincheloe & Garofalo, L.L.P. and David L. Levy, the attorneys who previously represented the Company in *Eshelman v. Puma Biotechnology, Inc., et al.* in the Superior Court of Mecklenburg County, North Carolina. The Company is alleging legal malpractice based on the defendants' negligent handling of the defense of the Company in *Eshelman v. Puma Biotechnology, Inc., et al*. as detailed above. The Company is 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. On October 7, 2021, Judge R. Stuart Albright entered into an Order staying all proceedings in the legal malpractice case for six months to allow time to resolve the damages issues in the Eshelman case. As a result, the amount of any potential damages that may be recovered in the legal malpractice case is uncertain at this time.

Patent-Related Proceedings

AstraZeneca Litigation

On September 22, 2021, Puma filed suit against AstraZeneca Pharmaceuticals, LP, AstraZeneca AB, and AstraZeneca PLC for infringement of United States Patent Nos. 10,603,314 ("the '314 patent") and 10,596,162 ("the '162 patent"). (*Puma Biotechnology, Inc. et al. v. AstraZeneca Pharmaceuticals LP et al*, 1:21CV01338 (D. Del. Sep. 22, 2021)). Puma's complaint alleges that AstraZeneca's commercial manufacture, use, offer for sale, sale, distribution, and/or importation of Tagrisso® (osimertinib) products for the treatment of gefitinib and/or erlotinib-resistant non-small cell lung cancer infringes the '314 and '162 patents. Puma is an exclusive licensee of the '314 and '162 patents under the Pfizer Agreement. Wyeth is a co-plaintiff. Plaintiffs seek a judgment that AstraZeneca's product infringes the asserted patents and an award of monetary damages in an amount to be proven at trial. AstraZeneca AB and AstraZeneca Pharmaceuticals LP filed an answer and counterclaims on November 5, 2021, including claims challenging the asserted patents as not infringed and/or invalid, and accusing plaintiffs of patent misuse. The parties stipulated to dismiss AstraZeneca PLC as a defendant and Pfizer as a Counterclaim Defendant on December 10, 2021, which the Court so ordered on December 13, 2021. Puma filed its answer to AstraZeneca's counterclaims on December 17, 2021, denying those claims. The case was recently reassigned to visiting Judge Matthew Kennelly of the Northern District of Illinois. The parties filed a joint status report about the case and attended a teleconference with the Court on February 9, 2022. The parties submitted a joint discovery plan and proposed schedule for consideration by the Court on February 15, 2022. On February 16, 2022, Judge Kennelly entered a schedule for the case, including setting the matter for trial to begin on or after May 13, 2024. The parties are conducting fact discovery and have begun the claim construction process. On May 27, 2022, AstraZeneca filed a motion for judgment on the pleadings, seeking a ruling from the Court that plaintiffs have no right to pursue or collect any monetary damages in this case based on activities that took place before the patents-in-suit were issued. The Court agreed with Plaintiffs, however, that AstraZeneca's motion is premature. Accordingly, the Court denied AstraZeneca's motion without prejudice, with leave to refile it at the time for summary judgment motions, which are anticipated no earlier than November 2023 under the current schedule.

Sandoz Litigation

On November 10, 2021, Puma filed suit against Sandoz, Inc. for infringement of U.S. Patent No. 7,399,865 B2 (“the '865 patent”) (*Puma Biotechnology, Inc. et al. v. Sandoz Inc.*, 1:21CV19918 (D.N.J. Nov. 10, 2021**)** in the U.S. District Court for the District of New Jersey. The Complaint was filed within 45 days of Sandoz providing notice of its abbreviated new drug application (“ANDA”) seeking approval to market a generic version of Puma’s NERLYNX (neratinib) Tablets, 40 mg prior to the expiration of the '865 patent. Puma and Wyeth seek judgment that Sandoz’s purported ANDA product would, if allowed on the market, infringe the ‘865 patent, and ask that the Court order that, pursuant to 35 U.S.C. 271(e)(4)(A), the FDA’s approval of the Sandoz NDA can be no earlier than the date the ‘865 patent expires. Sandoz has stated that, due to Paragraph III certifications filed for other patents listed in the Orange Book in conjunction with NERLYNX, Sandoz cannot launch its ANDA product until November 21, 2030, at the earliest. Puma’s complaint alleges that Sandoz has infringed the '865 patent by seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of NERLYNX in the United States prior to the expiration of the '865 patent. Puma is the exclusive licensee of the '865 patent under the Pfizer Agreement. Wyeth is a co-plaintiff. Sandoz submitted its answer to the complaint on January 14, 2022 and asserted counterclaims challenging the ‘865 patent as invalid. Puma and Wyeth filed an answer to those counterclaims on February 4, 2022. The filing of Puma’s Complaint against Sandoz triggered a 30-month stay of marketing approval for Sandoz’s ANDA. The parties appeared before the Magistrate Judge on February 15, 2022, for an initial hearing, and submitted a scheduling order on February 18, 2022. The Magistrate Judge entered the scheduling order on February 22, 2022, including setting the close of fact discovery on June 14, 2023, and the close of expert discovery on March 2, 2024. The parties are currently engaged in fact discovery.

