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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 September 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. 45,640,135 shares of Common Stock, par value $0.0001 per share, were outstanding as of October 31, 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 other drug candidates, including alisertib and 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)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 77,960	$ 63,131
Marketable securities	—	18,975
Accounts receivable	28,030	32,526
Inventory, net	5,452	7,109
Prepaid expenses, current	6,801	8,984
Restricted cash, current	—	8,850
Other current assets	4,110	447
Total current assets	122,353	140,022
Lease right-of-use assets, net	12,053	14,017
Property and equipment, net	1,282	1,756
Intangible assets, net	60,114	66,125
Restricted cash, long-term	2,591	3,311
Prepaid expenses and other, long-term	377	1,354
Total assets	$ 198,770	$ 226,585
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 14,927	$ 11,174
Accrued expenses, current	39,691	92,575
Post-marketing commitment liability, current	1,381	2,263
Lease liabilities, current	3,988	3,574
Total current liabilities	59,987	109,586
Accrued expenses, long-term	37	915
Lease liabilities, long-term	12,923	15,975
Post-marketing commitment liability, long-term	5,674	5,463
Long-term debt, net	97,994	97,092
Total liabilities	176,615	229,031
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Common stock - $.0001 par value per share; 100,000,000 shares authorized; 45,608,814 shares issued and outstanding at September 30, 2022 and 41,175,507 issued and outstanding at December 31, 2021	5	4
Additional paid-in capital	1,383,299	1,364,309
Accumulated other comprehensive loss	—	(2)
Accumulated deficit	(1,361,149)	(1,366,757)
Total stockholders' equity (deficit)	22,155	(2,446)
Total liabilities and stockholders' equity (deficit)	$ 198,770	$ 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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 54,287	$ 43,426	$ 146,319	$ 138,098
License revenue	—	—	—	50,250
Royalty revenue	2,815	2,819	16,037	9,450
Total revenue	57,102	46,245	162,356	197,798
Operating costs and expenses:				
Cost of sales	12,495	10,279	38,257	51,806
Selling, general and administrative	23,961	26,084	64,939	93,832
Research and development	11,253	18,836	38,456	57,702
Acquired in-process research and development	7,000	—	7,000	—
Total operating costs and expenses	54,709	55,199	148,652	203,340
Income (loss) from operations	2,393	(8,954)	13,704	(5,542)
Other income (expenses):				
Interest income	216	13	294	147
Interest expense	(2,947)	(3,121)	(8,313)	(10,089)
Legal verdict expense	(19)	(24,498)	(92)	(9,781)
Loss on debt extinguishment	—	(8,146)	—	(8,146)
Other income	64	71	176	173
Total other income (expenses)	(2,686)	(35,681)	(7,935)	(27,696)
Net income (loss) before income taxes	$ (293)	$ (44,635)	$ 5,769	$ (33,238)
Income tax expense	(67)	(37)	(161)	(112)
Net income (loss)	$ (360)	$ (44,672)	$ 5,608	$ (33,350)
Net income (loss) per share of common stock—basic	$ (0.01)	$ (1.09)	$ 0.13	$ (0.82)
Net income (loss) per share of common stock—diluted	$ (0.01)	$ (1.09)	$ 0.13	$ (0.82)
Weighted-average shares of common stock outstanding—basic	45,567,739	40,813,609	44,290,432	40,520,041
Weighted-average shares of common stock outstanding—diluted	45,567,739	40,813,609	44,464,682	40,520,041

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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income (loss)	$ (360)	$ (44,672)	$ 5,608	$ (33,350)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net of tax of $0 and $0	—	(1)	2	(2)
Comprehensive income (loss)	$ (360)	$ (44,673)	$ 5,610	$ (33,352)

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 September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at June 30, 2022	45,274,635	$ 5	$ 1,380,522	$ —	$ (1,360,789)	$ 19,738
Stock-based compensation	—	—	2,830	—	—	2,830
Shares issued or restricted stock units vested under employee stock plans	334,179	—	—	—	—	—
Issuance costs of approximately $0.1M for private investments in public equity	—	—	(53)	—	—	(53)
Net loss	—	—	—	—	(360)	(360)
Balance at September 30, 2022	45,608,814	$ 5	$ 1,383,299	$ —	$ (1,361,149)	$ 22,155

For the Three Months Ended September 30, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at June 30, 2021	40,733,928	$ 4	$ 1,355,775	$ (1)	$ (1,326,309)	$ 29,469
Stock-based compensation	—	—	4,282	—	—	4,282
Shares issued or restricted stock units vested under employee stock plans	126,914	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(44,672)	(44,672)
Balance at September 30, 2021	40,860,842	$ 4	$ 1,360,057	$ (2)	$ (1,370,981)	$ (10,922)

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 Nine Months Ended September 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	—	—	9,198	—	—	9,198
Shares issued or restricted stock units vested under employee stock plans	849,079	—	—	—	—	—
Shares issued under private investments in public equity, net of issuance costs of approximately $0.2M	3,584,228	1	9,792	—	—	9,793
Unrealized gain on available-for-sale securities	—	—	—	2	—	2
Net income	—	—	—	—	5,608	5,608
Balance at September 30, 2022	45,608,814	$ 5	$ 1,383,299	$ —	$ (1,361,149)	$ 22,155

For the Nine Months Ended September 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	—	—	28,381	—	—	28,381
Shares issued or restricted stock units vested under employee stock plans	774,455	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(33,350)	(33,350)
Balance at September 30, 2021	40,860,842	$ 4	$ 1,360,057	$ (2)	$ (1,370,981)	$ (10,922)

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 Nine Months Ended September 30,	
	2022	**2021**
Operating activities:		
Net income (loss)	$ 5,608	$ (33,350)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	6,713	8,327
Stock-based compensation	9,198	28,381
Provision for credit loss recovery	—	(1,000)
Disposal of property and equipment	1	—
Loss on debt extinguishment	—	8,146
Changes in operating assets and liabilities:		
Accounts receivable, net	4,496	2,744
Inventory, net	1,657	(3,752)
Prepaid expenses and other	3,160	2,574
Other current assets	(3,663)	3,190
Accounts payable	3,753	7,971
Accrued expenses and other	(53,762)	3,713
Post-marketing commitment liability	(671)	(859)
Net cash provided by (used in) operating activities	(23,510)	26,085
Investing activities:		
Purchase of available-for-sale securities	—	(38,073)
Maturity of available-for-sale securities	18,977	22,571
Net cash provided by (used in) investing activities	18,977	(15,502)
Financing activities:		
Gross proceeds from private investments in public equity	10,000	—
Issuance costs associated with private investments in public equity	(208)	—
Proceeds from debt	—	98,500
Payment of debt	—	(100,000)
Payment of prepayment costs, end of loan payment and other extinguishment costs	—	(8,519)
Payment of debt issuance costs	—	(1,910)
Installment payment for purchase of intangible asset	—	(20,000)
Net cash provided by financing activities	9,792	(31,929)
Net increase (decrease) in cash, cash equivalents and restricted cash	5,259	(21,346)
Cash, cash equivalents and restricted cash, beginning of period	75,292	97,454
Cash, cash equivalents and restricted cash, end of period	80,551	76,108
Supplemental disclosures of non-cash investing and financing activities:		
Amounts in accounts payable for acquired in-process research and development	$ 7,000	$ —
Supplemental disclosure of cash flow information:		
Interest paid	$ 7,412	$ 7,914
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.

In September 2022, the Company entered an exclusive license agreement with a subsidiary of Takeda Pharmaceutical Company Limited (“Takeda”) to license the worldwide research and development and commercial rights to alisertib, a selective, small-molecule, orally administered inhibitor of aurora kinase A.

The Company has reported net loss of approximately $0.4 million and net income of approximately $5.6 million for the three and nine months ended September 30, 2022, respectively, and cash flows used in operations of approximately $23.5 million for the nine months ended September 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 $78.0 million available at September 30, 2022. The Company believes that its existing cash and cash equivalents and marketable securities as of September 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 to successfully commercialize neratinib in the United States and to develop its newly acquired asset, alisertib. 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, delays in the development of alisertib, 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 September 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 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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Options outstanding	4,458,414	4,757,783	4,458,414	4,757,783
Warrant outstanding	2,116,250	2,116,250	2,116,250	2,116,250
Unvested restricted stock units	1,350,925	1,891,958	2,113,930	1,891,958
Totals	7,925,589	8,765,991	8,688,594	8,765,991

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 11—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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net income (loss)	$ (360)	$ (44,672)	$ 5,608	$ (33,350)
Denominator:				
Weighted average common stock outstanding for basic net income (loss) per share	45,568	40,814	44,290	40,520
Net effect of dilutive common stock equivalents	—	—	175	—
Weighted average common stock outstanding for diluted net income (loss) per share	45,568	40,814	44,465	40,520
Net income (loss) per share of common stock				
Basic	$ (0.01)	$ (1.09)	$ 0.13	$ (0.82)
Diluted	$ (0.01)	$ (1.09)	$ 0.13	$ (0.82)

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 nine months ended September 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 September 30, 2022, and, therefore, the transaction price was not reduced further during the quarter ended September 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 September 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 $2.8 million and $16.0 million for the three and nine months ended September 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 13—Commitments and Contingencies).

Royalty Expenses:

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

Research and Development Expenses:

Research and development expenses ("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.

Acquired In-Process Research and Development Expense

The Company has acquired, and may continue to acquire, the rights to develop new product candidates. Payments to acquire a new product candidate are immediately expensed as acquired in-process research and development provided that the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

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 11—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 September 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 September 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 September 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):

September 30, 2022	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents	$ 46,136	$ —	$ —	$ 46,136
Totals	$ 46,136	$ —	$ —	$ 46,136

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):

September 30, 2022	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 46,136	$ —	$ —	$ 46,136
Totals		$ 46,136	$ —	$ —	$ 46,136

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 September 30, 2022 were approximately $80.5 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 September 30, 2022 the Company's inventory balance consisted primarily of raw materials and work-in-process purchased subsequent to FDA approval of NERLYNX.

	September 30, 2022	December 31, 2021
Raw materials	$ 2,025	$ 4,569
Work-in-process (materials, labor and overhead)	2,945	1,385
Finished goods (materials, labor and overhead)	482	1,155
Total Inventories	$ 5,452	$ 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 6—Leases.

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

The incremental borrowing rate ("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 September 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.

In September 2022, the Company entered an exclusive license agreement with Takeda to license the worldwide research and development and commercial rights to alisertib, a selective, small-molecule, orally administered inhibitor of aurora kinase A. The up-front payment of $7.0 million was expensed as acquired in-process research and development as the product candidate has not achieved regulatory approval for marketing and has no alternative future use.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. In connection with the FDA approval of NERLYNX in July 2017, the Company triggered a one-time milestone payment pursuant to its license agreement with Pfizer. In June 2020, the Company entered into a letter agreement with Pfizer relating to the method of payment associated with a milestone payment under the Company's license agreement with Pfizer (see Note 13—Commitments and Contingencies). The Company capitalized the milestones as intangible assets and is amortizing the assets to cost of sales on a straight-line basis over the estimated useful life of the licensed patent through 2030. The Company recorded amortization expense related to its intangible assets of approximately $2.0 million and $6.0 million for the three and nine months ended September 30, 2022, respectively. As of September 30, 2022 estimated future amortization expense related to the Company's intangible assets was approximately $2.0 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 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):

	September 30, 2022	December 31, 2021
Trade accounts receivable	$ 24,505	$ 29,646
Royalty revenue receivable	3,525	2,880
Total accounts receivable	$ 28,030	$ 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 September 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 September 30, 2022 and December 31, 2021.

Note 4—Prepaid Expenses and Other:

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

	September 30, 2022	December 31, 2021
Current:		
CRO services	$ 271	$ 340
Other clinical development	2,503	2,933
Insurance	589	3,178
Professional fees	877	398
Other	2,561	2,135
	6,801	8,984
Long-term:		
CRO services	160	166
Other clinical development	—	577
Other	217	611
	377	1,354
Totals	$ 7,178	$ 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—Other Current Assets:

Other current assets consisted of the following at September 30, 2022 (in thousands):

	September 30, 2022	December 31, 2021
CARES Act Credit Receivable	$ 3,848	$ —
Other	262	447
Totals	$ 4,110	$ 447

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

Note 6—Leases:

In December 2011, the Company entered into a non-cancelable operating lease for office space in Los Angeles, California, which was subsequently amended in November 2012, December 2013, March 2014, July 2015, and December 2017. The initial term of the lease was for seven years and commenced on December 10, 2011. As amended, the Company rents approximately 65,656 square feet. The term of the lease runs until March 2026 and rent amounts payable by the Company increase approximately 3% per year. Concurrent with the execution of the lease, the Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $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 nine months ended September 30, 2022 and September 30, 2021, was approximately $3.7 million and $3.8 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 nine months ended September 30, 2022:		
Operating cash flows used for operating leases (in thousands)	$	4,384
Right-of-use assets obtained in exchange for new operating lease liabilities		—
Weighted average remaining lease term (in years)		3.5
Weighted average discount rate		10.9%

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

		Amount
2022 (remaining)	$	1,377
2023		5,631
2024		5,805
2025		5,983
2026		1,508
Total minimum lease payments	$	20,304
Less: imputed interest		(3,393)
Total lease liabilities	$	16,911

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 $0.3 million for the three and nine months ended September 30, 2022, respectively, in other income (expenses) in the consolidated statements of operations.

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

	Amount
2022 (remaining)	$ 122
2023	495
2024	510
2025	525
2026	134
Total	$ 1,786

Note 7—Property and Equipment, Net:

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

	September 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	(7,290)	(6,861)
Totals	$ 1,282	$ 1,756

For the three and nine months ended September 30, 2022, the Company incurred depreciation expense of $0.2 million and $0.5 million, respectively.

Note 8—Intangible Assets, Net:

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

	September 30, 2022	December 31, 2021
Acquired and in-licensed rights	$ 90,000	$ 90,000
Less: accumulated amortization	(29,886)	(23,875)
Total intangible asset, net	$ 60,114	$ 66,125

For the three and nine months ended September 30, 2022 the Company incurred amortization expense of $2.0 million and $6.0, respectively. The estimated remaining useful life of the intangible assets as of September 30, 2022 is 7.5 years.

Note 9—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Current:		
Accrued legal verdict expense	$ 2,930	$ 57,137
Accrued royalties	9,067	8,829
Accrued CRO services	1,843	2,663
Accrued variable consideration	12,376	11,406
Accrued bonus	4,843	5,083
Accrued compensation	4,179	3,878
Accrued other clinical development	916	911
Accrued professional fees	679	672
Accrued legal fees	2,346	674
Accrued manufacturing costs	326	690
Other	186	632
	39,691	92,575
Long-term:		
Accrued CRO services	—	878
Accrued other	37	37
	37	915
Totals	$ 39,728	$ 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. On November 9, 2021, the Court granted the parties' request, ordering that settlement documents should be filed by December 3, 2021. That same day, the court also clarified an earlier order by making clear that no judgment was entered against any party and that the court would retain jurisdiction over the settlement process. The parties' settlement provides that there will be no judgment for liability entered against the Company or its Chief Executive Officer, Alan H. 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 and dismissed the case. This matter is now concluded.

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 September 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 10—Debt:

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

	September 30, 2022	Maturity Date
Total debt, inclusive of $2.0 million exit payment	$ 102,000	July 23, 2026
Less: debt issuance costs and discounts	(4,006)	
Total long-term debt, net	$ 97,994	

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%.

On September 16, 2022, the Company entered into a third amendment to the Note Purchase Agreement in which the Secured Overnight Financing Rate (“SOFR”) is to be used in place of the LIBOR rate in calculating interest on the Athyrium Notes, beginning on October 1, 2022. The Athyrium Notes bear interest at an annual rate equal to the sum of (a) eight percent (8.00%) plus (b) adjusted three-month term SOFR for such interest period. The adjusted three-month term SOFR means, with respect to any interest period, the lesser of (a) the sum of (i) three-month term SOFR and (ii) 0.26161% (26.161 basis points) and (b) three and one-half of one percent (3.50%) per annum. The interest rate applicable to the Athyrium Notes during the period from September 16, 2022, until the expiration of the interest period ending on September 30, 2022, was equal to the sum of (a) eight percent (8.00%) plus (b) Adjusted Three-Month LIBOR. The modification of the Note Purchase Agreement did not meet the requirements of a debt extinguishment under ASC 470-50 - *Debt Modifications and Exchanges* and no gain or loss was recognized. The Company performed a quantitative analysis and determined that the terms of the new debt and original debt instrument are not substantially different. Accordingly, the September 16, 2022 amendment is accounted for as a debt modification.

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 September 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 September 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):

	September 30, 2022	December 31, 2021
Debt issuance costs and discounts (Athyrium Notes)	$ 5,410	$ 5,410
Less: accumulated amortization	(1,404)	(502)
Included in long-term debt	$ 4,006	$ 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 nine months ended September 30, 2022 and 2021, the Company recorded approximately $0.6 million and $1.5 million, respectively, of interest expense related to the amortization of debt issuance costs in the consolidated statements of operations.

Note 11—Stockholders' Equity:

Common Stock:

The Company issued 0 shares of common stock upon exercise of stock options during the nine months ended September 30, 2022 and 2021 respectively. The Company issued 849,079 and 774,455 shares of common stock upon vesting of RSUs during the nine months ended September 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 H. 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 September 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 September 30, 2022, 5,164,484 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 3,356,079 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 nine months ended September 30:

	2022	2021
Dividend yield	0.0%	0.0%
Expected volatility	86.3%	86.5%
Risk-free interest rate	1.9%	0.8%
Expected life in years	5.60	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 September 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 September 30, 2022 a total of 933,411 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 1,305,785 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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock-based compensation:				
Options:				
Selling, general, and administrative	$ 753	$ 971	$ 2,233	$ 2,942
Research and development	139	147	414	426
Restricted stock units:				
Selling, general, and administrative	1,185	1,979	4,015	6,753
Research and development	753	1,185	2,536	4,673
Warrant modification:				
Selling, general, and administrative	—	—	—	13,587
Total stock-based compensation expense	$ 2,830	$ 4,282	$ 9,198	$ 28,381

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	582,353	$ 2.43	9.5	
Expired	(719,186)	$ 45.34		
Outstanding at September 30, 2022	4,458,414	$ 57.35	5.1	$ 19
Nonvested at September 30, 2022	869,770	$ 6.25	8.9	$ 14
Exercisable	3,588,644	$ 69.73	4.2	$ 5

At September 30, 2022 total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $3.4 million, which is expected to be recognized over a weighted-average period of 1.3 years. At September 30, 2022 the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately $6.9 million, which is expected to be recognized over a weighted-average period of 1.3 years. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2022 and 2021 was $1.72 and $7.90 per share, respectively. The weighted average grant date fair value of RSUs awarded during the nine months ended September 30, 2022 and 2021 was $2.46 and $11.73 per share, respectively.