China Litigation

On January 18, 2022, Shanghai Acebright Pharmaceuticals Group Co., Ltd. (“Acebright”) filed an ANDA with the National Medical Products Administration in China (“NMPA”) seeking approval to market a generic version of Puma’s NERLYNX (neratinib) tablet, 40mg in China. Acebright seeks approval prior to the expiration of three patents listed on the China Patent Information Registration Platform for Marketed Drugs (“Chinese Orange Book”), namely, Chinese Patent Nos. ZL201410082103.7, ZL201080060546.6, and ZL200880118789.3 (“NERLYNX Patents”), alleging in a Type 4.2 patent declaration that its generic version of NERLYNX does not fall within the scope of the claims of NERLYNX Patents listed on the Chinese Orange Book. The patent declaration of Acebright were published on the Chinese Orange Book on January 19, 2022. On March 2, 2022, Puma filed petitions with the China National Intellectual Property Administration (“CNIPA”) and requested administrative determination that Acebright’s generic neratinib tablet falls within the scope of the claims of NERLYNX Patents listed on the Chinese Orange Book. Puma’s request for administrative determination was accepted by CNIPA on March 18, 2022. Puma has notified NMPA of the acceptance of the request for administrative determination for NMPA to institute a stay of Acebright’s ANDA for nine months. If, during the nine-month stay period, an administrative determination is made that Acebright’s generic neratinib tablet falls within the scope of the claims of the NERYLYNX Patents listed on the Chinese Orange Book, NMPA will be prohibited from approving Acebright’s ANDA until the NERLYNX Patents expire.

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, 2021.

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. Our lead product is NERYLYNX®, an oral version of neratinib, which is a potent irreversible tyrosine kinase inhibitor ("TKI") that blocks signal transduction through the human epidermal growth factor receptors, HER1, HER2 and HER4. In 2017, we obtained approval from the FDA to market, and commence commercialization of NERYLYNX in the United States for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. More recently, in February 2020, we received FDA approval to expand the indication for NERLYNX to include its use 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 metastatic setting. 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 epidermal growth factor receptor ("EGFR") such as 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 ("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 ("EC") granted marketing authorization for NERLYNX in the European Union ("EU") 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.

In July 2021, we announced that the U.S. Food and Drug Administration ("FDA") approved a labeling supplement to the U.S. Prescribing Information for NERLYNX that incorporates the use of NERLYNX dose escalation as evaluated in the Phase II CONTROL Trial. In July 2021, our Canadian partner, Knight Therapeutics, Inc., received Health Canada's approval of an alternate dosing regimen (two-week dose escalation) to be incorporated into the prescribing information.

On July 23, 2021, we entered into a note purchase agreement with Athyrium Opportunities IV Co-Invest 1 LP ("Athyrium") for an aggregate principal amount of $100.0 million. The borrowings under the Athyrium Note Purchase Agreement ("Athyrium Notes"), together with cash on hand, were used to repay the outstanding indebtedness, including the applicable exit and prepayment fees owed to lenders under our Oxford Credit facility. See Note 9—Debt for further details regarding both the Athyrium Notes and Oxford Loan and Security Agreement.

In the fourth quarter of 2021, Puma received additional approvals for the use of NERLYNX in the extended adjuvant population. On November 11, 2021, Bixink, Puma's partner in South Korea announced the approval of NERLYNX by the Korean Ministry of Food and Drug Safety and on December 13, 2021, Pint Pharma, Puma's partner in Latin America announced that the Brazilian Health Authority ("ANVISA") had approved NERLYNX in Brazil.

In December 2021, NERLYNX (neratinib) was included in the updated National Reimbursement Drug List ("NRDL") by the China National Healthcare Security Administration ("NHSA") for patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer after adjuvant trastuzumab based therapy. The addition of NERLYNX to the China NRDL now enables broad access to neratinib to more women throughout China.

During the six months ended June 30, 2022 we entered into a Securities Purchase Agreement (the "Purchase Agreement") with Alan Auerbach, our President, Chief Executive Officer and Chairman of the Board, and Athyrium Opportunities IV Co-Invest 2 LP, an affiliate of the administrative agent and a purchaser under our existing note purchase agreement (together with Mr. Auerbach, the "Purchasers"). Pursuant to the Purchase Agreement, we sold an aggregate of 3,584,228 shares of our common stock to the Purchasers for aggregate gross proceeds of approximately $10.0 million before deducting any offering expenses (the "Private Placement"). The purchase price for each share was $2.79, which was equal to the closing price of our common stock on NASDAQ on the date of the Purchase Agreement. Each Purchaser purchased approximately $5.0 million of the shares. The Private Placement closed on March 10, 2022.

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. Many clinics, hospitals and other healthcare facilities have imposed additional restrictions which has reduced our commercial team's abilities to engage with customers overall and has significantly reduced face to face interactions as compared to pre-pandemic levels. 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 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 on for our international sales, have been impacted in similar ways by the COVID-19 pandemic. This impact has negatively impacted sales of Nerlynx and may continue to do so in the future. 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, 2022 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, 2022, 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 as stated in the Athyrium Notes.

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, 2022 from our accounting policies at December 31, 2021, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. We accounted for the following related to sub-license agreements and our legal contingencies and expense during the six months ended June 30, 2022:

License Revenue:

We recognize license revenue under certain of our sub-license agreements that are within the scope of Accounting Standards Codification ("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 using an input measure.

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 12—Commitments and Contingencies in the notes to the unaudited condensed consolidated financial statements included in this Quarterly Report).

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.

Product revenue also consists of product sales under sub-license agreements to our sub-licensees, who then sell into their respective international territories.

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 ("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 ("R&D Expenses") include costs associated with services provided by consultants who conduct and perform clinical services on our behalf and contract organizations for the manufacturing of clinical materials. During the three and six months ended June 30, 2022 and 2021 our R&D Expenses consisted primarily of clinical research organization ("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, 2022 Compared to Three Months Ended June 30, 2021

Total revenue:

Total revenue for the three months ended June 30, 2022 was approximately $59.5 million, compared to $53.4 million for the three months ended June 30, 2021. This increase in total revenue was due to an increase in product sales of $2.5 million and an increase in royalty revenue of $3.9 million, primarily attributable to an increase in China related sales in the three months ended June 30, 2022.

Product revenue, net:

Product revenue, net was approximately $51.3 million for the three months ended June 30, 2022, compared to $48.9 million for the three months ended June 30, 2021. This increase in product revenue, net was primarily attributable to an increase in net selling price compared to the three months ended June 30, 2021, partially offset by a decrease of approximately 4.6% in bottles of NERLYNX sold compared to the three months ended June 30, 2021. The relative deductions to gross revenue for variable consideration were slightly higher compared to the three months ended June 30, 2021.

Royalty revenue:

Royalty revenue was approximately $8.2 million for the three months ended June 30, 2022, compared to approximately $4.3 million for the three months ended June 30, 2021. The increase was due to increased product sales by our sub-licensees as they continue to commercialize NERLYNX in additional territories, including an increase in China sales.

Cost of sales:

Cost of sales was approximately $14.9 million for the three months ended June 30, 2022, compared to approximately $12.0 million for the three months ended June 30, 2021. The increase was due primarily to higher royalties due on increased non-U.S. partner sales.

Selling, general and administrative expenses:

For the three months ended June 30, 2022 SG&A Expenses were approximately $20.6 million, compared to approximately $39.4 million for the three months ended June 30, 2021. SG&A Expenses for the three months ended June 30, 2022 and 2021 were as follows:

Selling, general, and administrative expenses (in thousands)	**For the Three Months Ended June 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Payroll and related costs	$ 5,817	$ 10,088	$ (4,271)	-42.3%
Professional fees and expenses	8,854	9,633	(779)	-8.1%
Travel and meetings	1,514	1,030	484	47.0%
Facilities and equipment costs	1,349	1,401	(52)	-3.7%
Stock-based compensation	2,111	16,731	(14,620)	-87.4%
Other	931	527	404	76.7%
	$ 20,576	$ 39,410	$ (18,834)	-47.8%

For the three months ended June 30, 2022 SG&A Expenses decreased by approximately $18.8 million compared to the same period in 2021, primarily attributable to the following:

- a decrease in payroll and related costs of approximately $4.3 million, consisting of approximately $2.3 million from lower headcount and a $2.0 million payroll tax credit under the CARES Act;
- a decrease in professional fees and expenses of approximately $0.8 million, consisting primarily of a decrease of approximately $1.4 million for professional fees, primarily related to decreased consultancy efforts related to marketing and commercialization support, and a decrease of approximately $0.3 million in insurance and other expenses, partially offset by an increase of approximately $0.9 million in legal fees;
- an increase in travel and meetings of approximately $0.5 million, primarily due to the easing of COVID-19 travel restrictions;
- a decrease in stock-based compensation expense of approximately $14.6 million, primarily due to the $13.6 million incremental expense resulting from the modification to the term of Mr. Auerbach's warrant in 2021, and approximately $1.0 million due to the impact of headcount reductions at the end of 2021; and
- an increase in other expenses of approximately $0.4 million, primarily due to a $1.0 million recovery in 2021 of a 2020 bad debt expense, offset by a decrease of approximately $0.6 million primarily consisting of lower software/subscriptions, sponsorships, bank fees, and other immaterial expenses.

Research and development expenses:

For the three months ended June 30, 2022 R&D Expenses were approximately $12.0 million, compared to approximately $18.6 million for the three months ended June 30, 2021. R&D Expenses for the three months ended June 30, 2022 and 2021, and were as follows:

Research and development expenses (in thousands)	**For the Three Months Ended June 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Clinical trial expense	$ 4,694	$ 6,982	$ (2,288)	-32.8%
Internal R&D	5,319	8,209	(2,890)	-35.2%
Consultant and contractors	844	1,940	(1,096)	-56.5%
Stock-based compensation	1,109	1,507	(398)	-26.4%
	$ 11,966	$ 18,638	$ (6,672)	-35.8%

For the three months ended June 30, 2022 R&D Expenses decreased by approximately $6.7 million compared to the same period in 2021, primarily attributable to the following:

- a decrease in clinical trial expense of approximately $2.3 million, primarily due to the reduction in the number of patients in certain clinical trials;
- a decrease in internal R&D of approximately $2.9 million, consisting of approximately $1.8 million from a payroll tax credit under the CARES Act and approximately $1.1 million from a lower headcount and decrease in clinical trial activity;
- a decrease in consultant and contractors expense of approximately $1.1 million, primarily due to the close of the CONTROL study and a reduction in the number of patients being treated in the SUMMIT study; and
- a decrease in stock-based compensation expense of approximately $0.4 million, primarily due to the impact of headcount reductions in 2021.