Stock Option Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2021	835,297	$ 7.76
Granted	582,353	1.72
Vested	(547,880)	6.51
Nonvested shares at September 30, 2022	869,770	$ 4.50

Restricted Stock Unit Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2021	1,399,317	$ 11.03
Granted	1,331,811	2.46
Forfeited	(242,568)	7.48
Vested	(849,079)	9.24
Nonvested shares at September 30, 2022	1,639,481	$ 5.52

Note 12—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately $1.2 million and $1.3 million for the nine months ended September 30, 2022 and 2021, respectively.

Note 13—Commitments and Contingencies:

Contractual Obligations:

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent liabilities for which the Company cannot reasonably predict future payment. The Company's contractual obligations result primarily from obligations for various contract manufacturing organizations and clinical research organizations, which include potential payments we may be required to make under our agreements. The contracts also contain variable costs and milestones that are hard to predict as they are based on such things as patients enrolled and clinical trial sites. The timing of payments and actual amounts paid under contract manufacturing organization ("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 Agreements:

Pfizer 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 Company may trigger additional milestone payments in the future. It is possible that a commercial milestone related to global sales of NERLYNX will be reached during fiscal year 2022. If such milestone is reached, the Company will pay Pfizer $12.5 million within 60 days after reaching the milestone. The payment will be recorded as an intangible asset, and amortized over the estimated remaining useful life and amortized to cost of sales. 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.

Takeda License Agreement

In September 2022, the Company entered an exclusive license agreement with Takeda to license the worldwide research and development and commercial rights to alisertib, a selective, small-molecule, orally administered inhibitor of aurora kinase A. Under the terms of the exclusive license agreement, Puma will assume sole responsibility for the global development and commercialization of alisertib. Takeda received an upfront license fee of $7 million in October 2022 and is eligible to receive potential future milestone payments of up to $287.3 million upon the Company's achievement of certain regulatory and commercial milestones over the course of the exclusive license agreement, as well as tiered royalty payments for any net sales of alisertib. The Company recorded in-process research and development expense of $7.0 million during the nine months ended September 30, 2022, in connection with the up-front payment related to the asset acquisition. As of September 30, 2022, no milestones had been accrued as the underlying contingencies were not probable or estimable.

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 reached a settlement in principle. On November 9, 2021, the Court ordered the parties to file settlement documents by December 3, 2021. That same day, the court also clarified an earlier order by making clear that no judgment was entered against any party and that the court would retain jurisdiction over the settlement process. The parties' settlement provides that there will be no judgment for liability entered against the Company or its Chief Executive Officer, Alan H. 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 and dismissed the case. This matter is now concluded.

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 nine months ended September 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.* 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. The Company filed a voluntary dismissal of the legal malpractice action, without prejudice, on August 19, 2022. The Company intends to re-file the action after the conclusion of the re-trial of the damages phase of the Eshelman case.

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. 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. The parties are conducting fact discovery and preparing briefing relating to claim construction. The Court will hold a hearing in December 2022 to discuss the logistics for the *Markman* hearing, which is scheduled for January 2023.

Sandoz Litigation

On November 10, 2021, Puma filed suit against Sandoz, Inc. ("Sandoz") 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 ANDA 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, and it has been modified since by agreement of the parties. 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 in the Chinese Orange Book. The patent declaration of Acebright were published in 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 in 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. On July 11, 2022, CNIPA decided that claims 5 and 6 of patent No. ZL200880118789.3 are not eligible for registration in the Chinese Orange Book on the ground that these two pharmaceutical method-of-use claims fall in the scope of “patents of crystalline forms”, which are not eligible for listing in the Chinese Orange Book. On September 9, 2022, CNIPA decided that the generic drug in Acebright’s ANDA does not fall within the protection scope of claims 1, 3, 5 and 6 of patent No. ZL201410082103.7 and claims 1-4, 7 and 9-13 of patent No. ZL201080060546.6. The three CNIPA administrative decisions on NERLYNX Patents have lifted the stay of Acebright’s ANDA by NMPA. Puma has the right to appeal each CNIPA administrative decision within six months of receiving the decision. Puma also has the right to enforce NERLYNX Patents in civil litigation before the Chinese court.

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.

In September 2022, the Company entered an exclusive license agreement with a subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") to license the worldwide research and development and commercial rights to alisertib, a selective, small-molecule, orally administered inhibitor of aurora kinase A. Alisertib is an adenosine triphosphate–competitive and reversible inhibitor of aurora kinase A and results in disruption of mitosis leading to apoptosis of rapidly proliferating tumor cells that are dependent on aurora kinase A. Alisertib has been tested in clinical trials in patients with metastatic cancers including breast cancer, small cell lung cancer, head and neck cancer, ovarian cancer, peripheral T cell lymphoma and acute myeloid leukemia. Under the terms of the exclusive license agreement, Puma will assume sole responsibility for the global development and commercialization of alisertib. Takeda received an upfront license fee of $7 million in October 2022 and is eligible to receive potential future milestone payments of up to $287.3 million upon the Company's achievement of certain regulatory and commercial milestones over the course of the exclusive license agreement, as well as tiered royalty payments for any net sales of alisertib. The Company recorded in-process research and development expense of $7.0 million during the three months ended September 30, 2022, in connection with the up-front payment related to the asset acquisition. As of September 30, 2022, no milestones had been accrued as the underlying contingencies were not probable or estimable.

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 10—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.

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.

During the nine months ended September 30, 2022, we 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 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. We intend to satisfy our near-term liquidity requirements through a combination of our existing cash and cash equivalents and marketable securities as of September 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.

Impact of COVID-19

Our priorities during the COVID-19 pandemic have been 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 to some extent 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 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 certain restrictions which has reduced our commercial team's abilities to engage with customers overall and has reduced face to face interactions as compared to pre-pandemic levels. Although we see recent easing of local restrictions, these have been somewhat inconsistent and as we move to a broader 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,, and we may experience additional disruptions in those clinical trials or future clinical trials.

Our ability to continue to operate without any significant negative impacts will in part depend on the future 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 nine months ended September 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.

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 nine months ended September 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 nine months ended September 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 13—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 nine months ended September 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.

Acquired In-Process Research and Development Expense

Acquired in-process research and development expense includes the rights to develop new product candidates. Payments to acquire a new product candidate are immediately expensed as acquired in-process research and development provided that the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

Results of Operations

Three Months Ended September 30, 2022 Compared to Three Months Ended September 30, 2021

Total revenue:

Total revenue for the three months ended September 30, 2022 was approximately $57.1 million, compared to $46.2 million for the three months ended September 30, 2021. This increase in total revenue was due to an increase in product sales of $10.9 million in the three months ended September 30, 2022.

Product revenue, net:

Product revenue, net was approximately $54.3 million for the three months ended September 30, 2022, compared to $43.4 million for the three months ended September 30, 2021. This increase in product revenue, net was primarily attributable to an increase in net selling price compared to the three months ended September 30, 2021, and an increase of approximately 8.5% in bottles of NERLYNX sold compared to the three months ended September 30, 2021. The relative deductions to gross revenue for variable consideration were lower compared to the three months ended September 30, 2021, due primarily to a more favorable payor mix as well as certain adjustments.

Royalty revenue:

Royalty revenue was approximately $2.8 million for the three months ended September 30, 2022, compared to approximately $2.8 million for the three months ended September 30, 2021.

Cost of sales:

Cost of sales was approximately $12.5 million for the three months ended September 30, 2022, compared to approximately $10.3 million for the three months ended September 30, 2021. The increase was due primarily to higher royalties due on increased domestic revenue, net.

Selling, general and administrative expenses:

SG&A Expenses were approximately $24.0 million for the three months ended September 30, 2022, compared to approximately $26.1 million for the three months ended September 30, 2021. SG&A Expenses for the three months ended September 30, 2022 and 2021 were as follows:

Selling, general, and administrative expenses (in thousands)	**For the Three Months Ended September 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Payroll and related costs	$ 7,780	$ 9,514	$ (1,734)	-18.2%
Professional fees and expenses	10,794	9,612	1,182	12.3%
Travel and meetings	1,130	1,338	(208)	-15.5%
Facilities and equipment costs	1,331	1,380	(49)	-3.6%
Stock-based compensation	1,938	2,948	(1,010)	-34.3%
Other	988	1,292	(304)	-23.5%
	$ 23,961	$ 26,084	$ (2,123)	-8.1%

SG&A Expenses decreased by approximately $2.1 million for the three months ended September 30, 2022, compared to the same period in 2021, primarily attributable to the following:

- a decrease in payroll and related costs of approximately $1.7 million, and a decrease in stock-based compensation expense of approximately $1.0 million, primarily due to the impact of headcount reductions at the end of 2021;
- an increase in professional fees and expenses of approximately $1.2 million, consisting primarily of an increase of approximately $3.3 million in legal fees (See Part II, Item 1. "Legal Proceedings"), partially offset by a decrease of approximately $2.2 million in consulting fees related to marketing and commercialization support, and a decrease of approximately $0.1 million in insurance expenses;
- a decrease in travel and meetings of approximately $0.2 million, primarily due to the timing of an annual company sales meetings; and
- a decrease in other expenses of approximately $0.3 million, primarily due to lower training and sponsorship expenses.

Research and development expenses:

R&D Expenses were approximately $11.3 million for the three months ended September 30, 2022, compared to approximately $18.8 million for the three months ended September 30, 2021. R&D Expenses for the three months ended September 30, 2022 and 2021, and were as follows:

Research and development expenses (in thousands)	**For the Three Months Ended September 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Clinical trial expense	$ 2,737	$ 8,396	$ (5,659)	-67.4%
Internal R&D	6,844	7,761	(917)	-11.8%
Consultant and contractors	780	1,347	(567)	-42.1%
Stock-based compensation	892	1,332	(440)	-33.0%
	$ 11,253	$ 18,836	$ (7,583)	-40.3%

R&D Expenses decreased by approximately $7.6 million for the three months ended September 30, 2022, compared to the same period in 2021, primarily attributable to the following:

- a decrease in clinical trial expense of approximately $5.7 million, primarily due to the reduction in the number of patients in certain clinical trials;
- a decrease in internal R&D of approximately $0.9 million, primarily due to a lower headcount and decrease in clinical trial activity;
- a decrease in consultant and contractors expense of approximately $0.6 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.

Acquired In-Process Research and Development Expense

In September 2022, we entered into an exclusive license agreement with Takeda to license the worldwide research and development and commercial rights to alisertib, a new product candidate. We recorded acquired in-process research and development expense related to the up-front payment of $7.0 during the three months ended September 30, 2022.

Other income (expenses):

Other income (expenses) (in thousands)	**For the Three Months Ended September 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Interest income	$ 216	$ 13	$ 203	1561.5%
Interest expense	(2,947)	(3,121)	174	-5.6%
Legal verdict expense	(19)	(24,498)	24,479	-99.9%
Loss on debt extinguishment	—	(8,146)	8,146	-100.0%
Other income	64	71	(7)	-9.9%
	$ (2,686)	$ (35,681)	$ 32,995	-92.5%

Interest income:

For the three months ended September 30, 2022, we recognized approximately $0.2 million in interest income, compared to approximately $13,000 of interest income for the three months ended September 30, 2021. The increase in interest income was primarily the result of increased interest rates.

Interest expense:

For the three months ended September 30, 2022, we recognized approximately $2.9 million in interest expense, compared to approximately $3.1 million of interest expense for the three months ended September 30, 2021. The decrease in interest expense was primarily the result of $0.3 million interest accrued in the three months ended September 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:

For the three months ended September 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 September 30, 2021, we recorded additional legal expense of $24.5 million related to the *Hsu v. Puma Biotechnology, Inc., et al.* class action matter.

Loss on debt extinguishment:

For the three months ended September 30, 2021, we recognized approximately $8.1 million in loss on debt extinguishment related to our debt refinancing during July 2021.

Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

Total revenue:

Total revenue was approximately $162.4 million for the nine months ended September 30, 2022, compared to $197.8 million for the nine months ended September 30, 2021. This decrease was primarily attributable to our receipt of a one-time license fee of $50.0 million in the nine months ended September 30, 2021, which was partially offset by an increase in product revenue, net of approximately $8.2 million and an increase in royalty revenue of approximately $6.6 million in the nine months ended September 30, 2022.

Product revenue, net:

Product revenue, net was approximately $146.3 million for the nine months ended September 30, 2022, compared to $138.1 million for the nine months ended September 30, 2021. This increase in product revenue, net was primarily attributable to an increase in net selling price compared to the nine months ended September 30, 2021, partially offset by a volume decrease of approximately 4.9% in bottles of NERLYNX sold. The relative deductions to gross revenue for variable consideration were slightly lower compared to the nine months ended September 30, 2021.

License revenue:

License revenue was approximately $50.3 million for the nine months ended September 30, 2021 due to an upfront payment in connection with an amendment to the Pierre Fabre sub-license agreement. We had no license revenue in the nine months ended September 30, 2022.

Royalty revenue:

Royalty revenue was approximately $16.0 million for the nine months ended September 30, 2022, compared to approximately $9.5 million for the nine months ended September 30, 2021. The increase was due to increased product sales, net 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 $38.3 million for the nine months ended September 30, 2022, compared to approximately $51.8 million for the nine months ended September 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 nine months ended September 30, 2021, partially offset by higher royalties due on increased domestic revenue, net.

Selling, general and administrative expenses:

SG&A Expenses were approximately $64.9 million for the nine months ended September 30, 2022, compared to approximately $93.8 million for the nine months ended September 30, 2021. SG&A Expenses for the nine months ended September 30, 2022 and 2021 were as follows:

Selling, general, and administrative expenses (in thousands)	**For the Nine Months Ended September 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Payroll and related costs	$ 21,172	$ 30,113	$ (8,941)	-29.7%
Professional fees and expenses	27,192	30,028	(2,836)	-9.4%
Travel and meetings	3,636	3,380	256	7.6%
Facilities and equipment costs	4,042	4,175	(133)	-3.2%
Stock-based compensation	6,248	23,281	(17,033)	-73.2%
Other	2,649	2,855	(206)	-7.2%
	$ 64,939	$ 93,832	$ (28,893)	-30.8%

SG&A Expenses decreased by approximately $28.9 million for the nine months ended September 30, 2022, compared to the same period in 2021, primarily attributable to the following:

- a decrease in payroll and related costs of approximately $8.9 million, consisting of approximately $6.9 million due to the impact of headcount reductions at the end of 2021, and approximately $2.0 million in a payroll tax credit under the CARES Act;
- a decrease in professional fees and expenses of approximately $2.8 million, consisting primarily of a decrease of approximately $6.3 million for professional fees, primarily related to decreased consultancy efforts related to marketing and commercialization support, and a decrease of approximately $0.5 million in insurance and other expenses, partially offset by an increase of approximately $3.8 million in legal fees (See Part II, Item 1. "Legal Proceedings");
- an increase in travel and meetings of approximately $0.3 million, primarily due to the easing of COVID-19 travel restrictions;
- a decrease in facilities and equipment costs of approximately $0.1 million, primarily due to lower depreciation expense for fully depreciated assets;
- a decrease in stock-based compensation expense of approximately $17.0 million, primarily due to the $13.6 million incremental expense resulting

from the modification to the term of Mr. Auerbach's warrant that we recognized in 2021 with no corresponding warrant expense in 2022, and a decrease of approximately $3.4 million due to the impact of headcount reductions at the end of 2021; and

- a decrease in other expense of approximately $0.2 million, primarily due to the reversal of a $1.0 million bad debt expense in 2021 for the recovery of a 2020 bad debt write-off, offset by a decrease of approximately $1.2 million decrease primarily due to education and training, software, sponsorships, and other business related fees.

Research and development expenses:

R&D Expenses were approximately $38.5 million for the nine months ended September 30, 2022, compared to approximately $57.7 million for the nine months ended September 30, 2021. R&D Expenses for the nine months ended September 30, 2022 and 2021 were as follows:

Research and development expenses (in thousands)	**For the Nine Months Ended September 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Clinical trial expense	$ 13,048	$ 21,504	$ (8,456)	-39.3%
Internal R&D	19,964	26,230	(6,266)	-23.9%
Consultant and contractors	2,494	4,870	(2,376)	-48.8%
Stock-based compensation	2,950	5,098	(2,148)	-42.1%
	$ 38,456	$ 57,702	$ (19,246)	-33.4%

R&D Expenses decreased by approximately $19.2 million for the nine months ended September 30, 2022, compared to the same period in 2021, primarily attributable to the following:

- a decrease in clinical trial expense of approximately $8.5 million, primarily due to the reduction in the number of patients in certain clinical trials;
- a decrease in internal R&D expenses of approximately $6.3 million, consisting of approximately $4.7 million due to a decrease in headcount and clinical trial activity, and a decrease of approximately $1.8 million for a payroll tax credit under the CARES Act, partially offset by an increase of approximately $0.2 million for travel expenses;
- a decrease in consultant and contractors' expense of approximately $2.4 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 $2.1 million, primarily due to the impact of lower headcount.

Acquired In-Process Research and Development Expense

In September 2022, we entered into an exclusive license agreement with Takeda to license the worldwide research and development and commercial rights to alisertib, a new product candidate. We recorded acquired in-process research and development expense related to the up-front payment of $7.0 during the three months ended September 30, 2022.

Other income (expenses):

Other income (expenses) (in thousands)	**For the Nine Months Ended September 30,**		**Change**	
			$	**%**
	2022	**2021**	**2022/2021**	**2022/2021**
Interest income	$ 294	$ 147	$ 147	100.0%
Interest expense	(8,313)	(10,089)	1,776	-17.6%
Legal verdict expense	(92)	(9,781)	9,689	-99.1%
Loss on debt extinguishment	—	(8,146)	8,146	0.0%
Other income	176	173	3	1.7%
	$ (7,935)	$ (27,696)	$ 19,761	-71.3%

Interest expense:

For the nine months ended September 30, 2022, we recognized approximately $8.3 million in interest expense, compared to approximately $10.1 million of interest expense for the nine months ended September 30, 2021. The decrease in interest expense was primarily the result of $0.8 million of interest accrued in the nine months ended September 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:

For the nine months ended September 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 nine months ended September 30, 2021, we reduced our legal expense accrual by approximately $20.0 million with respect to the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment, and we increased our legal expense accrual by approximately $29.6 million with respect to the *Hsu v. Puma Biotechnology, Inc., et.al* judgment, which resulted in a net legal verdict expense of $9.8 million for the period.

Loss on debt extinguishment:

For the nine months ended September 30, 2021, we recognized approximately $8.1 million in loss on debt extinguishment related to our debt refinancing during July 2021.

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. On November 9, 2021, the Court granted the parties' request, ordering that settlement documents should be filed by December 3, 2021. That same day, the court also clarified an earlier order by making clear that no judgment was entered against any party and that the court would retain jurisdiction over the settlement process. The parties' settlement provides that there will be no judgment for liability entered against the Company or its Chief Executive Officer, Alan H. Auerbach, and provides for two installment payments by the Company of approximately $27.1 million each. 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 nine months ended September 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 September 30, 2022 and December 31, 2021 and for the nine months ended September 30, 2022 and 2021, is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	**As of September 30, 2022**	**As of December 31, 2021**
Cash and cash equivalents	$ 77,960	$ 63,131
Marketable securities	$ —	$ 18,975
Working capital	$ 62,366	$ 30,436
Stockholders' Equity (deficit)	$ 22,155	$ (2,446)

	Nine Months Ended September 30, 2022	**Nine Months Ended September 30, 2021**
Cash provided by (used in):		
Operating activities	$ (23,510)	$ 26,085
Investing activities	18,977	(15,502)
Financing activities	9,792	(31,929)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 5,259	$ (21,346)

Operating Activities:

Cash used in operating activities for the nine months ended September 30, 2022 was $23.5 million and consisted of net income of approximately $5.6 million, offset by a decrease of approximately $15.9 million of non-cash items, including stock-based compensation, and depreciation and amortization. Further changes in cash flows from operations included a decrease in accrued expenses and other of approximately $53.8 million related primarily to the $54.3 million in payments towards our class action lawsuit settlement, an increase in other assets of approximately $3.7 million due to a tax credit receivable related to the CARES Act, an increase of approximately $3.8 million in accounts payable, a decrease in our post-marketing commitment liability of approximately $0.7 million, offset by a decrease of approximately $4.5 million in accounts receivable, a decrease of $3.2 million in prepaid expense, and a decrease in inventory of approximately $1.7 million.

Cash provided by operating activities for the nine months ended September 30, 2021 was $26.1 million and consisted of a net loss of approximately $33.4 million, offset by a decrease of approximately $39.5 million of non-cash items, including stock-based compensation, depreciation and amortization, loss on extinguishment of debt of approximately $3.8 million related to the write off of debt issuance costs and provision for credit loss recovery. Changes in our operating assets and liabilities include an increase in accrued expenses and other of approximately $3.7 million and an increase in inventory of approximately $3.8 million, offset by decreases of approximately $5.8 million in accounts receivable, net and other current assets, an increase of approximately $8.0 million in accounts payable, and a decrease in our post-marketing commitment liability of approximately $0.9 million.

Investing Activities:

Cash provided by investing activities for the nine months ended September 30, 2022 was approximately $19.0 million, compared to net cash used in investing activities of approximately $15.5 million for the same period in 2021, primarily due to maturity of available-for-sale securities.

Cash used in investing activities for the nine months ended September 30, 2021 consisted of approximately $38.0 million in purchases of available-for-sale securities, partially offset by maturities of approximately $22.6 million of available-for-sale securities.

Financing Activities:

Cash provided by financing activities for the nine months ended September 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.

Cash used in financing activities for the nine months ended September 31, 2021 was $31.9 million and consisted of approximately $8.5 million for the payment of prepayment costs, end of loan payment costs and other extinguishment costs related to the credit facility with Oxford, approximately $1.9 million in payment of debt issuance costs related to the Athyrium Notes, and $20.0 million for installment payments relating to the milestone achieved under the license agreement with Pfizer.

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 our option, we 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.

On September 16, 2022, we entered into a third amendment to the Note Purchase Agreement in which the Secured Overnight Financing Rate ("SOFR") is to be used in place of the LIBOR rate in calculating interest on the Athyrium Notes, beginning on October 1, 2022. The Athyrium Notes bear interest at an annual rate equal to the sum of (a) eight percent (8.00%) plus (b) adjusted three-month term SOFR for such interest period. The adjusted three-month term SOFR means, with respect to any interest period, the lesser of (a) the sum of (i) three-month term SOFR and (ii) 0.26161% (26.161 basis points) and (b) three and one-half of one percent (3.50%) per annum. The interest rate applicable to the Athyrium Notes during the period from September 16, 2022, until the expiration of the interest period ending on September 30, 2022, was equal to the sum of (a) eight percent (8.00%) plus (b) Adjusted Three-Month LIBOR. The modification of the Note Purchase Agreement did not meet the requirements of a debt extinguishment under ASC 470-50 - *Debt Modifications and Exchanges* and no gain or loss was recognized. The Company performed a quantitative analysis and determined that the terms of the new debt and original debt instrument are not substantially different. Accordingly, the September 16, 2022 amendment is accounted for as a debt modification.

The Athyrium Notes include affirmative and negative covenants applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage, and satisfy certain requirements regarding deposit accounts. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions. We are 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 September 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 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. For example, we recently in-licensed alisertib from Takeda and assumed sole responsibility for its global development and commercialization. These efforts will likely require funding in addition to the cash and cash equivalents totaling approximately $78.0 million at September 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, successfully commercialize neratinib and develop alisertib. 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 nine months ended September 30, 2022, stock-based compensation represented approximately 8.0% and 8.9% of our operating expenses, respectively, compared to 9.5% and 18.7% for the same respective periods in 2021, in each case excluding cost of sales and acquired in-process research and development. 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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP net (loss) income	$ (360)	$ (44,672)	$ 5,608	$ (33,350)
Adjustments:				
Stock-based compensation -				
Selling, general and administrative (1)	1,938	2,950	6,248	23,282
Research and development (2)	892	1,332	2,950	5,099
Non-GAAP adjusted net income	$ 2,470	$ (40,390)	$ 14,806	$ (4,969)
GAAP net (loss) income per share—basic	$ (0.01)	$ (1.09)	$ 0.13	$ (0.82)
Adjustment to net (loss) income (as detailed above)	0.06	0.10	0.20	0.70
Non-GAAP adjusted basic net income per share	$ 0.05 (3)	$ (0.99) (4)	$ 0.33 (3)	$ (0.12) (4)
GAAP net (loss) income per share—diluted	$ (0.01)	$ (1.09)	$ 0.13	$ (0.82)
Adjustment to net (loss) income (as detailed above)	0.06	0.10	0.20	0.70
Non-GAAP adjusted diluted net income per share	$ 0.05 (5)	$ (0.99) (6)	$ 0.33 (5)	$ (0.12) (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 45,567,739 and 44,290,432 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2022, respectively.
(4) Non-GAAP adjusted basic net loss per share was calculated based on 40,813,609 and 40,520,041 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2021, respectively.
(5) Non-GAAP adjusted diluted net income per share was calculated based on 45,797,841 and 44,464,682 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2022, respectively.
(6) Non-GAAP adjusted diluted net loss per share was calculated based on 40,813,609 and 40,520,041 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2021, respectively.

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 September 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 September 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) until September 30, 2022. As described in Note 10, we modified the interest paid, beginning October 1, 2022, to the adjusted three-month term SOFR and the lesser of (a) the sum of (i) three-month term SOFR and (ii) 0.26161% (26.161 basis points) and (b) three and one-half of one percent (3.50%) per annum. If overall interest rates had increased by one hundred basis points during the quarter ended September 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 September 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 September 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 September 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 October 29, 2021, the parties informed the court that they had reached a settlement in principle. On November 9, 2021, the Court ordered the parties to file settlement documents by December 3, 2021. That same day, the court also clarified an earlier order by making clear that no judgment was entered against any party and that the court would retain jurisdiction over the settlement process. The parties' settlement provides that there will be no judgment for liability entered against the Company or its Chief Executive Officer, Alan H. 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 and dismissed the case. This matter is now concluded.

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, 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.* 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. The Company filed a voluntary dismissal of the legal malpractice action, without prejudice, on August 19, 2022. The Company intends to re-file the action after the conclusion of the re-trial of the damages phase of the Eshelman case.

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. 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. The parties are conducting fact discovery and preparing briefing relating to claim construction. The Court will hold a hearing in December 2022 to discuss the logistics for the *Markman* hearing, which is scheduled for January 2023.

Sandoz Litigation

On November 10, 2021, Puma filed suit against Sandoz, Inc. ("Sandoz") 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 ANDA 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, and it has been modified since by agreement of the parties. 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 was 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. On July 11, 2022, CNIPA decided that claims 5 and 6 of patent No. ZL200880118789.3 are not eligible for registration in the Chinese Orange Book on the ground that these two pharmaceutical method-of-use claims fall in the scope of “patents of crystalline forms”, which are not eligible for listing in the Chinese Orange Book. On September 9, 2022, CNIPA decided that the generic drug in Acebright’s ANDA does not fall within the protection scope of claims 1, 3, 5 and 6 of patent No. ZL201410082103.7 and claims 1-4, 7 and 9-13 of patent No. ZL201080060546.6. The three CNIPA administrative decisions on NERLYNX Patents have lifted the stay of Acebright’s ANDA by NMPA. Puma has the right to appeal each CNIPA administrative decision within six months of receiving the decision. Puma also has the right to enforce NERLYNX Patents in civil litigation before the Chinese court.

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 recently in-licensed alisertib, a new product candidate, for which we have assumed all responsibility for global development and commercialization. Our development of alisertib will be expensive, lengthy and unpredictable, and any failure to successfully develop alisertib will have a material adverse effect on our business and financial position.

In September 2022, we in-licensed alisertib, a new product candidate, from Takeda Pharmaceuticals, or Takeda. Pursuant to our exclusive license agreement with Takeda, we are responsible for global development and commercialization of alisertib. Clinical development of alisertib will be expensive, lengthy and unpredictable. Failure or delay can occur at any time during the development process. There are numerous risks associated with our planned development alisertib, including, among others:

- We have no prior experience developing alisertib;
- The results of pre-clinical studies and early clinical studies of alisertib may not be predictive of later clinical studies, and success in previous stages cannot ensure positive outcome of future stages of clinical studies;
- Alisertib may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through pre-clinical studies and early clinical studies;
- Even if we complete clinical development of alisertib, the results may not be sufficient to obtain regulatory approval in the United States or other countries;
- Our license agreement with Takeda may be terminated by Takeda if we materially breach the agreement, in which case we would lose all rights to develop and commercialize alisertib;
- We plan to rely on third party contractors to formulate and manufacture alisertib for clinical trials and these third-party contractors may be unable to formulate and manufacture alisertib in the volume and quality we require;
- We plan to rely on third-party contractors to conduct our clinical trials of alisertib and if those parties fail to perform their services within expected timelines or fail to comply with regulatory requirements, our development efforts could be delayed;
- Clinical trials are expensive, time-consuming and difficult to design and implement;
- Development of alisertib could distract management's attention from other important aspects of our business

Even if we are successful in developing alisertib, we cannot assure you that we will be able to successfully commercialize alisertib. Any delays or failure in our development of alisertib could have material adverse effects on our business, operations and financial condition.

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+	Third Amendment to Note Purchase Agreement, dated September 16, 2022, by and between the Company and Athyrium Opportunities IV Co-Invest 1 LP, as Administrative Agent.
10.2+	Exclusive License Agreement, dated September 16, 2022, by and between the Company and Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.
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 September 30, 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 September 30, 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: November 3, 2022

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

Date: November 3, 2022

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

Exhibit 10.1

Execution Version

THIRD AMENDMENT TO NOTE PURCHASE AGREEMENT

This THIRD AMENDMENT TO NOTE PURCHASE AGREEMENT (the "Agreement") dated as of September 16, 2022 is entered into by and among PUMA BIOTECHNOLOGY, INC., a Delaware corporation (the "Issuer"), the Guarantors party hereto, the Purchasers party hereto and ATHYRIUM OPPORTUNITIES IV CO-INVEST 1 LP, as the Administrative Agent. All capitalized terms used herein and not otherwise defined herein shall have the meanings given to such terms in the Note Purchase Agreement (as defined below).

RECITALS

WHEREAS, the Issuer, the Guarantors, the Purchasers and the Administrative Agent entered into that certain Note Purchase Agreement dated as of July 23, 2021 (as amended or modified from time to time, the "Note Purchase Agreement");

WHEREAS, the Credit Parties have requested that the Note Purchase Agreement be amended as set forth below, subject to the terms and conditions specified in this Agreement; and

WHEREAS, the parties hereto are willing to amend the Note Purchase Agreement, subject to the terms and conditions specified in this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Amendments. The Note Purchase Agreement is hereby amended as follows:

(a) The following definitions are hereby added to Section 1.01 of the Note Purchase Agreement in appropriate alphabetical order to read as follows:

"Adjusted Three-Month Term SOFR" means, with respect to any Interest Period, the lesser of (a) the sum of (i) Three-Month Term SOFR and (ii) 0.26161% (26.161 basis points) and (b) three and one-half of one percent (3.50%) per annum.

"CME" means CME Group Benchmark Administration Limited.

"Conforming Changes" means, with respect to the use, administration of or any conventions associated with SOFR or Three-Month Term SOFR, as applicable, any conforming changes to the definitions of "SOFR", "Three-Month Term SOFR" and "Interest Period", timing and frequency of determining rates and making payments of interest and other technical, administrative or operational matters (including, for the avoidance of doubt, the definitions of "Business Day" and "U.S. Government Securities Business Day", timing of borrowing requests or prepayment, conversion or continuation notices and length of lookback periods) that the Administrative Agent, in consultation with the Issuer, reasonably decides may be appropriate to reflect the adoption and implementation of such applicable rate(s) and to permit the administration thereof by the Administrative Agent in a manner substantially consistent with market practice (or, if the Administrative Agent reasonably decides that adoption of any portion of such market practice is not administratively feasible or that no market practice for the administration of such rate exists, in such other manner of administration as the Administrative Agent, in consultation with the Issuer reasonably decides is reasonably necessary in connection with the administration of this Agreement and any other Note Document).

"Existing Note Purchase Agreement" means this Agreement as in effect immediately prior to the Third Amendment Effective Date.

"SOFR Unavailability Event" has the meaning set forth in Section 3.05.

"Takeda Investment" means the license of certain intellectual property rights pursuant to the Takeda License Agreement.

"Takeda License Agreement"[1] means that certain Exclusive License Agreement, dated as of September 16, 2022, by and between Millennium Pharmaceuticals, Inc., a Delaware corporation, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, and the Issuer, in effect as of the Third Amendment Effective Date.

"Term SOFR Screen Rate" means the forward-looking SOFR term rate administered by CME (or any successor administrator reasonably satisfactory to the Administrative Agent) and published on the applicable Reuters screen page (or such other commercially available source providing such quotations as may be reasonably designated by the Administrative Agent from time to time).

"Third Amendment Effective Date" means September 16, 2022.

"Three-Month Term SOFR" means, for any Interest Period, the rate per annum equal to the greater of (a) one and one-half of one percent (1.50%) and (b) the three month Term SOFR Screen Rate two U.S. Government Securities Business Days prior to the first day of such Interest Period; provided, that, if the rate is not published prior to 11:00 a.m. on such determination date then Three-Month Term SOFR means the three month Term SOFR Screen Rate on the first U.S. Government Securities Business Day immediately prior thereto.

"U.S. Government Securities Business Day" means any Business Day, except any Business Day on which any of the Securities Industry and Financial Markets Association, the New York Stock Exchange or the Federal Reserve Bank of New York is not open for business because such day is a legal holiday under the federal laws of the United States or the laws of the State of New York, as applicable.

(b) The definition of "Interest Rate" set forth in Section 1.01 of the Note Purchase Agreement is hereby deleted in its entirety and replaced with the following:

"Interest Rate" means, for any Interest Period, a rate per annum equal to the sum of (a) eight percent (8.00%) plus (b) Adjusted Three-Month Term SOFR for such Interest Period; provided, that, notwithstanding anything herein to the contrary, (i) the Interest Rate applicable to the Notes during the period from the Third Amendment Effective Date until the expiration of the Interest Period ending on September 30, 2022 shall be a rate per annum equal to the sum of (A) eight percent (8.00%) plus (B) Adjusted Three-Month LIBOR for such Interest Period (as determined under the Existing Note Purchase Agreement) and (ii) any provisions of the Existing Note Purchase Agreement applicable to Adjusted Three-Month LIBOR are incorporated herein by reference, *mutatis mutandis*, and the parties hereto hereby agree that such provisions shall continue to apply to such Notes until the end of the Interest Period ending on September 30, 2022.

[1] NTD: Exclusive License Agreement subject to further review.

(c) The definition of "SOFR" set forth in Section 1.01 of the Note Purchase Agreement is hereby deleted in its entirety and replaced with the following:

"SOFR" means the Secured Overnight Financing Rate as administered by the Federal Reserve Bank of New York (or a successor administrator).

(d) The definitions "Adjusted Three-Month LIBOR", "Available Tenor", "Benchmark", "Benchmark Replacement", "Benchmark Replacement Conforming Changes", "Benchmark Transition Event", "Corresponding Tenor", "Early Opt-in Effective Date", "Early Opt-in Election", "LIBOR Screen Rate", "Other Rate Early Opt-in", "SOFR Administrator", "SOFR Early Opt-in", "Term SOFR", and "Three-Month LIBOR" are hereby deleted from Section 1.01 to the Note Purchase Agreement in their entirety.

(e) Clause (c) of Section 2.06 of the Note Purchase Agreement is hereby amended to read as follows:

(c) Interest Generally. Interest on each Note shall be due and payable in arrears on each Interest Payment Date and at such other times as may be specified herein. Interest hereunder shall be due and payable in accordance with the terms hereof before and after judgment, and before and after the commencement of any proceeding under any Debtor Relief Law. Each determination of an interest rate by the Administrative Agent pursuant to any provision of this Agreement shall be determinative in the absence of manifest error.

(f) Clause (a)(iii) of Section 3.02 of the Note Purchase Agreement is hereby amended to read as follows:

(iii) impose on any Purchaser any other condition, cost or expense (other than taxes) affecting this Agreement or any Note;

(g) Clause (d) of Section 3.02 of the Note Purchase Agreement is hereby amended to read as follows:

(d) [Reserved].

(h) Section 3.04 of the Note Purchase Agreement is hereby amended to read as follows:

3.04 Illegality. If any Purchaser determines that any Law has made it unlawful, or that any Governmental Authority has asserted that it is unlawful, for any Purchaser or its Purchasing Office to perform any of its obligations hereunder or to make, maintain or fund or charge interest with respect to any Note, then, on notice thereof by such Purchaser to the Issuer through the Administrative Agent, any obligation of such Purchaser to issue, make, maintain, fund or charge interest with respect to any such Note or to purchase any Note shall be suspended until such Purchaser notifies the Administrative Agent and the Issuer that the circumstances giving rise to such determination no longer exist. Upon receipt of such notice, the Issuer shall, upon demand from such Purchaser (with a copy to the Administrative Agent), prepay the Notes of such Purchaser immediately.