Other income (expenses):

Other income (expenses) (in thousands)	**For the Three Months Ended June 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Interest income	$ 65	$ 121	$ (56)	-46.3%
Interest expense	(2,702)	(3,518)	816	-23.2%
Legal verdict (expense) credit	(55)	14,902	(14,957)	-100.4%
Other income	62	60	2	3.3%
	$ (2,630)	$ 11,565	$ (14,195)	-122.7%

Interest expense:

For the three months ended June 30, 2022 we recognized approximately $2.7 million in interest expense, compared to approximately $3.5 million of interest expense for the three months ended June 30, 2021. The decrease in interest expense was primarily the result of $0.3 million interest accrued in the three months ended June 30, 2021, related to a milestone payment due to Pfizer in installments, as well as lower costs related to our outstanding debt.

Legal verdict (expense) credit:

For the three months ended June 30, 2022 legal expense related to the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment was immaterial. See Part II, Item 1. "Legal Proceedings" in this Quarterly Report for further details.

For the quarter ended June 30, 2021, we recognized $14.9 million in legal verdict contra-expense, which represented an adjustment to the amount originally recorded for the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment due to a subsequent ruling on the matter, partially offset by.an estimate of service fees incurred related to the class action administrator and pre-judgment interest as a result of the *Hsu v. Puma Biotechnology, Inc., et al.* claims process.

Six Months Ended June 30, 2022 Compared to Six Months Ended June 30, 2021

Total revenue:

For the six months ended June 30, 2022 total revenue was approximately $105.3 million, compared to $151.6 million for the six months ended June 30, 2021. This decrease was primarily attributable to a one-time license fee of $50.0 million in the six months ended June 30, 2021.

Product revenue, net:

Product revenue, net was approximately $92.0 million for the six months ended June 30, 2022, compared to $94.7 million for the six months ended June 30, 2021. This decrease in product revenue, net was primarily attributable to a volume decrease of approximately 10.9% in bottles of NERLYNX sold, offset by an increase in net selling price compared to the six months ended June 30, 2021. The relative deductions to gross revenue for variable consideration were slightly higher compared to the six months ended June 30, 2021.

Royalty revenue:

Royalty revenue was approximately $13.2 million for the six months ended June 30, 2022, compared to approximately $6.6 million for the six months ended June 30, 2021. The increase was due to increased product sales by our sub-licensees as they continue to commercialize NERLYNX in additional territories, including an increase in China sales.

Cost of sales:

Cost of sales was approximately $25.8 million for the six months ended June 30, 2022, compared to approximately $41.5 million for the six months ended June 30, 2021. The decrease was primarily attributable to a one-time expense of $20.0 million related to the termination of the CANbridge Biomed Limited distribution agreement during the six months ended June 30, 2021, partially offset by higher royalties due on increased non-U.S. partner sales.

Selling, general and administrative expenses:

For the six months ended June 30, 2022 SG&A Expenses were approximately $41.0 million, compared to approximately $67.7 million for the six months ended June 30, 2021. SG&A Expenses for the six months ended June 30, 2022 and 2021 were as follows:

Selling, general, and administrative expenses (in thousands)	**For the Six Months Ended June 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Payroll and related costs	$ 13,392	$ 20,599	$ (7,207)	-35.0%
Professional fees and expenses	16,398	20,416	(4,018)	-19.7%
Travel and meetings	2,506	2,042	464	22.7%
Facilities and equipment costs	2,711	2,795	(84)	-3.0%
Stock-based compensation	4,310	20,333	(16,023)	-78.8%
Other	1,661	1,563	98	6.3%
	$ 40,978	$ 67,748	$ (26,770)	-39.5%

For the six months ended June 30, 2022 SG&A Expenses decreased by approximately $26.8 million compared to the same period in 2021, primarily attributable to the following:

- a decrease in payroll and related costs of approximately $7.2 million, consisting of approximately $5.2 million from decreased headcount and a $2.0 million payroll tax credit under the CARES Act;
- a decrease in professional fees and expenses of approximately $4.0 million, consisting primarily of a decrease of approximately $4.0 million for professional fees, primarily related to decreased consultancy efforts related to marketing and commercialization support, and a decrease of approximately $0.4 million in insurance and other expenses, partially offset by an increase of approximately $0.4 million in legal fees;
- an increase in travel and meetings of approximately $0.5 million, primarily due to the easing of COVID-19 travel restrictions; and
- a decrease in stock-based compensation expense of approximately $16.0 million, primarily due to the $13.6 million incremental expense resulting from the modification to the term of Mr. Auerbach's warrant in 2021, and a decrease of approximately $2.4 million due to the impact of headcount reductions at the end of 2021.