(i) Section 3.05 of the Note Purchase Agreement is hereby amended to read as follows:

3.05. Inability to Determine Rates. Notwithstanding anything to the contrary in this Agreement or any other Note Document, if the Administrative Agent determines (which determination shall be conclusive absent manifest error) that (a) adequate and reasonable means do not exist for ascertaining Three-Month Term SOFR, including, without limitation, because the Term SOFR Screen Rate is not available or published on a current basis and such circumstances are unlikely to be temporary, (b) the CME (or any successor administrator reasonably satisfactory to the Administrative Agent) has made a public statement identifying a specific date after which SOFR shall or will no longer be made available, or permitted to be used for determining the interest rate of syndicated loans denominated in Dollars, or shall or will otherwise cease, provided, that, in each case, at the time of such statement, there is no successor administrator that is reasonably satisfactory to the Administrative Agent that will continue to provide SOFR or (c) the Administrative Agent or the Required Purchasers determine that for any reason that Three-Month Term SOFR for the relevant Interest Period does not adequately and fairly reflect the cost of funds to the Purchasers (each a "SOFR Unavailability Event"), then (a) the Administrative Agent will promptly so notify the Issuer and each Purchaser and (b) thereafter, (i) the Issuer and the Required Purchasers shall negotiate in good faith to amend this Agreement to replace Three-Month Term SOFR with an alternate benchmark rate, giving due consideration to any evolving or then-prevailing market convention, including any applicable recommendations made by the Relevant Governmental Body, for U.S. dollar denominated credit facilities for such alternative benchmarks and (ii) until such time as the Issuer and the Required Purchasers amend this Agreement as contemplated by the foregoing clause (i), the Interest Rate for any Interest Period will be a rate per annum equal to eleven and one half percent (11.50%) for the Interest Period during which such SOFR Unavailability Event occurs being set on the date such SOFR Unavailability Event occurs and thereafter re-set on the first Business Day of each Interest Period occurring thereafter).

(j) [2]Clause (k) of Section 8.02 of the Note Purchase Agreement is hereby renumbered as clause (l), the "and" is hereby removed from the end of clause (j), and the following is hereby inserted as new clause (k):

(k) the Takeda Investment; and

(k) A new clause (f) is hereby inserted at the end of Section 8.12 of the Note Purchase Agreement to read as follows:

(f) Amend, modify or change (or permit the amendment, modification or change of) any of the terms or provisions of the Takeda License Agreement in any manner materially adverse to the Administrative Agent or any Purchaser.

[2] NTD: Subject to review of the Exclusive License Agreement.

2. Condition Precedent. This Agreement shall be effective as of the date hereof upon satisfaction of the following conditions precedent:

(a) receipt by the Administrative Agent of counterparts of this Agreement duly executed by the Issuer, the Guarantors, the Purchasers and the Administrative Agent; and

(b) receipt by the Administrative Agent of a supplement to Schedule 1.01(a) of the Disclosure Letter[3].

3. Reaffirmation of Representations and Warranties; No Default. The Issuer and each other Credit Party represents and warrants to the Administrative Agent and each Purchaser that after giving effect to this Agreement (a) the representations and warranties of the Issuer and each other Credit Party contained in Article VI of the Note Purchase Agreement or any other Note Document, or which are contained in any document furnished at any time under or in connection therewith, are true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) on and as of the date hereof, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) as of such earlier date, and except that for purposes of this paragraph 3, the representations and warranties contained in clauses (a) and (b) of Section 6.05 of the Note Purchase Agreement shall be deemed to refer to the most recent statements furnished pursuant to clauses (a) and (b) of Section 7.01 of the Note Purchase Agreement, respectively, and (b) no Default or Event of Default exists.

4. Miscellaneous.

(a) The Note Purchase Agreement and the obligations of the Credit Parties thereunder and under the other Note Documents, are hereby ratified and confirmed and shall remain in full force and effect according to their terms.

(b) Sections 11.14 and 11.15 of the Note Purchase Agreement are incorporated herein by reference and shall apply, *mutatis mutandis*, to this Agreement as if fully set forth herein.

(c) As a material part of the consideration for the Administrative Agent and the Purchasers entering into this Agreement, the Credit Parties agree that the Administrative Agent, the Purchasers, each of their respective Affiliates and each of the foregoing Persons' respective officers, managers, members, directors, advisors, sub-advisors, partners, agents and employees, and their respective successors and assigns (hereinafter all of the above collectively referred to as the "Purchaser Group"), are irrevocably and unconditionally released, discharged and acquitted from any and all actions, causes of action, claims, demands, damages and liabilities of whatever kind or nature, in law or in equity, now known or unknown, suspected or unsuspected to the extent that any of the foregoing arises from any action or failure to act under or otherwise arising in connection with the Note Documents, in each case arising on or prior to the date hereof, except to the extent such actions, causes of action, claims, demands, damages and liabilities result from the gross negligence or willful misconduct of any of the Purchaser Group as determined by a court of competent jurisdiction in a final and nonappealable judgment.

(d) This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be an original, but all of which shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Agreement.

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[3] NTD: Schedule should be updated to include the new Product pursuant to Section 7.01(j).

(e) **THIS AGREEMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL BE GOVERNED BY AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK.**

[Signature pages follow]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the date first above written.

ISSUER:

PUMA BIOTECHNOLOGY, INC.,
a Delaware corporation

By:/s/ Alan Auerbach
Name: Alan Auerbach
Title: CEO

ADMINISTRATIVE AGENT:

ATHYRIUM OPPORTUNITIES
IV CO-INVEST 1 LP, a Delaware limited partnership

By: ATHYRIUM OPPORTUNITIES ASSOCIATES IV CO-INVEST LLC

By:/s/ Rashida Adams
Name: Rashida Adams
Title: Authorized Signatory

PURCHASERS:

ATHYRIUM OPPORTUNITIES
IV CO-INVEST 1 LP, a Delaware limited partnership

By: ATHYRIUM OPPORTUNITIES ASSOCIATES IV CO-INVEST LLC

By:/s/ Rashida Adams
Name: Rashida Adams
Title: Authorized Signatory

Exhibit 10.2

Execution Version

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

EXCLUSIVE LICENSE AGREEMENT

This **EXCLUSIVE LICENSE AGREEMENT** (this "**Agreement**") is entered into as of September [●], 2022 (the "**Effective Date**") by and between **MILLENNIUM PHARMACEUTICALS, INC.**, a corporation incorporated under the laws of the State of Delaware and wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("**Takeda**"), and **PUMA BIOTECHNOLOGY, INC.**, a corporation incorporated under the laws of the State of Delaware ("**Puma**"). Puma and Takeda are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Takeda owns or controls certain rights to patents and other intellectual property related to the Licensed Compound (as defined below);

WHEREAS, Puma desires to license these intellectual property rights from Takeda in order to commercially develop, manufacture, use and distribute Licensed Product(s) (as defined below) throughout the Territory (as defined below), and Takeda desires to grant this license to Puma, in accordance with the terms and conditions of this Agreement; and

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1.
DEFINITIONS

All references to particular Exhibits, Articles or Sections shall mean the Exhibits to, and Articles and Sections of this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

1.1 "**Abandoned Patent Right**" has the meaning set forth in Section 4.3.

1.2 "**Accounting Standards**" means International Financial Reports Standards (IFRS) with respect to Takeda, and U.S. Generally Accepted Accounting Principles (GAAP), with respect to Puma, and GAAP or IFRS, as applicable, with respect to any Affiliate or Sublicensee, in each case, as generally and consistently applied through the Party's (or such Affiliate or Sublicensee's) organization. Each Party will promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained; *provided, however* that each Party may only use internationally recognized accounting principles (*e.g.* IFRS, GAAP, etc.).

1.3 "**Acting Party**" has the meaning set forth in Section 3.12.5.

1.4 "**Affiliate**" means, with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person, for as long as such control exists. For purposes of the definition of "Affiliate", "control" means the direct or indirect ownership of fifty percent (50%) or more of the voting or economic interest of a Person, or the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of a Person, *provided* that in the case of jurisdictions in which the maximum percentage ownership permitted by applicable Law for a foreign investor is less than 50%, such lower percentage will be substituted. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party.

1.5 "**Agreement**" has the meaning set forth in the Preamble.

1.6 "**Alisertib Patents**" means the Patent Rights set forth on Exhibit D-1, as it may be updated from time to time with the mutual agreement of the Parties in accordance with Section 5.9.

1.7 "**Anti-Corruption Laws**" means Laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including without limitation, the U.S. Foreign Corrupt Practices Act (FCPA) and similar laws governing corruption and bribery, whether public, commercial or both, to the extent applicable.

1.8 "**Assigned Third Party Agreements**" means the agreements listed as such on Exhibit A or Exhibit F ([***]).

1.9 "**Assignment and Assumption Agreement**" means each agreement entered into by and between the Parties and/or their respective Affiliates, in each case substantially in the form of Exhibit J-1 or J-2 hereto.

1.10 "**Audited Party**" has the meaning set forth in Section 3.11.

1.11 "**Calendar Quarter**" means any period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of any Calendar Year.

1.12 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.13 "**cGMP**" means all then-current and phase-appropriate applicable standards relating to current good manufacturing practices for fine chemicals, intermediates, bulk Licensed Products or finished pharmaceutical drugs, including (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, 21 C.F.R. Parts 210 and 211, (b) all applicable requirements detailed in the EMA's "EU guidelines for Good Manufacturing Practice for Medicinal Licensed Products for Human and Veterinary Use," and (c) all applicable Laws promulgated by any Governmental Authority having jurisdiction over the manufacture of the applicable compound or pharmaceutical drug Licensed Product, as applicable.

1.14 "**Clinical Trial**" means a Phase 1 Clinical Trial, Phase 2 Clinical Trial or Phase 3 Clinical Trial, and any other human clinical trial of a Licensed Product.

1.15 "**Combination Patents**" means the Patent Rights set forth on Exhibit D-2, as it may be updated from time to time with the mutual agreement of the Parties in accordance with Section 5.9.

1.16 "**Combination Product**" means a Licensed Product that includes a Licensed Compound and [***].

1.17 "**Commercially Reasonable Efforts**" means such reasonable, diligent and good faith efforts and resources as are commensurate with those commonly used in the pharmaceutical industry by a similarly situated company engaged in the development or commercialization of pharmaceutical products at a similar stage of development or commercialization, in each case taking into account issues of safety and efficacy, product profile, the proprietary position, the then-current competitive environment for such product and the likely timing of such product's entry into the market, the regulatory environment and status of such product.

1.18 "**Commercial Milestone Events**" has the meaning set forth in Section 3.3.

1.19 "**Commercial Milestone Payments**" has the meaning set forth in Section 3.3.

1.20 "**Confidential Information**" has the meaning set forth in Section 8.1.

1.21 "**Control**" or "**Controlled**" means, with respect to any Know-How, material, Patent Right, or other intellectual property right, the possession (whether by ownership or license) by a Party or its Affiliate of the ability to grant to the other Party a license, sublicense or access as provided herein to such Know-How, material, Patent Right, or other intellectual property right, without violating the terms of any agreement or other arrangement with any Third Party, or being obligated to pay any royalties or other consideration therefor, in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license, sublicense or access.

1.22 "**Covered**" by a Patent Right means [***].

1.23 "**Data Controller**" means the natural or legal person which, alone or jointly with others determines the purposes and means of the Processing of Personal Data.

1.24 "**Data Protection Laws**" means all applicable laws in relation to data protection, privacy, interception and monitoring of communications, or requirements relating to the Processing of Personal Data of any kind, in each case as amended, consolidated, re-enacted or replaced from time to time.

1.25 "**Data Subject**" has the meaning set forth in Section 1.71.

1.26 "**Data Subject Request**" means any communication addressed to one or both Parties under this Agreement made by a Data Subject exercising one or several of his/her data protection rights under applicable Data Protection Laws.

1.27 "**Defending Party**" has the meaning set forth in Section 4.4.4.

1.28 "**Delayed Third Party Agreements**" means the agreements listed as such on Exhibit A or Exhibit F (for clarity, those listed on Exhibit A shall be deemed both IIR Agreements and Delayed Third Party Agreements).

1.29 "**Development Milestone Events**" has the meaning set forth in Section 3.2.

1.30 "**Development Milestone Payments**" has the meaning set forth in Section 3.2.

1.31 "**Disclosing Party**" has the meaning set forth in Section 8.1.1.

1.32 "**Document Access Agreement**" has the meaning set forth in Section 5.4.

1.33 "**Dollar**" means the U.S. dollar, and "$" will be interpreted accordingly.

1.34 "**Drug Approval Application**" means any (a) new drug application, supplemental new drug application, biologics license application or other marketing authorization application, in each case submitted to the FDA, including any amendments thereto or (b) comparable applications filed in or for countries or jurisdictions outside of the United States, in each of (a) and (b) to obtain Regulatory Approval to commercialize a Licensed Product in that country or jurisdiction.

1.35 "**Effective Date**" has the meaning set forth in the Preamble.

1.36 "**EMA**" means the European Medicines Agency or any successor entity thereto.

1.37 "**Enforcing Party**" has the meaning set forth in Section 4.4.3.

1.38 "**European Union**" or "**EU**" means the European Union member states as of the Effective Date.

1.39 "**Executive Officer**" means [***].

1.40 "**Exploit**" means to research, develop, make, have made, use, offer for sale, sell, import, export, transfer possession of or title in or otherwise exploit a compound or product.

1.41 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

1.42 "**FDCA**" means the Federal Food Drug and Cosmetic Act, as amended from time to time.

1.43 "**Field**" means the treatment, diagnosis and prophylaxis of disease in humans and animals.

1.44 "**First Commercial Sale**" means, with respect to a Licensed Product in any country, the first sale for end use or consumption of such Licensed Product in such country after Marketing Approval has been granted in such country.

1.45 "**Generic Product**" means, with respect to a Licensed Product, any pharmaceutical product that [***] or (c) in any other country or jurisdiction pursuant to all equivalents of such provisions.

1.46 "**GCP**" means the then-current good clinical practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including those set forth in FDA regulations in 21 C.F.R. Parts 11, 50, 54, 56, 312, 314, and 320 and all related FDA rules, regulations, orders, and guidances, and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline.

1.47 "**GLP**" means the then-current good laboratory practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including those as set forth in FDA regulations in 21 C.F.R. Part 58 and all applicable FDA rules, regulations, orders, and guidances, and the requirements with respect to good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council) and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline.

1.48 "**Governmental Authority**" means any court, tribunal, agency, commission, department, ministry, official, authority or other instrumentality of any national, federal, state, county, provincial, local, municipal, city or other political subdivision thereof or of any multinational governmental body, or any council, court or other tribunal entitled to exercise any administrative, executive, judicial, legislative, regulatory or taxing authority or power.

1.49 "**IIR**" means an investigator-initiated study of a Licensed Product conducted pursuant to an IIR Agreement.

1.50 "**IIR Agreement**" means the agreements set forth on Exhibit A.

1.51 "**Indication**" means [***].

1.52 "**Initiation**" means, with respect to a Clinical Trial, the first dosing in the first subject in such Clinical Trial. "**Initiated**" shall have a corresponding meaning.

1.53 "**Know-How**" means all non-public technical, scientific, and other information, know-how, data, inventions, discoveries, trade secrets, specifications, instructions, techniques, processes, designs, drawings, formulae, methods, practices, protocols, expertise and other information and technology applicable to formulations, compositions or products or to their manufacture, development, registration, use, marketing or sale or to methods of assaying or testing them, and all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data relevant to any of the foregoing. For clarity, Know-How includes any such information comprised or embodied in any applicable physical materials and excludes Patent Rights.

1.54 "**Law**" means applicable laws, statutes, rules, regulations, and other pronouncements having the effect of law of any Governmental Authority that may be in effect from time to time, including disclosure obligations required by any stock exchange or securities commission having authority over a Party and any applicable rules, regulations, guidances, or other requirements of any Regulatory Authority that may be in effect from time to time, including cGMP, GLP and GCP.

1.55 "**Licensed Compound**" means Takeda's proprietary compound known as alisertib (a.k.a. MLN-8237), having the chemical structure set forth on Exhibit B, including any [***].

1.56 "**Licensed Know-How**" means any Know-How that is set forth on Exhibit C, as it may be updated from time to time with the mutual agreement of the Parties in accordance with Section 5.9. For clarity, Know-How relating to the Licensed Compound or Licensed Products in combination with any Other Product, and any Know-How not relating to the Licensed Compound or Licensed Product (for example clinical trial information arising from a trial arm that did not include the Licensed Compound) is explicitly excluded from Licensed Know-How.

1.57 "**Licensed Patents**" means (i) the Alisertib Patents, (ii) the Combination Patents, and (iii) any Patent Rights which Takeda Controls after the Effective Date during the Term which are necessary to Exploit the Licensed Compound in the form it exists as of the Effective Date.

1.58 "**Licensed Product**" means any therapeutic or diagnostic product consisting of, or containing, the Licensed Compound, in all forms, presentations, formulations and dosage forms, including combinations with active ingredients other than the Licensed Compound.

1.59 "**Licensed Technology**" means the Licensed Patents and the Licensed Know-How.

1.60 "**Losses**" has the meaning set forth in Section 7.1.

1.61 "**Major Market Country**" means each of the United States, the United Kingdom, France, Germany, Italy, Spain and Japan.

1.62 "**Marketing Approval**" means all Regulatory Approvals granted by a Regulatory Authority or other regulatory agency in a country or region, necessary for the manufacture, use, storage, import, marketing, distribution and sale of a Licensed Product in such country or region.