Research and development expenses:

For the six months ended June 30, 2022 R&D Expenses were approximately $27.2 million, compared to approximately $38.9 million for the six months ended June 30, 2021. R&D Expenses for the six months ended June 30, 2022 and 2021 were as follows:

Research and development expenses (in thousands)	**For the Six Months Ended June 30,**		**Change**	
			$	%
	2022	**2021**	**2022/2021**	**2022/2021**
Clinical trial expense	$ 10,311	$ 13,108	$ (2,797)	-21.3%
Internal R&D	13,120	18,469	(5,349)	-29.0%
Consultant and contractors	1,714	3,523	(1,809)	-51.3%
Stock-based compensation	2,058	3,766	(1,708)	-45.4%
	$ 27,203	$ 38,866	$ (11,663)	-30.0%

For the six months ended June 30, 2022 R&D Expenses decreased by approximately $11.7 million compared to the same period in 2021, primarily attributable to the following:

- a decrease in clinical trial expense of approximately $2.8 million, primarily due to the reduction in the number of patients in certain clinical trials;
- a decrease in internal R&D expenses of approximately $5.3 million, consisting of approximately $3.6 million due to a decrease in headcount and clinical trial activity, and a decrease of approximately $1.8 million from a payroll tax credit under the CARES Act;
- a decrease in consultant and contractors' expense of approximately $1.8 million, primarily due to the close of the CONTROL study and a reduction in the number of patients being treated in the SUMMIT study; and
- a decrease in stock-based compensation expense of approximately $1.7 million, primarily due to the impact of headcount reductions in 2021.

Other income (expenses):

Other income (expenses) (in thousands)	**For the Six Months Ended June 30,**		**Change**	
			$	%
	2022	**2021**	**2022/2021**	**2022/2021**
Interest income	$ 78	$ 134	$ (56)	-41.8%
Interest expense	(5,366)	(6,968)	1,602	-23.0%
Legal verdict (expense) credit	(73)	14,717	(14,790)	-100.5%
Other income	112	102	10	9.8%
	$ (5,249)	$ 7,985	$ (13,234)	-165.7%

Interest expense:

For the six months ended June 30, 2022 we recognized approximately $5.4 million in interest expense, compared to approximately $7.0 million of interest expense for the six months ended June 30, 2021. The decrease in interest expense was primarily the result of $0.6 million of interest accrued in the six months ended June 30, 2021 related to a milestone payment due to Pfizer in installments, as well as lower costs related to our outstanding debt.

Legal verdict (expense) credit:

For the six months ended June 30, 2022 legal expense related to the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment was immaterial. See Part II, Item 1. "Legal Proceedings" in this Quarterly Report for further details.

For the quarter ended June 30, 2021, we recognized $14.9 million in legal verdict contra-expense, which represented an adjustment to the amount originally recorded for the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment due to a subsequent ruling on the matter, partially offset by.an estimate of service fees incurred related to the class action administrator and pre-judgment interest as a result of the *Hsu v. Puma Biotechnology, Inc., et al.* claims process.

Liquidity and Capital Resources

On October 29, 2021, the parties to our class action lawsuit, *Hsu v. Puma Biotechnology, Inc. et al,* informed the court that they had reached a settlement in principle, and the court entered judgement in the amount of claimed damages and prejudgment interest totaling approximately $54.2 million. The first payment of $27.1 million was made in January of 2022 with the remaining balance paid in June of 2022.

Historically, in connection with the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment, we secured a bond for the potential damages, which was collateralized by an automatically renewable stand-by letter of credit in the amount of $8.9 million, which was classified as restricted cash, current, as of December 31, 2021. In the six months ended June 30, 2022, the bond was cancelled and the stand-by letter of credit was released, which increased our cash by $8.9 million on the accompanying consolidated balance sheets.

The following table, which summarizes our liquidity and capital resources as of June 30, 2022 and December 31, 2021 and for the six months ended June 30, 2022 and 2021, is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	As of June 30, 2022	As of December 31, 2021
Cash and cash equivalents	$ 52,756	$ 63,131
Marketable securities	$ 7,998	$ 18,975
Working capital	$ 57,446	$ 30,436
Stockholders' Equity (deficit)	$ 19,738	$ (2,446)

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Cash provided by (used in):		
Operating activities	$ (40,769)	$ 15,587
Investing activities	10,979	(11,032)
Financing activities	9,845	—
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (19,945)	$ 4,555

Operating Activities:

Cash used in operating activities for the six months ended June 30, 2022 consisted of net income of approximately $6.0 million, offset by a decrease of approximately $10.9 million of non-cash items, including stock-based compensation, depreciation and amortization. Further changes in cash flows from operations included a decrease in accrued expenses and other of approximately $52.2 million related primarily to the $54.3 million in payments towards our class action lawsuit settlement, a decrease of approximately $1.3 million in accounts payable, a decrease in our post-marketing commitment liability of approximately $0.5 million, an increase in other assets of approximately $3.8 million due to a tax credit receivable related to the CARES Act, and an increase of approximately $1.5 million in accounts receivable, partially offset by a decrease of $1.3 million in prepaid expenses and other and a decrease in inventory of approximately $0.4 million.

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 inventory of approximately $4.2 million, an increase in accounts receivable, net of approximately $4.0 million, 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, a decrease in accrued expenses and other of approximately $18.5 million, a decrease in other current assets of approximately $3.2 million, and a decrease in accounts payable and other immaterial fluctuations of approximately $1.2 million.