1.63 "**Net Sales**" means, with respect to a Licensed Product, the gross amount invoiced by Puma, its Affiliates or Sublicensee(s) (the "**Selling Party**") for sales of such Licensed Product in the Territory to Third Parties, less the following deductions with respect to such sales that are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented as a deduction in accordance with the applicable Accounting Standards (without duplication):

(a) sales taxes, excise taxes, use taxes, VAT and duties paid by the Selling Party in relation to the Licensed Product and any other equivalent governmental charges imposed upon the importation, use or sale of the Licensed Product (excluding taxes when assessed on income derived from sales);

(b) credits and allowances for defective or returned Licensed Product, including allowances for spoiled, damaged, outdated, rejected, returned, withdrawn or recalled Licensed Product;

(c) governmental and other rebates, discounts, refunds, and chargebacks (or equivalents thereof) granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), federal, state, provincial, local and other governments, their agencies and purchasers and reimbursers or to trade customers, in each case with respect to the Licensed Product;

(d) reasonable fees paid to wholesalers, distributors, selling agents (excluding any sales representatives of a Selling Party), group purchasing organizations, Third Party payors, other contractees and managed care entities, in each case with respect to the Licensed Product;

(e) reasonable transportation charges relating to the Licensed Product, including freight, export licenses, shipping, postage, handling charges and insurance premiums relating thereto to the extent included as a separate entry on the invoice for such Licensed Product;

(f) retroactive price reductions granted to the Third Party applicable to sales of such Licensed Product;

(g) bad debts actually written off with respect to such Licensed Products (with any such amounts actually received being included in Net Sales when recovered); and

(h) trade, cash, prompt payment or quantity rebates and discounts, allowed and taken directly by the Third Party.

Net Sales will be determined from books and records maintained in accordance with the applicable Accounting Standards, consistently applied throughout the organization and across all Licensed Products of the entity whose sales of the Licensed Product are giving rise to Net Sales.

Net Sales shall also include, with respect to a Licensed Product sold, or otherwise disposed of, for any consideration other than exclusively monetary consideration on bona fide, arms' length terms, an amount equal to the average sales price for a Licensed Product having the same dosage form and strength during the applicable reporting period in the country where such sale or other disposal occurred when the Licensed Product is sold alone and not with other Licensed Products, or if the Licensed Product is not sold alone in such country during the applicable reporting period, then an amount equal to the average sales price during the applicable reporting period generally achieved for a Licensed Product having the same dosage form and strength. For the avoidance of doubt, disposition of Licensed Product for, or use of Licensed Product in, Clinical Trials or other scientific testing, as free samples, or under compassionate use, patient assistance, or test marketing programs or other similar programs or studies, in each case to the extent the consideration received for such Licensed Product does not exceed the cost for such Licensed Product, shall not result in any Net Sales. Sales of a Licensed Product between or among Puma and its Affiliates or Sublicensees shall be excluded from the computation of Net Sales and no payments shall be payable on such sales except where such Affiliates or Sublicensees are end users.

Notwithstanding the foregoing, in the event a Licensed Product is sold in a country in the Territory as a Combination Product, Net Sales of the Combination Product will be calculated as follows:

(i) If the Licensed Compound contained in the Combination Product and Other Active Ingredient(s) contained in the Combination Product each are sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction A/(A+B), where A is the average gross selling price in such country of the Licensed Compound sold separately in the same formulation and dosage, and B is the sum of the average gross selling prices in such country of such Other Active Ingredient(s) sold separately in the same formulation and dosage, during the applicable Calendar Year.

(ii) If the Licensed Compound contained in the Combination Product is sold independently of the Other Active Ingredient(s) contained in the Combination Product in such country, but the average gross selling price of such Other Active Ingredient(s) in such country cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction A/C where A is the average gross selling price in such country of such Licensed Compound sold independently and C is the average gross selling price in such country of the entire Combination Product, during the applicable Calendar Year.

(iii) If the Other Active Ingredient(s) contained in the Combination Product are sold independently of the Licensed Compound contained in the Combination Product in such country, but the average gross selling price of such Licensed Compound in such country cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction (1-(B/C)), where B is the average gross selling price in such country of such Other Active Ingredient(s) and C is the average gross selling price in such country of the entire Combination Product, during the applicable Calendar Year.

(iv) If the Licensed Compound contained in the Combination Product and Other Active Ingredient(s) contained in the Combination Product are not sold separately in such country, or if they are sold separately but the average gross selling price of neither such Licensed Compound nor such Other Active Ingredient(s) can be determined in such country, Net Sales of the Combination Product in such country will be calculated by mutual agreement of the Parties.

(v) Notwithstanding the foregoing, no Selling Party will sell any Licensed Product as a Combination Product in such a manner as to disproportionately discount the selling price of the Licensed Product included in such Combination Product as compared with the weighted average discount applied to the other products in such Combination Product, as a percent of the respective list prices (or if not available, a good faith estimate thereof) of such products and the stand alone Combination Product prior to applying the discount.

1.64 "**Non-Acting Party**" has the meaning set forth in Section 3.12.5.

1.65 "**Other Active Ingredient**" means the [***] other than a Licensed Compound.

1.66 "**Other Product**" means a product containing an Other Active Ingredient and which is not a Combination Product.

1.67 "**Party**" has the meaning set forth in the Preamble.

1.68 "**Patent Rights**" means the rights and interests in and to all U.S. and foreign (a) patents, including, without limitation, certificates of invention, registrations, reissues, extensions, substitutions, confirmations, renewals, re-registrations, re-examinations, revalidations, patents of additions or like filing thereof; and (b) patent applications, including, without limitation, provisional, converted provisional, non-provisional, continued prosecution application, continuation, divisional or continuation-in-part thereof, any patents issuing therefrom, and any substitution, extension, registration, confirmation, reissue, re-examination, renewal or like filing thereof.

1.69 "**Payments**" has the meaning set forth in Section 3.12.1.

1.70 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

1.71 "**Personal Data**" shall mean any information relating to an identified or identifiable natural person ("**Data Subject**"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person. The Personal Data to be processed by and shared between the Parties under this Agreement relates to personal data of subjects enrolled in clinical trials related to the Licensed Compound and Licensed Products.

1.72 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.5.

1.73 "**Phase 1 Clinical Trial**" means any initial stage human clinical trial in which a Licensed Product is introduced into humans and is conducted mainly, but not limited to, to evaluate the safety, metabolism and pharmacokinetic properties, clinical pharmacology, and if possible, to gain early evidence on effectiveness of such Licensed Product that would satisfy the requirements of 21 C.F.R. § 312.21(a) or its non-U.S. equivalents.

1.74 "**Phase 2 Clinical Trial**" means any human clinical trial of a Licensed Product conducted mainly to test the effectiveness and to determine the common short-term side effects and risks associated with such Licensed Product for purposes of identifying the appropriate dose for a Phase 3 Clinical Trial for a particular indication or indications that would satisfy the requirements of 21 CFR § 312.21(b) or its non-U.S. equivalents. A "Phase 2/3 Clinical Trial" shall be deemed to be a Phase 2 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 2 component, in accordance with the applicable protocol.

1.75 "**Phase 3 Clinical Trial**" means any human clinical trial of a Licensed Product designed to: (a) gather additional information about the effectiveness and safety of such Licensed Product that is needed to evaluate the overall benefit-risk relationship of the Licensed Product for its intended use; (b) provide the clinical basis of commercial labeling; and (c) support regulatory approval of the Licensed Product, that would satisfy the requirements of 21 CFR § 312.21(c) or its non-U.S. equivalents. A "Phase 2/3 Clinical Trial" shall be deemed to be a Phase 3 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 3 component, in accordance with the applicable protocol.

1.76 "**Pre-Launch Level**" has the meaning set forth in Section 3.5.

1.77 "**Process**" **or** "**Processing**" shall mean any operation or set of operations which is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

1.78 "**Puma**" has the meaning set forth in the Preamble.

1.79 "**Puma Indemnified Parties**" has the meaning set forth in Section 7.2.

1.80 "**Receiving Party**" has the meaning set forth in Section 8.1.1.

1.81 "**Regulatory Approval**" means approval of a Drug Approval Application by the FDA, or approval of a Drug Approval Application or a comparable document filed with an equivalent health regulatory authority in any other country or in the European Union (using the centralized process, decentralized process or mutual recognition or member state national authorization), including, where applicable, pricing or reimbursement approval if required in order to Exploit the Licensed Product in the relevant jurisdiction.

1.82 "**Regulatory Authority**" means any Governmental Authority or other authority responsible for granting Regulatory Approval or Marketing Approval for a Licensed Product, including the FDA, EMA and any corresponding national or regional regulatory authorities.

1.83 "**Regulatory Exclusivity**" means, with respect to a Licensed Product, any exclusive marketing rights or data exclusivity rights conferred by an applicable Regulatory Authority with respect to such Licensed Product (including any such rights that would satisfy the requirements of Sections 505(b)(1) or 505(b)(2) of the FDCA or its non-U.S. equivalents) other than a Patent Right.

1.84 "**Regulatory Filing**" means any all (a) submissions, non-administrative correspondence, notifications, registrations, licenses, authorizations, applications and other filings with any Governmental Authority with respect to the research, clinical investigation, development, manufacture, distribution, pricing, reimbursement, marketing or sale of a Licensed Product and (b) Drug Approval Applications for a Licensed Product.

1.85 "**Reserved IIR**" means an investigator-initiated study of a Licensed Product conducted pursuant to a Reserved IIR Agreement.

1.86 "**Reserved IIR Agreement**" means an agreement set forth on Exhibit E.

1.87 "**Reserved IIR IP**" has the meaning set forth in Section 2.5.

1.88 "**Royalty Report**" has the meaning set forth in Section 3.7.

1.89 "**Royalty Term**" has the meaning set forth in Section 3.6.

1.90 "**Safety Database**" has the meaning set forth in Section 5.5.

1.91 "**SCCs**" has the meaning set forth in Section 5.10.

1.92 "**Security Incident Affecting Personal Data**" means any actual or reasonably suspected accidental, unlawful or unauthorized loss, destruction, alteration, access, use, disclosure of, damage or corruption to Personal Data Processed under this Agreement.

1.93 "**Selling Party**" has the meaning set forth in the definition of "Net Sales."

1.94 "**Sublicensee(s)**" means (a) any Person other than an Affiliate of Puma to whom Puma has granted a sublicense under this Agreement, or (b) any other Person to whom a Sublicensee in (a) or an Affiliate of Puma has granted a sublicense under this Agreement.

1.95 "**Takeda**" has the meaning set forth in the Preamble.

1.96 "**Takeda Indemnified Parties**" has the meaning set forth in Section 7.1.

1.97 "**Tax**" means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding in the nature of a tax (including any related fine, penalty, surcharge or interest) imposed by, or payable to, any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official in the Territory.

1.98 "**Tax Action**" has the meaning set forth in Section 3.12.5.

1.99 "**Tax Benefit**" has the meaning set forth in Section 3.12.5.

1.100 "**Term**" has the meaning set forth in Section 9.1.

1.101 "**Territory**" means the entire world.

1.102 "**Third Party**" means a Person other than (a) Takeda or any of its Affiliates, and (b) Puma or any of its Affiliates.

1.103 "**Third Party IP**" has the meaning set forth in Section 9.5(d).

1.104 "**Transaction Documents**" has the meaning set forth in Section 10.1.

1.105 "**Transition Plan**" means the plan for the transfer of the Licensed Know- How and other transition activities attached as Exhibit G hereto.

1.106 "**Valid Claim**" means a claim of any issued and unexpired patent, or any patent application within the Licensed Patents that has not been pending for more than [***] from its priority date, which has not been (a) revoked or held invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction (and which decision can no longer be appealed or was not appealed within the time allowed) or (b) held to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

1.107 "**VAT**" means, within the EU, such tax as may be levied in accordance with (but subject to derogations from) Directive 2006/112/EC and, outside the EU, value added tax or any form of consumption tax levied by a relevant tax authority, as well as all other forms of consumption taxes levied by the relevant tax authority on the purchase of a good or a service, including but not limited to sales tax and good and service tax.

ARTICLE 2.
LICENSE GRANT

Section 2.1 Exclusive License Grant. Subject to the terms and conditions of this Agreement, Takeda hereby grants to Puma an exclusive (even as to Takeda but subject to Section 2.4), royalty-bearing, sublicensable (but only in accordance with Section 2.2), license under its interest in the Licensed Technology to Exploit Licensed Compounds and Licensed Products in the Field in the Territory. For clarity, to the extent the Licensed Technology relates to, claims, or Covers the Exploitation of an Other Product, Puma's license under this Section 2.1 does not include the right to Exploit the Other Product.

Section 2.2 Sublicenses. Puma and its Affiliates shall be entitled to grant one or more sublicenses of the rights granted to it under Section 2.1, in full or in part (with the right to sublicense through multiple tiers), to Third Parties by a written agreement, *provided, however*, that as a condition precedent to and requirement of any such sublicense: (a) any such permitted sublicense shall be consistent with and subject to the terms and conditions of this Agreement, including the limitations applicable to any Patent Right as set forth in Exhibit D; (b) Puma will continue to be responsible for full performance of Puma's obligations under this Agreement and will be responsible for all actions of such Sublicensee as if such Sublicensee were Puma hereunder; (c) any such Sublicensee shall agree in writing to be bound by the obligations of Puma hereunder that are relevant to the rights sublicensed by Puma to Sublicensee under such sublicense agreement; and (d) any such Sublicensee shall agree either to permit Takeda to conduct an audit of such Sublicensee on the same terms as Section 3.11 or to allow Puma to conduct such an audit on such terms (with the result being reportable to Takeda as provided in Section 3.11). Puma shall, within [***] of entering into any such sublicense, provide Takeda with a copy of the sublicense agreement, which may be redacted to omit terms and conditions not applicable to Puma's obligations under this Agreement.

Section 2.3 Limited Grant. Puma acknowledges that the rights and licenses granted under this Article 2 and elsewhere in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, notwithstanding anything in this Agreement to the contrary, nothing in this Agreement shall be construed as granting by implication, estoppel or otherwise, any right, title or interest in, to or under any Takeda patents other than the Licensed Patents regardless of whether such other patents are dominant or subordinate to any Licensed Patent.

Section 2.4 Reserved Rights. All rights that are not specifically granted herein are reserved to Takeda. In addition, Takeda shall retain the right (a) to utilize the Licensed Compound and Licensed Products for non-clinical research and non-clinical development purposes, and (b) to perform or have performed any activities allocated to it under this Agreement, which activities include the conduct of the Reserved IIRs and Delayed Third Party Agreements (until such time as the applicable Delayed Third Party Agreement becomes an Assigned Third Party Agreement) and such rights granted by Takeda to Third Parties pursuant to the Reserved IIR Agreements and Delayed Third Party Agreements (until such time as the applicable Delayed Third Party Agreement becomes an Assigned Third Party Agreement), to which the rights granted to Puma pursuant to Section 2.1 are subject. For clarity, such rights also include the right to conduct and supply Licensed Compound and/or Licensed Product for any compassionate use, single patient IND or similar agreements entered into following the date hereof, if entered into in accordance with the Transition Plan.

Section 2.5 Reserved IIR IP. [***]. If [***], then Takeda shall (a) provide Puma [***], (b) [***], (c) take such actions as necessary to [***], in each case subject to Puma's written agreement [***].

ARTICLE 3.
PAYMENTS

Section 3.1 Upfront Payment. In partial consideration of the rights granted herein to Puma, Puma shall pay to Takeda a one-time, non-refundable, non-creditable payment of Seven Million Dollars ($7,000,000) within [***] following the Effective Date.

Section 3.2 Development Milestone Payments. In partial consideration of the rights granted herein to Puma, Puma shall pay to Takeda milestone payments ("**Development Milestone Payments**") following the first occurrence of the milestone events set forth in the table below (the "**Development Milestone Events**"). Puma shall pay to Takeda the applicable Development Milestone Payment within [***] after the first occurrence of an applicable Development Milestone Event. For clarity, (a) each Development Milestone Payment is payable only once, and (b) no Development Milestone Payment shall be payable for subsequent or repeated achievements of such Development Milestone Event with respect to a Licensed Product. Each of the Development Milestone Payments shall be non- refundable and non-creditable. The Development Milestone Events and Development Milestone Payments shall be as follows:

Milestone No.	Development Milestone Event	Development Milestone Payment
1.	[***]	$[***]
2.	[***]	$[***]
3.	[***]	$[***]
4.	[***]	$[***]
5.	[***]	$[***]
6.	[***]	$[***]

Section 3.3 Commercial Milestones. Puma shall pay to Takeda certain milestone payments ("**Commercial Milestone Payments**") following the first occurrence of certain milestone events, as set forth in this Section 3.3 (the "**Commercial Milestone Events**"). Puma shall pay to Takeda the applicable Commercial Milestone Payment within [***].

Commercial Milestone Event	**Commercial Milestone Payment**
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]

Section 3.4 Royalties. During the Royalty Term, Puma shall pay to Takeda a royalty on worldwide, aggregate annual Net Sales of Licensed Products as follows:

Increments of Worldwide Aggregate Annual Net Sales of Licensed Products in a Calendar Year	**Royalty Rate**
[***]	[***]%
[***]	[***]%

Section 3.5 Royalty Reductions.

3.5.1 Third Party Intellectual Property. On a Calendar Quarter-by-Calendar Quarter basis during the applicable Royalty Term, Puma will be entitled to deduct against royalties otherwise payable to Takeda hereunder up to [***] as of the Effective Date.

3.5.2 [***]. If, on a country-by-county and Licensed Product-by-Licensed Product basis, [***] in a given country and [***], the royalty rates set forth above would be reduced by [***] for such country for so long as [***].

3.5.3 Royalty Floor. Notwithstanding the foregoing, on a Calendar Quarter-by-Calendar Quarter, Licensed Product-by-Licensed Product and country-by-country basis during the applicable Royalty Term, Puma will not be entitled to deduct more than [***] of the royalties otherwise payable to Takeda hereunder with respect to a given Licensed Product in a given Calendar Quarter for Net Sales in a given country.

Section 3.6 Royalty Term. Puma's obligation to pay royalties with respect to a Licensed Product in a particular country shall commence upon the First Commercial Sale of such Licensed Product in such country and shall expire on a country-by-country basis on the latest of (a) the date on which the Exploitation of such Licensed Product is no longer Covered by a Valid Claim of a Licensed Patent in such country, (b) the date on which there is no longer any Regulatory Exclusivity for such Licensed Product in such country, or (c) the tenth (10th) anniversary of the First Commercial Sale of such Licensed Product in such country (the "**Royalty Term**").

Section 3.7 Royalty Reporting and Payment. Beginning upon the First Commercial Sale of the first Licensed Product and continuing until the expiration of the last to expire Royalty Term, Puma shall, within [***] after the end of each Calendar Quarter, (a) prepare and deliver to Takeda royalty reports of the sale of Licensed Product(s) by the Selling Parties for each Calendar Quarter specifying in the aggregate: (i) total gross amounts for the Licensed Product(s) sold or otherwise disposed of by a Selling Party; (ii) amounts deducted in accordance with the definition of Net Sales from gross amounts to calculate Net Sales; (iii) Net Sales; and (iv) royalties payable (each such report, a "**Royalty Report**"), and (b) pay to Takeda the amount of royalties payable specified in such Royalty Report for such Calendar Quarter. In addition, Puma shall provide a quarterly estimate of expected Net Sales for each Calendar Quarter by [***], and an annual forecast of expected Net Sales for the following Calendar Year by [***].

Section 3.8 Payment Method. Unless otherwise agreed by the Parties, all payments due from Puma to Takeda under this Agreement shall be paid in Dollars by wire transfer or electronic funds transfer of immediately available funds to such account as may be specified to Puma by Takeda in writing from time to time following the Effective Date.

Section 3.9 Currency Conversion. In the case of sales outside the United States, payments received by Puma will be expressed in the U.S. Dollar equivalent calculated on a quarterly basis in the currency of the country of sale and converted to their U.S. Dollar equivalent using the average rate of exchange over the applicable Calendar Quarter to which the sales relate, in accordance with GAAP and the then current standard methods of Puma or the applicable Sublicensee, to the extent reasonable and consistently applied; *provided, however*, that if, at such time, Puma or such Sublicensee does not use a rate for converting into U.S. Dollar equivalents that is maintained in accordance with GAAP, then Puma or such Sublicensee shall use a rate of exchange which corresponds to the rate of exchange for such currency reported in The Wall Street Journal, Internet U.S. Edition at www.wsj.com, as of [***]. Puma will inform Takeda as to the specific exchange rate translation methodology used for a particular country or countries and cause any Sublicensees to comply with the terms of this Section 3.9.

Section 3.10 Late Payments. In the event that any payment due hereunder that is not being disputed in good faith is not made when due, the payment shall accrue interest beginning on the day following the due date thereof, calculated at the annual rate of the sum of (a) [***] plus (b) the prime interest rate quoted by The Wall Street Journal, Internet U.S. Edition at www.wsj.com on [***], the interest being compounded on [***]; *provided, however*, that in no event shall said annual interest rate exceed the maximum rate permitted by Law.

Section 3.11 Records and Audits. Puma will keep complete and accurate records of the underlying revenue and expense data relating to its calculations of Net Sales and payments required under this Agreement for the longer of (i) the time period required by applicable Law, or (ii) [***] following the Calendar Year to which such records pertain. Takeda will have the right, [***] at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by Takeda and reasonably acceptable to Puma, review any such records of Puma or its Affiliates or subject to the last sentence of this Section 3.11, Sublicensees (the "**Audited Party**") in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than [***] prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under this Article 3 within the [***] preceding the date of the request for review. Puma will receive a copy of the portions of each such report necessary to verify the accuracy of any purported discrepancy. Should such inspection lead to the discovery of a discrepancy to Takeda's detriment, Puma will, within [***] after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy together with interest at the rate set forth in Section 3.10. Takeda will [***] unless the underpayment of amounts due to Takeda is greater than [***] of the amount due for the entire period being examined, in which case Puma will [***]. Should the audit lead to the discovery of a discrepancy to Puma's detriment, Puma may credit the amount of the discrepancy, [***], against future payments payable to Takeda under this Agreement, and if there are no such payments payable, then Takeda shall pay to Puma the amount of the discrepancy, [***], within [***] of Takeda's receipt of the report. Puma shall use commercially reasonable efforts to obtain consent from Sublicensees to allow Takeda to audit records of Sublicensees as required by this Section 3.11, *provided* that [***], as required in this Section 3.11.

Section 3.12 Taxes.

3.12.1 Withholding. Except as otherwise provided in this Agreement, the amounts payable pursuant to this Agreement ("**Payments**") shall not be reduced on account of any Taxes unless required by applicable Law. Puma shall deduct and withhold from the Payments any Taxes that it is required by applicable Law to deduct or withhold. Notwithstanding the foregoing, if Takeda is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, it may [***]. [***] the withheld amount, which withheld amount shall be treated as [***] payment within [***] following that payment.

3.12.2 Tax Cooperation. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

3.12.3 No Other Reductions. Except as provided in this Section 3.12 and those deductions expressly included in the definition of Net Sales, the amounts payable hereunder will not be reduced on account of any Taxes, unless required by applicable Law.

3.12.4 VAT. Unless otherwise stated, any consideration payable under this Agreement shall be exclusive of VAT. If a Party makes a supply pursuant to this Agreement, and VAT is payable on that supply, the consideration for the supply (VAT exclusive consideration) is increased by an amount equal to the VAT exclusive consideration multiplied by the rate of VAT prevailing at the time the supply is made (additional VAT amount). VAT (if any) will become due and payable upon presentation of a valid VAT invoice (or, where there is no provision in the legislation for the jurisdiction concerned that a VAT invoice is required to be issued, a written demand containing such information as is customary in that jurisdiction).

3.12.5 Redomicile, Assignment or Sublicense. Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that if [***] at the request of the other Party) (each, a "**Tax Action**" and such Party, the "**Acting Party**"), and such action leads to [***] (the "**Non-Acting Party**") [***], then the amount of such payment will be [***] (a) would not have been imposed but for a [***] or (b) is attributable to a [***]. To the extent the [***] Taxes otherwise due in any taxable period ending [***], the Non-Acting Party shall [***].

ARTICLE 4.
PATENT PROSECUTION, MAINTENANCE AND INFRINGEMENT

Section 4.1 Inventorship of Intellectual Property. All determinations of inventorship under this Agreement will be in accordance with U.S. patent law.

Section 4.2 Prosecution and Maintenance of Alisertib Patents. Except as set forth in Exhibit D-1, Puma shall have the first right to file, prosecute and maintain all Patent Rights within the Alisertib Patents, [***]. Puma will use Commercially Reasonable Efforts to prepare, file, prosecute, defend and maintain all Patent Rights within the Alisertib Patents; *provided, however*, that Puma does not represent or warrant that any patent will issue or be granted based on patent applications contained in the Alisertib Patents. Should Puma wish to [***] that is not, as of the Effective Date, [***], Puma will consult with Takeda on [***], and the [***] will be mutually agreed upon by both Parties (such consent not to be unreasonably withheld by Takeda). Puma will assume all costs associated with [***]. Takeda shall reasonably cooperate with Puma's requests for data, affidavits, and other information and assistance to support prosecution and maintenance of the Patent Rights in the Alisertib Patents; *provided, however*, that [***]. Puma shall keep Takeda reasonably informed, in person or by telephone or email, regarding the status of such prosecution and maintenance activities, and Puma shall promptly upon receipt forward to Takeda copies of any significant office actions, communications, and correspondence relating to the Alisertib Patents. Takeda shall have the right to comment on and to discuss prosecution and maintenance activities with Puma, and Puma shall consider the same in good faith and shall provide Takeda with copies of all proposed filings and correspondence at least [***] in advance to give Takeda the opportunity to review and comment. [***]. Any such Patent Rights shall be [***], shall be [***], and shall be considered part of the [***]. [***].

Section 4.3 Takeda Step-In Right. Notwithstanding the foregoing, if Puma declines to file, prosecute or maintain any Patent Rights within the Alisertib Patents, elects to allow any such Patent Rights to lapse in any country, or elects to abandon any such Patent Rights which Cover a Licensed Product or the Licensed Compound, prior to having exhausted all available avenues available within the respective patent office (each, an "**Abandoned Patent Right**"), then:

(a) Puma shall provide Takeda with reasonable notice of such decision so as to permit Takeda to decide whether to file, prosecute or maintain such Abandoned Patent Rights and to take any necessary action (which notice shall, in any event, be given no later than [***] prior to the next deadline for any action that may be taken with respect to such Abandoned Patent Right with the U.S. Patent & Trademark Office or any foreign patent office),

(b) Takeda, [***], may assume control of the filing, prosecution or maintenance of such Abandoned Patent Rights,

(c) Takeda shall have the right to transfer the responsibility for such filing, prosecution and maintenance of such Abandoned Patent Rights to patent counsel ([***]) selected by Takeda,

(d) Puma shall assist and cooperate with Takeda's reasonable requests to support prosecution and maintenance of such Abandoned Patent Rights; *provided, however*, that Takeda shall reimburse Puma for its reasonable expenses with respect to such cooperation, and

(e) In the event a patent issues with respect to any such Abandoned Patent Rights, Takeda shall provide reasonable notice to Puma thereof and such Abandoned Patent Right shall be excluded from the license granted by Takeda to Puma under Section 2.1, unless Puma:

(i) reimburses Takeda for its internal and external costs and expenses related to the prosecution and maintenance of such Abandoned Patent Right within [***] of notice of issuance of any such patent, and

(ii) assumes, in writing, the responsibility for the continued prosecution and maintenance of such Patent Rights in accordance with the provisions of Article 4.

Section 4.4 Enforcement of Alisertib Patents.

4.4.1 Puma Enforcement. Each Party will notify the other promptly in writing when any infringement of an Alisertib Patent by a Third Party is uncovered or reasonably suspected. As between the Parties, Puma shall have the first right, but not the obligation, to enforce the Alisertib Patents against any infringement or alleged infringement thereof, and shall at all times keep Takeda informed as to the status thereof. Puma may, [***], institute suit against any such infringer or alleged infringer and control and defend and settle such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 4.5. Takeda shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) [***]. Puma shall not enter into any settlement of any claim described in this Section 4.4.1 that results in any financial liability on the part of Takeda or requires an admission of liability, wrongdoing or fault on the part of Takeda, without Takeda's prior written consent, in each case, such consent not to be unreasonably withheld.

4.4.2 Takeda Enforcement. If Puma elects not to enforce any Alisertib Patent, then it shall so notify Takeda in writing within [***] of receiving notice or discovering that an infringement exists or is reasonably suspected (or such shorter period as may be necessary to prevent exhaustion of a statute of limitations (or laches) applicable to such infringement), and Takeda may, in its sole judgment, and [***], take steps to enforce any such patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover any damages, awards or settlements resulting therefrom, subject to Section 4.5. Puma shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) [***]. Takeda shall not enter into any settlement of any claim described in this Section 4.4.2 that results in any financial liability on the part of Puma or requires an admission of liability, wrongdoing or fault on the part of Puma without Puma's prior written consent, such consent not to be unreasonably withheld.

4.4.3 Cooperation with Respect to Enforcement. Irrespective of which Party controls an action pursuant to this Section 4.4, the Parties will discuss in good faith the enforcing Party's choice of counsel with respect to such enforcement action and the enforcing Party will consider in good faith the comments of the other Party with respect to strategic decisions and their implementation with respect to such action. In furtherance of the foregoing, the Party initiating or defending any such enforcement action (the "**Enforcing Party**") shall keep the other Party reasonably informed of the progress of any such enforcement action, and such other Party shall have the individual right to participate with counsel of its own choice [***].

4.4.4 Defense of Third Party Claims. If either (a) any Licensed Product Exploited by or under authority of Puma becomes the subject of a Third Party's claim or assertion of infringement of a patent relating to the Exploitation of such Licensed Product in the Field in the Territory, or (b) a declaratory judgment action is brought naming either Party as a defendant and alleging invalidity or unenforceability of any of the Alisertib Patents, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Subject to Article 7, unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the "**Defending Party**"). If Takeda is named in such legal action but not Puma, then Puma shall have the right to join, [***], any such legal action and to be represented in such action by its own counsel. Neither Party shall enter into any settlement of any claim described in this Section 4.4.4 that admits to the invalidity, narrowing of scope or unenforceability of the Alisertib Patents or this Agreement, incurs any financial liability on the part of the other Party, or requires an admission of liability, wrongdoing or fault on the part of the other Party, without such other Party's prior written consent, in each case, such consent not to be unreasonably withheld, conditioned or delayed. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's request and the Defending Party shall reimburse the other Party's reasonable out-of-pocket costs associated therewith.

Section 4.5 Recovery. Except as otherwise provided, the costs and expenses of the Party bringing suit under Section 4.4 shall be borne by such Party, and any damages, settlements or other monetary awards recovered shall be shared as follows: (a) the amount of such recovery actually received by the Party controlling such action shall first be applied to the out-of-pocket costs of each Party in connection with such action; and then (b) the remainder of the recovery shall be shared as follows:

(a) If Puma is the Enforcing Party, [***]; and

(b) If Takeda is the Enforcing Party, [***].

Section 4.6 Patent Term Extensions and Filings for Regulatory Exclusivity Periods.

(a) Puma will in its sole discretion determine whether to seek patent term extension or supplementary protection certificates or their equivalent for the Alisertib Patents, in the jurisdictions where such protections are available. Puma will keep Takeda informed regarding their plans and timelines in seeking such protections.

(b) Puma shall have sole responsibility and authority regarding which Alisertib Patents to list on any patent listings required for any Regulatory Exclusivity for Licensed Products or any patent term extension or supplementary protection certificates or their equivalent for the Alisertib Patents.

Section 4.7 Prosecution, Maintenance, Enforcement and Defense of Combination Patents. Takeda shall be solely responsible, and have the sole right, at its own cost and expense, for the prosecution, maintenance, enforcement, and defense of all Patent Rights within the Combination Patents. Takeda will in its sole discretion determine whether to seek patent term extension or supplementary protection certificates or their equivalent for the Combination Patents, in the jurisdictions where such protections are available.

Section 4.8 Patent Marking. Puma will mark, and will cause all other Selling Parties to mark, the Licensed Product(s) with all Licensed Patents in accordance with applicable Law, which marking obligation will continue for as long as (and only for as long as) required under applicable Law.

ARTICLE 5.
DEVELOPMENT AND COMMERCIALIZATION

Section 5.1 Responsibility for Development and Commercialization.

(a) *Puma Responsibility*. Following the Effective Date and during the Term, except with respect to the Reserved IIRs and Delayed Third Party Agreements (until such time as the applicable Delayed Third Party Agreement becomes an Assigned Third Party Agreement), Puma shall be responsible for the research, development, commercialization and Exploitation of all Licensed Products in the Field in the Territory, including regulatory, manufacturing, distribution, marketing and sales activities. Puma shall be solely responsible for all expenses incurred in connection with the foregoing. Puma shall conduct all research, development, commercialization and Exploitation of all Licensed Products in accordance with applicable Law.

(b) *Clinical Development Plan*. Puma will conduct its clinical development activities for Licensed Products pursuant to the clinical development plan set forth on Exhibit H (as may be amended by Puma, the "**Clinical Development Plan**"). Puma will have the right to update the Clinical Development Plan in its sole discretion during the Term, and shall promptly notify Takeda of any material amendments to the Clinical Development Plan during the Term.

(c) *Takeda Responsibility*. As between the Parties, Takeda shall be responsible for all expenses associated with the [***]. Takeda shall disclose to Puma all results of the [***].

Section 5.2 Puma Diligence Obligations. Puma shall use Commercially Reasonable Efforts at all times during the Term to research, develop in accordance with the Clinical Development Plan, obtain Regulatory Approval for, and commercialize one Licensed Product in each of the Major Market Countries.

Section 5.3 Puma Reporting Obligations. On a [***] basis, Puma will provide Takeda with a written report describing any research, development, manufacturing and commercialization activities conducted by Puma, its Affiliates or Sublicensees with respect to Licensed Products in the Territory during the preceding [***] period. Such written report will include an updated copy of the Clinical Development Plan, unless such version has previously been provided to Takeda.

Section 5.4 Transfer of Licensed Know-How. Takeda shall transfer to Puma the Licensed Know-How listed on Exhibit C in accordance with the Transition Plan. The Licensed Know-How will be transferred in a customary electronic format to the extent available, or otherwise in the original paper format. [***]. With respect to paper documentation comprising any Licensed Know-How to be transferred to Puma in accordance with the Transition Plan, including records and documentation [***], the Parties shall enter into a document access or similar agreement to be mutually agreed to by the Parties and setting forth the terms of Puma's access to such documentation and responsibility for costs therefor (such agreement the "**Document Access Agreement**").

Section 5.5 Transfer of Regulatory Materials and Safety Database. Promptly following the Effective Date, Takeda will (a) assign (or cause its Affiliates to assign) to Puma all Regulatory Filings and Regulatory Approvals with respect to the Licensed Compound or the Licensed Products which are owned by Takeda as of the Effective Date in the Territory, and (b) initiate the transfer to Puma of the global safety database for the Licensed Product(s) (the "**Safety Database**"). Takeda and Puma shall jointly work to complete the transfer of such Safety Database within [***] after the Effective Date. For clarity, Takeda shall have no obligation to transfer any Regulatory Filings, Regulatory Approvals or safety information to the extent any of the foregoing [***]. In connection therewith, Takeda and Puma shall enter into a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"). In the event of any conflict between this Agreement and the Pharmacovigilance Agreement, as to any matters relating to the Safety Database or provisions of this Section 5.5, the Pharmacovigilance Agreement shall govern. Prior to the completion of the transfer of the Safety Database, Puma and Takeda shall reasonably cooperate and use diligent efforts to ensure compliance with safety reporting requirements related to the Licensed Product(s) and Takeda shall provide safety information to Puma as Puma might reasonably request or otherwise as necessary to satisfy Puma's regulatory or other legal obligations. Following the completion of the transfer of the Safety Database, Puma shall assume ownership and control of the Safety Database. For clarity, safety data from studies which are [***] is explicitly excluded from Takeda's obligations under this Section 5.5 to the extent [***]; *provided further, however*, that if Puma (or its Affiliate or its or their (sub)licensee) is required by a Regulatory Authority, or otherwise finds it necessary and provides reasonably sufficient rationale to Takeda, to report any safety data relating to [***].

Section 5.6 Transfer of Inventory. Within [***] after the Effective Date, Takeda will transfer to Puma the inventory of Licensed Compound, Licensed Products and materials intended for the manufacture thereof that are in Takeda's possession or control, as set forth on Exhibit I ([***]). [***]. Takeda will [***] pursuant to this Section 5.6. All inventory and materials provided by Takeda are provided on an as-is basis. Takeda makes no representations or warranties with respect to any inventory or materials except as expressly set forth in Article 6, including for clarity, any representations or warranties that the inventory of Licensed Compound and Licensed Product have remaining shelf life or are suitable for use under applicable Laws. Notwithstanding any provision to the contrary set forth in this Agreement, [***].

Section 5.7 Transfer of Third Party Agreements. Effective as of the Effective Date, Takeda agrees to assign, Puma agrees to accept, and the Parties will enter into an Assignment and Assumption Agreement substantially in the form of Exhibit J-1 hereto pursuant to which Takeda will assign, and Puma will accept, the Assigned Third Party Agreements in their entirety. [***]. Upon the occurrence of (i) and (ii) Takeda agrees to assign (or cause its Affiliate(s) to assign), Puma agrees to accept, and the Parties agree to enter into an Assignment and Assumption Agreement substantially in the form of Exhibit J-2 hereto pursuant to which Takeda (including Takeda's respective Affiliates, if applicable) will assign, and Puma will accept, [***]. Each [***] will be deemed an Assigned Third Party Agreement as of the date it is assigned pursuant to an Assignment and Assumption Agreement. The Parties will reasonably cooperate following the Effective Date to prepare and execute any further documentation as may be necessary to effectuate such assignments. Details of the plan for assignment of [***]. Puma shall be solely responsible for all future performance of and obligations under the Assigned Third Party Agreements (including [***]).