Investing Activities:

Cash provided by investing activities for the six months ended June 30, 2022 was approximately $11.0 million, compared to net cash used in investing activities of approximately $11.0 million for the same period in 2021.

Cash provided by investing activities for the six months ended June 30, 2022 consisted of approximately $11.0 million in maturities of available-for-sale securities.

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

Financing Activities:

Cash provided by financing activities for the six months ended June 30, 2022 was approximately $9.8 million, representing the cash raised from the Purchase Agreement entered into on March 8, 2022 from Mr. Auerbach and Athyrium Opportunities IV Co-Invest 2 LP.

Oxford Loan and Security Agreement:

In October 2017, we entered into a loan and security agreement with Silicon Valley Bank ("SVB"), as administrative agent, and the lenders party thereto from time to time (the "Original Lenders"), including Oxford Finance, LLC ("Oxford"), and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement (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 (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.

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.

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.

Athyrium Note Purchase Agreement:

We issued senior notes for an aggregate principal amount of $100.0 million pursuant to the note purchase agreement dated July 23, 2021, by us, and our subsidiaries, and Athyrium, as Administrative Agent, and certain other investor parties (the "Note Purchase Agreement"), with an initial maturity date of July 23, 2026 (the "Athyrium Notes"). The Athyrium Notes were issued for face amount of $100.0 million net of an original issue discount of $1.5 million. The Athyrium Notes also require a 2.0% exit payment to be made on each payment of principal. The borrowings under the Athyrium Notes, together with cash on hand, were used to repay our outstanding indebtedness, including the applicable exit and prepayment fees owed to lenders under its Oxford Credit Facility. We can borrow up to an additional $25.0 million under the Note Purchase Agreement for general corporate purposes and to further support commercial initiatives. The Athyrium Notes are secured by substantially all of our assets. We incurred $1.9 million of deferred financing costs with the borrowing.

The Athyrium Notes bear interest at an annual rate equal to the sum of (i) 8.0% and (ii) three-month London Interbank Offering Rate ("LIBOR") rate where the three-month LIBOR rate cannot be less than 1.5% or greater than 3.5%. (or a comparable or successor rate that gives due consideration to the then prevailing rate used by commercial banks in the United States, which rate is reasonably determined by Athyrium). Interest is payable quarterly on the last business day of March, June, September and December each year. Beginning June 30, 2024, principal payments are required to be made quarterly at 11.11% of the original face amount with the remaining balance paid at maturity. Each principal payment will also include a 2.0% exit payment. As of December 31, 2021, the effective interest rate for the loan was 10.98%.

At the Company's option, the Company may prepay the outstanding principal balance of the notes in whole or in part, subject to a prepayment fee of 2.0% of the amount prepaid if the prepayment occurs on or prior to the second anniversary of the issuance date of such notes, plus the present value of remaining interest that would have accrued through and including the second anniversary date, and 2.0% of the amount prepaid if the prepayment occurs after the second anniversary but on or prior to the third anniversary of the issuance date of such notes.

The Athyrium Notes include affirmative and negative covenants applicable to the Company. 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 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 Company is also required to achieve certain minimum product revenue targets, measured as of the last day of each fiscal quarter on a trailing year-to-date basis.

As of June 30, 2022 there were $102 million in term loans outstanding under the Athyrium Notes, representing all of our long-term debt outstanding as of that date, and we were in compliance with all applicable covenants.

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 $52.8 million and $8.0 million in marketable securities available at June 30, 2022. 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, third-party debt financing 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 ("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, 2022 stock-based compensation represented approximately 9.9% and 9.3% of our operating expenses, respectively, compared to 31.4% and 22.6% for the same respective periods in 2021, 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 (Loss) and GAAP Net Income (Loss) Per Share to Non-GAAP Adjusted Net Income (Loss) Per Share (in thousands except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
GAAP net (loss) income	$ 9,371	$ (5,106)	$ 5,968	$ 11,322
Adjustments:				
Stock-based compensation -				
Selling, general and administrative (1)	2,111	16,731	4,310	20,332
Research and development (2)	1,109	1,508	2,058	3,767
Non-GAAP adjusted net income	$ 12,591	$ 13,133	$ 12,336	$ 35,421
GAAP net (loss) income per share—basic	$ 0.21	$ (0.13)	$ 0.14	$ 0.28
Adjustment to net (loss) income (as detailed above)	0.07	0.45	0.14	0.60
Non-GAAP adjusted basic net income per share	$ 0.28 (3)	$ 0.32 (4)	$ 0.28 (3)	$ 0.88 (4)
GAAP net (loss) income per share—diluted	$ 0.21	$ (0.13)	$ 0.14	$ 0.28
Adjustment to net (loss) income (as detailed above)	0.07	0.45	0.14	0.59
Non-GAAP adjusted diluted net income per share	$ 0.28 (5)	$ 0.32 (6)	$ 0.28 (5)	$ 0.87 (6)

(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 45,058,924 and 43,641,193 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2022, respectively.
(4)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.
(5) Non-GAAP adjusted diluted net income per share was calculated based on 45,358,739 and 43,889,556 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2022, respectively.
(6) Non-GAAP adjusted diluted net income per share was calculated based on 40,479,577 and 40,939,688 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2021, respectively.