Section 5.8 Transfer of [***]. Puma may request that Takeda transfer to Puma [***] collected from clinical trials conducted by Takeda or its Affiliates with respect to the Licensed Product provided that, (i) in connection with any request, Puma shall be responsible for locating the relevant informed consent forms covering such [***] ([***]); (ii) upon locating the relevant informed consent form, Puma shall provide copies thereof to Takeda for Takeda's review; (iii) any such request shall be limited to performing studies, research or other work with respect to such [***] that were contemplated by the applicable informed consent forms; and (iv) Takeda will only provide [***] for uses that Takeda deems in its sole discretion to be permitted by the relevant informed consent forms and to be permitted by applicable Data Protection Laws and applicable laws regarding the conduct of clinical trials. [***]. If the informed consent forms cannot be located or do not provide adequate consent for any applicable use of the [***], the Parties may agree to receive approval from an independent ethics board, if in compliance with each Party's policies with respect to the use of such [***], and if permitted by applicable Data Protection Laws and applicable laws regarding the conduct of clinical trials.

Section 5.9 Wrong Pockets. If, during the [***] following execution of this Agreement, either Takeda or Puma discovers any Know-How owned by Takeda or its Affiliate prior to the Effective Date, or any contract to which Takeda or its Affiliate is a party and executed prior to the Effective Date, in each case, that specifically and solely relates to the Licensed Compound and is necessary or reasonably useful for the Exploitation of the Licensed Compound in the form it exists as of the Effective Date and which was not included on the schedules hereto or was not transferred to Puma in accordance herewith, such Party shall notify the other Party and the Parties shall cooperate and execute and deliver any instruments of transfer or assignment reasonably necessary to transfer and assign such contract or deliver such Know-How or license such Patent Right to Puma (including by updating the schedules or exhibits hereto to reflect the inclusion of such contract or Know-How). For the avoidance of doubt, Takeda will use reasonable efforts to locate any Know-How requested pursuant to this Section 5.9 but cannot guarantee that any such Know-How will exist or be reasonably accessible ([***]). Takeda shall have no obligation to incur additional costs or expenses in connection with this Section 5.9 or to provide any Know-How that is not reasonably accessible. For clarity, except with respect to requests for the use of [***] in accordance with Section 5.8, or as needed to respond to a request from a Regulatory Authority, Takeda shall have no obligation to respond to any requests or to provide additional information or materials under Section 5.4 through Section 5.9 more than [***] following the Effective Date.

Section 5.10 Data Privacy.

(a) Warranties; Fair and Lawful Processing.

(i) Puma and Takeda shall each comply with their respective obligations under all applicable Data Protection Laws in connection with the conduct of activities under this Agreement and each act as a Data Controller with respect to the Processing of Personal Data they each undertake pursuant to this Agreement, including entering into standard contractual clauses in a form mutually agreed by the Parties with respect to transfers of Personal Data outside the EEA, UK or Switzerland (the "**SCCs**").

(ii) Both parties acknowledge the importance of data privacy of individuals to whom shared data may relate and commit not to process Personal Data obtained from each other for any other purpose than those established under this Agreement, unless (A) authorized or required to do so by law, (B) as required to establish or defend legal claims, (C) as authorized by the other Party, or (D) to the extent Processing for such new purpose is permitted by and compliant with applicable Data Protection Laws and the notices provided to and any consents obtained from the relevant Data Subjects in connection therewith or, if not compliant with such notices and consents, upon obtaining appropriate further consent from the Data Subject.

(iii) Each Party represents and warrants that it has provided an appropriate data privacy notice and, if legally required, obtained appropriate consent from the Data Subjects whose Personal Data under this Agreement is being shared with the other Party, that such notice (and consent if appropriate) is in accordance with applicable Data Protection Laws, and allows for the desired use of such Personal Data under this Agreement. Should a Party learn that it has provided Personal Data under this Agreement that may not be shared pursuant to a consent or notice, or should a Data Subject withdraw such consent, such Party shall promptly notify the other Party so that the affected Personal Data under this Agreement can be deleted as required.

(iv) The Party receiving Personal Data under this Agreement shall ensure that the access to the Personal Data under this Agreement is limited to those of its personnel who need to have access to it for the performance of the obligations under this Agreement and that such personnel are informed of the confidential nature of the Personal Data under this Agreement.

(v) In relation to the Processing each Party undertakes under this Agreement, the Parties shall apply appropriate technical and organizational security measures reflective of current good industry practice and technological development to protect Personal Data under this Agreement against accidental or unlawful destruction or loss, alteration (including corruption), unauthorized disclosure, use or access, and against all other unlawful forms of Processing.

(b) Data Subjects' Rights.

(i) The Parties agree that the responsibility for complying with Data Subjects Requests falls to the Party receiving the Data Subject Request in respect of the Personal Data held and under the responsibility of that Party as Data Controller.

(ii) The Parties agree to cooperate and provide reasonable assistance as is necessary to each other to enable them to comply with applicable Data Protection Laws, comply with Data Subject Requests, and respond to any other queries or complaints from Data Subjects or supervisory authorities in connection with Personal Data Processed pursuant to this Agreement.

(c) Data Retention and Deletion.

(i) The Party receiving the Personal Data from the other Party shall not Process the Personal Data under this Agreement for longer than necessary to conduct the relevant activities or exercise its rights under this Agreement.

(d) Transfers.

(i) Each Party may transfer the Personal Data under this Agreement to its Affiliates or subcontractors to the extent such Affiliates or subcontractors have a legitimate need to process the Personal Data under this Agreement, *provided* those subcontracts are subject to appropriate contractual restrictions and in accordance with applicable Data Protection Laws. Each Party shall not disclose or transfer Personal Data under this Agreement to an Affiliate or a subcontractor outside the European Economic Area or the United Kingdom without ensuring that adequate protections in accordance with applicable Law will be afforded to the Personal Data under this Agreement.

(e) Security Incident Affecting Personal Data.

(i) In the event a Party suffers a Security Incident Affecting Personal Data, such Party shall ensure it complies with Data Protection Laws and, if applicable, complies with any obligations to notify data protection supervisory authorities, Data Subjects or other regulatory bodies as required by applicable law.

(ii) To the extent that a Party suffers a Security Incident Affecting Personal Data that (1) has an impact on the activities conducted under the Agreement or (2) relates to Personal Data under this Agreement which has been shared with such Party, such Party suffering the Security Incident Affecting Personal Data shall promptly notify the other Party about such Security Incident Affecting Personal Data and, in any event, no longer than 48 hours from discovery of any confirmed or suspected Security Incident Affecting Personal Data.

(f) Cooperation

(i) Each Party shall provide the other Party with such assistance as may be reasonably requested by the other Party in responding to requests from Data Subjects or supervisory authorities, conducting data protection impact assessments and contacting clinical trial sites, investigators or other subcontractors of the relevant disclosing Party to the extent required to enable the requesting Party to comply with its obligations under Data Protection Laws in relation to the Processing of Personal Data in connection with this Agreement.

(g) Modifications

(i) Each Party agrees to promptly negotiate and agree in good faith regarding any modifications or supplements to this Agreement, which may include entering into one or more additional data Processing agreement(s), data transfer agreement(s) or joint controller agreement(s), upon the other Party's request, to the extent required for the Parties to collect, Process and disclose Personal Data in connection with the Agreement in compliance with applicable Data Protection Law, including:

(A) to address changes to or the legal interpretation of Data Protection Laws;

(B) to comply with the Data Protection Laws, any national legislation implementing it and any guidance on the interpretation of their respective provisions;

(C) if the safeguards, mechanisms or findings of adequacy relied upon in relation to the transfer of Personal Data outside the European Economic Area or the United Kingdom are invalidated or amended,

(D) if changes to the membership status of a country in the European Union or the European Economic Area require such modification;

(E) if a Party Processes Personal Data on behalf of the other; or

(F) if the Parties jointly determine the purposes and means of Processing or are otherwise considered to be joint controllers under Data Protection Law with respect to such Personal Data.

ARTICLE 6.
REPRESENTATIONS AND WARRANTIES

Section 6.1 Mutual Representations and Warranties. Each of Takeda and Puma represent and warrant that:

(a) it is duly organized and validly existing under the Law of the jurisdiction of its incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

(c) it shall comply with all applicable Law (including applicable Law relating to data protection and privacy) and Anti-Corruption Laws in connection with the performance of its rights, duties and obligations under this Agreement; and

(d) this Agreement is legally binding upon it and enforceable in accordance with its terms. Except for consents required pursuant to the [***], the execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material applicable Law. The Parties agree that, solely with respect to any consents required in connection with the assignment of any agreement to Puma hereunder, the sole remedy for a breach of this Section as it relates to obtaining any such consent shall be that [***]. If such consent cannot be obtained, [***].

Section 6.2 Additional Puma Representations and Warranties. Puma represents and warrants that:

(a) it has not been debarred, excluded or the subject of debarment or exclusion proceedings by any Governmental Authority; and

(b) it has established and maintains reasonable internal policies and controls, including codes of conduct and ethics and reasonable reporting requirements, intended to ensure compliance with Anti-Corruption Laws and other applicable Law, to the extent applicable to it under the laws of the jurisdiction of its incorporation, including healthcare compliance, privacy laws and data protection laws.

Section 6.3 Additional Takeda Representations and Warranties. Takeda represents and warrants that, as of the Effective Date:

(a) Takeda Controls the Licensed Know-How set forth on Exhibit C and the Patent Rights listed on Exhibit D (which for clarity encompasses Exhibits D-1 and D-2), except for the Patent Rights listed as abandoned or to be abandoned;

(b) To Takeda's knowledge, the Licensed Patents on Exhibit D constitute all of the Patent Rights that are Controlled by Takeda as of the Effective Date and necessary for the Exploitation of the Licensed Compound(s) or Licensed Product existing as of the Effective Date in the Field in the Territory other than Patent Rights related to the use of the Licensed Compound or Licensed Products in combination with any Other Product;

(c) The Patent Rights listed on Exhibit D are not subject to any liens or encumbrances and Takeda has not granted to any Third Party any rights or licenses under such Patent Rights or Licensed Know-How that would conflict with the licenses granted to Puma hereunder, except for non-exclusive licenses granted pursuant to the IIR Agreements, Reserved IIR Agreements, Assigned Third Party Agreements and Delayed Third Party Agreements. No patent application or registration within the Licensed Patents is the subject of any pending interference, opposition, inter partes proceeding, abandonment, cancellation or patent protest pursuant to 37 C.F.R. §1.291 unless otherwise noted on Exhibit D; and

(d) Takeda has no knowledge of any claim or litigation that has been brought or threatened in writing by any Third Party alleging that the Licensed Patents are invalid or unenforceable or that the manufacture, sale, offer for sale, or importation of the Licensed Compound or the Licensed Product existing as of the Effective Date in the Field infringes or misappropriates or would infringe or misappropriate any right of any Third Party.

(e) Takeda has no knowledge of any Third Party intellectual property rights that would be infringed by the Exploitation of the Licensed Compound or the Licensed Product existing as of the Effective Date in the Field.

(f) Takeda has no knowledge that any Third Party is or was infringing or misappropriating the Licensed Technology in the Territory.

(g) neither Takeda nor, to its knowledge, its Third Party manufacturers has received any notice on Form 483 or other notices of material noncompliance with applicable Laws relevant to the manufacture of a Licensed Compound or Licensed Product in the Territory, and no such entity has entered into a consent decree or similar arrangement with respect to the manufacture of a Licensed Compound or Licensed Product.

(h) Except as set forth on Exhibit D, Takeda has no knowledge that any Third Party has any ownership interest in or to any Licensed Patent existing as of the Effective Date.

(i) Neither Takeda nor, to its knowledge, its Third Party independent contractors have used in connection with Licensed Compound or Licensed Product any Person that has been or is debarred pursuant to Section 306 of the FDCA, as amended, excluded or the subject of debarment or exclusion proceedings by any Governmental Authority.

(j) Takeda has not received any notices of violations of applicable Laws from the FDA or any other Regulatory Authority with respect to the development or use of a Licensed Compound or Licensed Product that could reasonably be deemed to adversely affect the Exploitation of a Licensed Compound or Licensed Product.

(k) To the extent material to the Exploitation of Licensed Compound or Licensed Product, all activities conducted by or on behalf of Takeda (which excludes, for clarity the IIRs) prior to the Effective Date in the course of developing the Licensed Compounds or Licensed Product have, to its knowledge, been in material compliance with all applicable Laws.

(l) Takeda is not aware of any litigation that has been brought or threatened in writing by any Third Party alleging that the Exploitation of a Licensed Product within the Territory to treat a human patient has caused a serious injury, harm or death of such patient. For clarity, adverse events reported in the course of any clinical trial with respect to a Licensed Product are not considered litigation hereunder, unless a separate law suit with respect to such adverse event has been brought or threatened.

Section 6.4 Disclaimer.

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 6, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENT RIGHTS, OR THAT ANY PATENTS WILL ISSUE BASED ON A PENDING APPLICATION. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT THE LICENSED PRODUCTS WILL BE SUCCESSFUL, IN WHOLE OR IN PART. EXCEPT AS EXPRESSLY PROVIDED HEREIN, ANY INVENTORY OR TANGIBLE MATERIALS PROVIDED BY TAKEDA HEREUNDER ARE PROVIDED AS-IS. EXCEPT AS EXPRESSLY PROVIDED HEREIN, TAKEDA DISCLAIMS ANY WARRANTY WITH RESPECT TO THE LICENSED TECHNOLOGY, THE INVENTION(S) CLAIMED IN THE LICENSED PATENTS OR WITH RESPECT TO THE LICENSED PATENTS THEMSELVES, INCLUDING BUT NOT LIMITED TO, ANY REPRESENTATIONS OR WARRANTIES ABOUT (I) THE VALIDITY, SCOPE OR ENFORCEABILITY OF ANY OF THE LICENSED PATENTS; (II) THE ACCURACY, SAFETY OR USEFULNESS FOR ANY PURPOSE OF ANY INFORMATION PROVIDED BY TAKEDA TO PUMA, WITH RESPECT TO THE INVENTION(S) CLAIMED IN THE LICENSED PATENTS OR WITH RESPECT TO THE LICENSED PATENTS THEMSELVES AND ANY LICENSED PRODUCTS DEVELOPED FROM OR COVERED BY THEM; (III) WHETHER THE PRACTICE OF ANY CLAIM CONTAINED IN ANY OF THE LICENSED PATENTS WILL OR MIGHT INFRINGE A PATENT OR OTHER INTELLECTUAL PROPERTY RIGHT OWNED OR LICENSED BY A THIRD PARTY; (IV) THE PATENTABILITY OF ANY INVENTION CLAIMED IN THE LICENSED PATENTS; OR (V) THE ACCURACY, SAFETY, OR USEFULNESS FOR ANY PURPOSE OF THE LICENSED TECHNOLOGY OR ANY LICENSED PRODUCT OR PROCESS MADE OR CARRIED OUT IN ACCORDANCE WITH OR THROUGH THE USE OF THE LICENSED PATENTS.

ARTICLE 7.
INDEMNIFICATION

Section 7.1 Indemnity by Puma. Puma agrees to defend Takeda and its (and its Affiliates') directors, officers, employees and agents (the "**Takeda Indemnified Parties**") at Puma's cost and expense, and will indemnify and hold Takeda and the other Takeda Indemnified Parties harmless from and against any claims, losses, costs, damages, fees or expenses (including legal fees and expenses) (collectively, "**Losses**") to the extent resulting from any Third Party claim (including Licensed Product liability claims) arising out of or otherwise relating to (a) the negligence or willful misconduct of Puma, its Affiliates, or their respective Sublicensees in connection with its activities under this Agreement, (b) the breach of this Agreement, including the representations, warranties and covenants made hereunder, by Puma, or (c) the Exploitation of any Licensed Product by or on behalf of Puma, its Affiliates, or their respective Sublicensees (including from Licensed Product liability and intellectual property infringement claims). In the event of any such claim against the Takeda Indemnified Parties by a Third Party, the foregoing indemnity obligations shall be conditioned upon (x) Takeda promptly notifying Puma in writing of the claim (*provided, however*, that any failure or delay to notify shall not excuse any obligation of Puma except to the extent Puma is actually prejudiced thereby) and (y) Takeda granting Puma sole management and control, at Puma's sole expense, over the defense of the claim and its settlement (*provided, however*, that Puma shall not settle any such claim without the prior written consent of Takeda if such settlement does not include a complete release from liability or if such settlement would involve undertaking an obligation (including the payment of money by a Takeda Indemnified Party), would bind or impair a Takeda Indemnified Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of Takeda or this Agreement is invalid, narrowed in scope or unenforceable), and (z) the Takeda Indemnified Parties cooperating with Puma (at Puma's expense). If, based on the reasonable advice of counsel to the Takeda Indemnified Parties, the Takeda Indemnified Parties have separate defenses from Puma or there is a conflict of interest between the Takeda Indemnified Parties and Puma, then the Takeda Indemnified Parties shall be permitted, at their own expense, to retain counsel of its choosing to represent them in such action or proceeding.

Section 7.2 Indemnity by Takeda. Takeda agrees to defend Puma and its (and its Affiliates') directors, officers, employees and agents (the "**Puma Indemnified Parties**") at Takeda's cost and expense, and will indemnify and hold Puma and the other Puma Indemnified Parties harmless from and against any Losses to the extent resulting from any Third Party claim arising out of or otherwise relating to (i) the Exploitation of any Licensed Product by or on behalf of Takeda, its Affiliates, or their respective Sublicensees (including from Licensed Product liability and intellectual property infringement claims) prior to the Effective Date, (ii) the practicing by Takeda or its Affiliates of the rights granted to Takeda under Section 9.5, or (iii) the gross negligence or willful misconduct or material breach of Takeda in performing its obligations under the Transition Plan (except to the extent such breach is caused by Puma's failure to perform its obligations under the Transition Plan). In the event of any such claim against the Puma Indemnified Parties by a Third Party, the foregoing indemnity obligations shall be conditioned upon (x) Puma promptly notifying Takeda in writing of the claim (*provided, however*, that any failure or delay to notify shall not excuse any obligation of Takeda except to the extent Takeda is actually prejudiced thereby), (y) Puma granting Takeda sole management and control, at Takeda's sole expense, over the defense of the claim and its settlement (*provided, however*, that Takeda shall not settle any such claim without the prior written consent of Puma if such settlement does not include a complete release from liability or if such settlement would involve undertaking an obligation (including the payment of money by a Puma Indemnified Party), would bind or impair a Puma Indemnified Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of Puma or this Agreement is invalid, narrowed in scope or unenforceable), and (z) the Puma Indemnified Parties cooperating with Takeda (at Takeda's expense). If, based on the reasonable advice of counsel to the Puma Indemnified Parties, the Puma Indemnified Parties have separate defenses from Takeda or there is a conflict of interest between the Puma Indemnified Parties and Takeda, then the Puma Indemnified Parties shall be permitted, at their own expense, to retain counsel of its choosing to represent them in such action or proceeding.