Off-Balance Sheet Arrangements

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

Contractual Obligations

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, 2021.

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, 2022. 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 the "Athyrium Notes". As of June 30, 2022 the aggregate outstanding principal amounts of the Athyrium Notes was $100.0 million. The Athyrium Notes bear interest at a rate per annum equal to the sum of (a) 8.00% plus (b) the lesser of (x) three-month London Interbank Offered Rate ("LIBOR") and (y) 3.5% (or a comparable or successor rate that gives due consideration to the then prevailing rate used by commercial banks in the United States, which rate is reasonably determined by Athyrium). If overall interest rates had increased by one hundred basis points during the quarter ended June 30, 2022, our interest expense would have increased by $1.0 million.

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, 2022. 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, 2022.

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, 2022 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. On October 29, 2021, the parties informed the Court that they had reached a settlement in principle. The parties' settlement provides that there will be no judgment for liability entered against the defendants and provided payment by us of approximately $54.2 million in two installments, to be paid in January and June of 2022. On December 13, 2021, lead plaintiff filed a motion for preliminary approval of the settlement, and on December 29, 2021, the Court issued an order preliminarily approving the settlement. On December 29, 2021, the Court issued an order preliminarily approving the parties' settlement. The first payment of $27.1 million was made in January of 2022, with the remaining balance paid in June 2022. On August 3, 2022, the Court ordered final approval of the parties' settlement.

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

In February 2016, Fredric N. Eshelman filed a lawsuit against the Company's Chief Executive Officer and President, Alan H. Auerbach, and the Company 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 Mr. Auerbach and the Company 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 the Company took place from March 11 to March 15, 2019. At trial, the jury found the Company liable and awarded Dr. Eshelman $15.9 million in compensatory damages and $6.5 million in punitive damages. The Company strongly disagreed 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. The Company has 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 prejudgment interest. In the Court's March 2020 ruling, it denied the motion for attorneys' fees but granted the request for prejudgment 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, et al* matter but found the $22.4 million damages award, payable by the Company, 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 eliminates 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. On October 18, 2021, the plaintiff filed a petition of *certiorari* with the Supreme Court seeking review of the Fourth Circuit's ruling, which was denied on December 13, 2021. On remand, the District Court set a trial date for the new trial on damages for November 7, 2022. We estimate the high end of potential damages in the matter could be approximately $2.9 million which also represents our estimate as the most likely outcome.

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.* and all legal fees and expenses incurred in appealing from the judgment and retrying the damages phase of the trial. 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. On October 7, 2021, Judge R. Stuart Albright entered an Order staying all proceedings in the legal malpractice case for a period of six months to allow time to resolve the damages issues in the Eshelman case. As a result, the amount of potential damages that may be recovered in the legal malpractice case is uncertain at this time.

Patent-Related Proceedings

AstraZeneca Litigation

On September 22, 2021, Puma filed suit against AstraZeneca Pharmaceuticals, LP, AstraZeneca AB, and AstraZeneca PLC for infringement of United States Patent Nos. 10,603,314 ("the '314 patent") and 10,596,162 ("the '162 patent"). (*Puma Biotechnology, Inc. et al. v. AstraZeneca Pharmaceuticals LP et al.*, 1:21CV01338 (D. Del. Sep. 22, 2021)). Puma's complaint alleges that AstraZeneca's commercial manufacture, use, offer for sale, sale, distribution, and/or importation of Tagrisso® (osimertinib) products for the treatment of gefitinib and/or erlotinib-resistant non-small cell lung cancer infringes the '314 and '162 patents. Puma is an exclusive licensee of the '314 and '162 patents under the Pfizer Agreement. Wyeth is a co-plaintiff. Plaintiffs seek a judgment that AstraZeneca's product infringes the asserted patents and an award of monetary damages in an amount to be proven at trial. AstraZeneca AB and AstraZeneca Pharmaceuticals LP filed an answer and counterclaims on November 5, 2021, including claims challenging the asserted patents as not infringed and/or invalid, and accusing plaintiffs of patent misuse. The parties stipulated to dismiss AstraZeneca PLC as a defendant and Pfizer as a Counterclaim Defendant on December 10, 2021, which the Court so ordered on December 13, 2021. Puma filed its answer to AstraZeneca's counterclaims on December 17, 2021, denying those claims. The case was recently reassigned to visiting Judge Matthew Kennelly of the Northern District of Illinois. The parties filed a joint status report about the case and attended a teleconference with the Court on February 9, 2022. The parties submitted a joint discovery plan and proposed schedule for

consideration by the Court on February 15, 2022. On February 16, 2022, Judge Kennelly entered a schedule for the case, including setting the matter for trial to begin on or after May 13, 2024. The parties are conducting fact discovery and have begun the claim construction process. On May 27, 2022, AstraZeneca filed a motion for judgment on the pleadings, seeking a ruling from the Court that plaintiffs have no right to pursue or collect any monetary damages in this case based on activities that took place before the patents-in-suit were issued. The Court agreed with Plaintiffs, however, that AstraZeneca's motion is premature. Accordingly, the Court denied AstraZeneca's motion without prejudice, with leave to refile it at the time for summary judgment motions, which are anticipated no earlier than November 2023 under the current schedule.

Sandoz Litigation

On November 10, 2021, Puma filed suit against Sandoz, Inc. for infringement of U.S. Patent No. 7,399,865 B2 ("the '865 patent") (*Puma Biotechnology, Inc. et al. v. Sandoz Inc.*, 1:21CV19918 (D.N.J. Nov. 10, 2021**)** in the U.S. District Court for the District of New Jersey. The Complaint was filed within 45 days of Sandoz providing notice of its abbreviated new drug application ("ANDA") seeking approval to market a generic version of Puma's NERLYNX (neratinib) Tablets, 40 mg prior to the expiration of the '865 patent. Puma and Wyeth seek judgment that Sandoz's purported ANDA product would, if allowed on the market, infringe the '865 patent, and ask that the Court order that, pursuant to 35 U.S.C. 271(e)(4)(A), the FDA's approval of the Sandoz NDA can be no earlier than the date the '865 patent expires. Sandoz has stated that, due to Paragraph III certifications filed for other patents listed in the Orange Book in conjunction with NERLYNX, Sandoz cannot launch its ANDA product until November 21, 2030, at the earliest. Puma's complaint alleges that Sandoz has infringed the '865 patent by seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of NERLYNX in the United States prior to the expiration of the '865 patent. Puma is the exclusive licensee of the '865 patent under the Pfizer Agreement. Wyeth is a co-plaintiff. Sandoz submitted its answer to the complaint on January 14, 2022 and asserted counterclaims challenging the '865 patent as invalid. Puma and Wyeth filed an answer to those counterclaims on February 4, 2022. The filing of Puma's Complaint against Sandoz triggered a 30-month stay of marketing approval for Sandoz's ANDA. The parties appeared before the Magistrate Judge on February 15, 2022, for an initial hearing, and submitted a scheduling order on February 18, 2022. The Magistrate Judge entered the scheduling order on February 22, 2022, including setting the close of fact discovery on June 14, 2023, and the close of expert discovery on March 2, 2024. The parties are currently engaged in fact discovery.

China Litigation

On January 18, 2022, Shanghai Acebright Pharmaceuticals Group Co., Ltd. ("Acebright") filed an ANDA with the National Medical Products Administration in China ("NMPA") seeking approval to market a generic version of Puma's NERLYNX (neratinib) tablet, 40mg in China. Acebright seeks approval prior to the expiration of three patents listed on the China Patent Information Registration Platform for Marketed Drugs ("Chinese Orange Book"), namely, Chinese Patent Nos. ZL201410082103.7, ZL201080060546.6, and ZL200880118789.3 ("NERLYNX Patents"), alleging in a Type 4.2 patent declaration that its generic version of NERLYNX does not fall within the scope of the claims of NERLYNX Patents listed on the Chinese Orange Book. The patent declarations of Acebright were published on the Chinese Orange Book on January 19, 2022. On March 2, 2022, Puma filed petitions with the China National Intellectual Property Administration ("CNIPA") and requested administrative determination that Acebright's generic neratinib tablet falls within the scope of the claims of NERLYNX Patents listed on the Chinese Orange Book. Puma's request for administrative determination was accepted by CNIPA on March 18, 2022. Puma has notified NMPA of the acceptance of the request for administrative determination for NMPA to institute a stay of Acebright's ANDA for nine months. If, during the nine-month stay period, an administrative determination is made that Acebright's generic neratinib tablet falls within the scope of the claims of the NERYLYNX Patents listed on the Chinese Orange Book, NMPA will be prohibited from approving Acebright's ANDA until the NERLYNX Patents expire.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, 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. Except as described below, 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.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm us.

Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, "phishing" attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures despite the implementation of security measures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. For example, in June 2022 we experienced a cyber incident where an unauthorized actor deployed malware to a limited number of our systems and acquired certain files from our network. While this incident did not result in any material adverse impact to our business or operations, and while we employ security measures to prevent, detect, and mitigate potential for harm from such unauthorized intrusions, these security measures may not be effective in every instance, and there can be no assurance that another incident will not occur. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. System failures, accidents or security breaches could cause interruptions in our operations and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs and the development of our drug candidates could be delayed.

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

Recent Sales of Unregistered Securities

None

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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	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)
3.2	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)
10.1	Securities Purchase Agreement, dated March 8, 2022, by and between Puma Biotechnology, Inc. and the Purchasers listed on the Schedule of Purchasers thereto (filed as Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed with the SEC on July 25, 2022, and incorporated herein by reference)
31.1+	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 March 31, 2022
31.2+	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 March 31, 2022
32.1++	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
32.2++	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
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

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 4, 2022

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

Date: August 4, 2022

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

Exhibit 31.1

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, 2022;

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 4, 2022

/s/ Alan H. Auerbach
Alan H. Auerbach
Principal Executive Officer

Exhibit 31.2

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, 2022;

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 4, 2022

/s/ Maximo F. Nougues
Maximo F. Nougues
Chief Financial Officer

Exhibit 32.1

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, 2022, 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, 2022, 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 4, 2022

/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.

Exhibit 32.2

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, 2022, 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, 2022, 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 4, 2022

/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.