Section 7.3 LIMITATION OF DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE UNDER THE TRANSACTION DOCUMENTS TO THE OTHER PARTY FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS, OR LOST SAVINGS) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 7.3 SHALL NOT APPLY WITH RESPECT TO (A) ANY BREACH OF ARTICLE 2 (LICENSE GRANT) OR ARTICLE 8 (CONFIDENTIALITY) OF THIS AGREEMENT, (B) THE INTENTIONAL MISCONDUCT OR GROSS NEGLIGENCE OF A PARTY, OR (C) THE INDEMNIFICATION RIGHTS OF A PARTY UNDER THIS ARTICLE 7 WITH RESPECT TO ANY DAMAGES PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD-PARTY CLAIM.

Section 7.4 Insurance. At least [***] prior to the Initiation of any Clinical Trial by or on behalf of Puma or its Affiliates, Puma shall at its own expense procure and maintain during the Term (and for [***] thereafter) Clinical Trial liability insurance coverage adequate to cover its obligations hereunder and which is/are consistent with normal business practices of prudent biotechnology or pharmaceutical companies engaged in clinical trials of products at the same stage conducted by Puma. Additionally, at least [***] prior to First Commercial Sale, Puma shall at its own expense procure and maintain during the Term (and for [***] thereafter) Licensed Product liability insurance coverage adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent pharmaceutical companies. Each insurance policy required by and procured by Puma under this Section 7.4 shall [***]. Such insurance shall not be construed to create a limit of Puma's liability with respect to its indemnification obligations under this Article 7. Puma shall provide Takeda with a certificate of insurance or other evidence of such insurance, upon request. Puma shall provide Takeda with written notice at least [***] prior to the cancellation, non-renewal or a material change in such insurance which materially adversely affects the rights of Takeda hereunder.

ARTICLE 8.
CONFIDENTIALITY

Section 8.1 Confidential Information.

8.1.1 Confidential Information. Each Party and its Affiliates ("**Disclosing Party**") may disclose to the other Party and its Affiliates ("**Receiving Party**"), and Receiving Party may receive during the course and conduct of activities under this Agreement, certain proprietary or confidential information of Disclosing Party in connection with this Agreement. The term "**Confidential Information**" means all information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by Disclosing Party or at the request of Receiving Party, including any of the foregoing that the Disclosing Party has received from Third Parties. For clarity, any data from studies relating to the Licensed Compound or Licensed Products in combination with any Other Product, as well as any data from studies which are unrelated to the Licensed Compound or Licensed Product (for example clinical trial information arising from a trial arm that did not include the Licensed Compound) will be deemed the Confidential Information of Takeda.

8.1.2 Restrictions. During the Term and for [***] thereafter, Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care). Receiving Party will not use Disclosing Party's Confidential Information except as necessary for the performance of its obligations and exercise of its rights under this Agreement. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent to Receiving Party's Affiliates and their employees or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this Agreement and who are required to comply with the restrictions on use and disclosure in this Section 8.1.2. Receiving Party will use diligent efforts to cause those entities and persons to comply with the restrictions on use and disclosure in this Section 8.1.2. Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.

8.1.3 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information: (a) was known to Receiving Party or any of its Affiliates prior to the time of disclosure by the Disclosing Party or its Affiliates; (b) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (c) is obtained by Receiving Party or any of its Affiliates from a Third Party under no obligation of confidentiality to Disclosing Party; or (d) has been independently developed by employees, subcontractors, consultants or agents of Receiving Party or any of its Affiliates without the use of Disclosing Party's Confidential Information, as evidenced by contemporaneous written records.

8.1.4 Permitted Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(a) in order to comply with applicable Law (including any securities law or regulation or the rules of a securities exchange) or with a legal or administrative proceeding;

(b) in connection with prosecuting or defending litigation, seeking, obtaining and maintaining Marketing Approvals and other Regulatory Filings and communications, and filing, prosecuting and enforcing patents in connection with Receiving Party's rights and obligations pursuant to this Agreement; and

(c) to Sublicensees or prospective Sublicensees, subcontractors or prospective subcontractors, payors, consultants, agents and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive (except for the duration of such restrictions, which shall be no less than [***]) than those set forth in this Article 8; *provided, however*, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 8.1.4(c) to treat such Confidential Information as required under this Article 8.

(d) to actual or prospective investors, acquirers, merger partners, and to any investment advisors, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in this Article 8 (except for the duration of such restrictions, which shall be no less than [***]); *provided, however*, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 8.1.4(d) to treat such Confidential Information as required under this Article 8.

With respect to Sections 8.1.4(a) or 8.1.4(b) (other than Marketing Approvals and other Regulatory Filings and communications), where reasonably practicable, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed.

Section 8.2 Terms of this Agreement. The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 8.1.4. Except as required by Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party not to be unreasonably withheld, conditioned or delayed. The Parties have agreed on an initial press release with respect to their execution of this Agreement, as set forth in Exhibit K.

Section 8.3 Publications.

8.3.1 Right to Publish. Subject to the provisions of Sections 8.1, 8.2 and 8.3.2, Puma shall have the right to publish with respect to Licensed Products in scientific publications, and to make scientific presentations on Licensed Products. Subject to the provisions of Sections 8.1, 8.2 and 8.3.2, Takeda shall have the right to publish, and to allow Third Parties to publish, with respect to Licensed Products in scientific publications, and to make scientific presentations on Licensed Products, in each case only to the extent such publication or right to publication is required pursuant to the terms and conditions of the Reserved IIRs.

8.3.2 Review. Except as required by Law or court order, for any proposed publication or presentation regarding a Licensed Product by Puma, Puma: (a) shall transmit a copy of the proposed publication for review and comment to Takeda at least [***] prior to the submission of such publication to a Third Party; and (b) upon request of Takeda (or its applicable licensee), shall remove all Confidential Information of Takeda (or its applicable licensee) unless such disclosure is permitted pursuant to Section 8.1. Except as required by Law or court order, for any proposed publication or presentation regarding a Licensed Product by Takeda or an investigator under a Reserved IIR based on a requirement to allow such publication under a Reserved IIR, Takeda: (a) shall transmit a copy of the proposed publication for review and comment to Puma promptly following receipt thereof from the investigator of such Reserved IIR; and (b) upon request of Puma (or its applicable licensee), shall request removal of all Confidential Information of Takeda that may be removed pursuant to the terms of the Reserved IIR, and request that the investigator of the Reserved IIR delay submission of such publication or the provision of such presentation for a reasonable time, not to exceed [***], to allow the submission of patent applications to protect any patentable inventions disclosed therein.

Section 8.4 Attorney-Client Privilege. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the applicable Law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.

ARTICLE 9.
TERM AND TERMINATION

Section 9.1 Term. The term of this Agreement (the "**Term**") shall commence on the Effective Date, and unless terminated earlier as provided in this Article 9, shall continue in full force and effect until expiration of the last-to-expire Royalty Term for the Licensed Product(s) in the Territory. Upon expiration (but not termination) of this Agreement, the licenses granted to Puma by Takeda under this Agreement to Exploit the Licensed Product(s) shall be fully paid-up, perpetual, irrevocable and non-exclusive.

Section 9.2 Termination by Takeda.

9.2.1 Breach.

(a) Takeda shall have the right to terminate this Agreement in full in the event Puma materially breaches this Agreement (including any breach of its obligation to use Commercially Reasonable Efforts, which shall be deemed a material breach), and such breach has not been cured by Puma within ninety (90) days after written notice thereof is provided to Puma by Takeda, *provided* that the foregoing cure period shall be forty-five (45) days for breaches that consist of a failure to pay amounts as and when due hereunder. Any termination of this Agreement under this Section 9.2.1 shall become effective at the end of the applicable cure period, unless Puma has cured such breach or default prior to the expiration of such cure period, or, if such breach or default cannot be cured within such cure period, such termination shall be effective upon such written notice of such breach or default from Takeda.

(b) If Puma disputes in good faith the existence or materiality of a breach specified in a notice provided by Takeda to Puma pursuant to Section 9.2.1(a), and Puma provides notice to Takeda of such dispute within the applicable cure period, Puma may require the Executive Officers to meet and confer in good faith to resolve such breach condition and Takeda shall not have the right to terminate this Agreement until forty-five (45) days following such notice. The Executive Officers of the Parties shall, as soon as reasonably practicable, after Puma's notice of such dispute, meet and confer in good faith regarding such dispute at such time and place as mutually agreed upon by the Parties. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

9.2.2 Termination for Shelving. If Puma (including via its Affiliates and Sublicensees), at any time during the Term ceases all *bona fide* development, manufacturing or commercialization activities with respect to all Licensed Products for a continuous period of longer than twelve (12) months, and such suspension of activity is not: (i) by written agreement of the Parties, or (ii) a result of Puma's, its Affiliates or its Sublicensee's reasonable response to guidance from or action by a Regulatory Authority in the Territory (such as a clinical hold, or a recall or withdrawal), then Takeda may, at its election, notify Puma that Takeda intends to terminate this Agreement. In such case, the Parties shall meet to discuss the basis for such cessation of activities for Licensed Products. Unless Puma provides a plan reasonably acceptable to Takeda to recommence activities with respect to Licensed Products within thirty (30) days of receiving such notice from Takeda, then Takeda may terminate this Agreement upon thirty (30) days' prior written notice to Puma.

9.2.3 Termination for IP Challenge. Takeda will have the right to terminate this Agreement in full upon written notice to Puma in the event Takeda discovers or receives notice that Puma or any of its Affiliates or Sublicensees directly challenged in a legal or administrative proceeding the enforceability or validity of any Licensed Patents; *provided, however*, that Takeda will not have the right to terminate this Agreement under this Section 9.2.2 if (a) for any such challenge by any Sublicensee, Puma terminates such sublicense within sixty (60) days of Takeda's notice to Puma under this Section 9.2.2, or (b) in any case such challenge is dismissed within sixty (60) days of Takeda's notice to Puma under this Section 9.2.2 and not thereafter continued.

Section 9.3 Termination by Puma.

9.3.1 Breach by Takeda.

(a) Puma shall have the right to terminate this Agreement in full in the event Takeda materially breaches this Agreement and such breach has not been cured within ninety (90) days after written notice thereof is provided to Takeda by Puma. Any termination of this Agreement under this Section 9.3.1 shall become effective, (i) at the end of the applicable cure period if no Licensed Product has entered a Clinical Trial, (ii) one hundred twenty (120) days after written notice thereof if any Licensed Product has entered a Clinical Trial, and (iii) one hundred eighty (180) days after written notice if any Licensed Product has received a Marketing Approval and is being sold commercially, in each case, unless Takeda has cured such breach or default prior to the expiration of such cure period.

(b) If Takeda disputes in good faith the existence or materiality of a breach specified in a notice provided by Puma to Takeda pursuant to Section 9.3.1(a), and Takeda provides notice to Puma of such dispute within the applicable cure period, Takeda may require the Executive Officers to meet and confer in good faith to resolve such breach condition and Puma shall not have the right to terminate this Agreement until forty-five (45) days following such notice. The Executive Officers of the Parties shall, as soon as reasonably practicable after Takeda's notice of such dispute, meet and confer in good faith regarding such dispute at such time and place as mutually agreed upon by such Parties. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

9.3.2 At Will. Puma may terminate this Agreement in its entirety at will, in its sole discretion, on not less than one hundred twenty (120) days' prior written notice to Takeda.

Section 9.4 Termination Upon Bankruptcy. Subject to applicable Law and Section 10.2, either Party may terminate this Agreement if, at any time, the other Party shall (a) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (b) propose a written agreement of composition or extension of its debts, (c) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition has not been dismissed within sixty (60) days after the filing thereof, (d) propose or be a party to any dissolution or liquidation, (e) make an assignment for the benefit of its creditors or (f) admit in writing its inability generally to meet its obligations as they fall due in the general course.

Section 9.5 Effects of Termination.

Upon the effective date of termination by a Party pursuant to Sections 9.2, 9.3 or 9.4:

(a) All rights and licenses granted by Takeda to Puma in Article 2 will terminate, and Puma and its Affiliates, and (subject to Section 9.5(e)) Sublicensees will cease all use of Licensed Know-How and Licensed Patents and all Exploitation of any Licensed Compound or Licensed Product, except to the extent required to fulfill its obligations under this Section 9.5.

(b) If requested by Takeda within [***] of the effective date of termination, Puma will, within [***] of such request, promptly transfer to Takeda (or its designated Affiliate or subcontractor) all [***], to the extent then-existing. Takeda will [***] for the transfer of such materials requested by Takeda under this Section 9.5(b) [***]. If Takeda does not request transfer of such items pursuant to this Section 9.5(b) within [***] of the effective date of termination, Puma may retain or destroy such items in its discretion, in each case in compliance with applicable Laws.

(c) If requested by Takeda within [***] of the effective date of termination, Puma will, within [***] of such request, [***].

(d) Puma agrees to grant, and hereby grants, to Takeda, effective upon such termination, [***]. If Puma has licensed any [***], then Puma shall notify Takeda of the existence of [***], including a description thereof and the [***]. In addition, Puma will, if requested by Takeda, [***].

(e) Any sublicenses granted by Puma or its Affiliates prior to the effective date of termination of this Agreement shall survive any such termination, *provided* that such Sublicensee is in material compliance with the applicable provisions of this Agreement and the terms and conditions of the applicable sublicense, and *provided* that in no event will Takeda be obligated to fulfill any of Puma's obligations under such sublicense.

(f) Notwithstanding the foregoing, [***].

Section 9.6 Survival. In addition to the termination consequences set forth in Section 9.5, the following provisions will survive termination or expiration of this Agreement: Article 1 (Definitions), to the extent applicable to the remaining surviving provisions, Section 2.3 (Limited Grant), Section 2.4 (Reserved Rights), Article 3 (Payments), solely as it relates to payments that become due prior to (but are not yet paid as of) the effective date of such termination or expiration, Section 3.11 (Records and Audits), Section 4.1 (Inventorship of Intellectual Property), Section 5.10 (Data Privacy), Section 6.4 (Disclaimer), Article 7 (Indemnification), Article 8 (Confidentiality) Section 9.1 (Term) (solely in case of expiration), Section 9.5 (Effects of Termination) and Article 10.

Section 9.7 Additional Rights and Remedies. Termination or expiration of this Agreement are neither Party's exclusive remedy and will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. Except as set forth in this Article 9 and except for any provisions which by their terms survive expiration or termination of this Agreement, all other rights and obligations will terminate upon termination or expiration of this Agreement.

ARTICLE 10.
MISCELLANEOUS

Section 10.1 Entire Agreement; Amendment. This Agreement and all Exhibits and Schedules attached to this Agreement, along with the Confidentiality Agreement between Puma and Takeda Pharmaceuticals U.S.A., Inc., an Affiliate of Takeda, dated September 1, 2021, any Assignment and Assumption Agreement entered into between the Parties, the Pharmacovigilance Agreement, the SCCs and the Document Access Agreement (collectively, the "**Transaction Documents**") constitute the entire agreement between the Parties as to the subject matter hereof. For clarity, all confidential information exchanged pursuant to the aforementioned Confidentiality Agreement shall be included in Confidential Information and subject to the terms and conditions of this Agreement. All prior and contemporaneous negotiations, representations, warranties, agreements, statements, promises and understandings with respect to the subject matter of this Agreement are hereby superseded and merged into, extinguished by and completely expressed by the Transaction Documents. None of the Parties shall be bound by or charged with any written or oral agreements, representations, warranties, statements, promises or understandings not specifically set forth in this Agreement. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by all Parties.

Section 10.2 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

Section 10.3 Independent Contractors. The relationship between Puma and Takeda created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties, including for tax purposes. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Each Party shall use its own discretion and shall have complete and authoritative control over its employees and the details of performing its obligations under this Agreement.

Section 10.4 Governing Law; Jurisdiction. This Agreement and its effect are subject to and shall be construed and enforced in accordance with the law of the State of New York, without regard to its conflicts of laws, except as to any issue which depends upon the validity, scope or enforceability of any Licensed Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued. Each of the Parties hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the State of New York for any matter arising out of or relating to this Agreement and the transactions contemplated hereby, and agrees not to commence any litigation relating thereto except in such courts. Each of the Parties hereby irrevocably and unconditionally waives any objection to the laying of venue of any matter arising out of this Agreement or the transactions contemplated hereby in the courts of the State of New York and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such matter brought in any such court has been brought in an inconvenient forum. The Parties agree that a final judgment in any such matter shall be conclusive and may be enforced in other jurisdictions by suits on the judgment or in any other manner provided by law. Any proceeding brought by either Party under this Agreement shall be exclusively conducted in the English language.

Section 10.5 Notice. All notices or communication required or permitted to be given by either Party hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, or sent by overnight courier, such as Federal Express, to the other Party at its respective address set forth below or to such other address as one Party shall give notice of to the other from time to time hereunder. Mailed notices shall be deemed to be received on the third (3rd) business day following the date of mailing. Notices sent by overnight courier shall be deemed received the following business day.

If to Puma:

Puma Biotechnology, Inc.
10880 Wilshire Blvd, Suite 2150
Los Angeles, CA 90024
Attention: [***]

With a copy, which shall not constitute notice to:

Latham & Watkins
650 Town Center Drive
20th Floor
Costa Mesa CA 92626-1925
Fax: [***]
Attention: [***]

If to Takeda:

Millennium Pharmaceuticals, Inc.
40 Landsdowne Street
Cambridge, MA 02139
Attention: [***]

With a copy, which shall not constitute notice to:

Millennium Pharmaceuticals, Inc.
40 Landsdowne Street
Cambridge, MA 02139
Attention: [***]
Email: [***]

Section 10.6 Compliance with Law; Severability. Nothing in this Agreement shall be construed to require the commission of any act contrary to Law. If any one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements and the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

Section 10.7 Non-Use of Names. Takeda shall not use the name, trademark, logo, or physical likeness of Puma or any of its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Puma's prior written consent. Takeda shall require its Affiliates to comply with the foregoing. Puma shall not use the name, trademark, logo, or physical likeness of Takeda or any of its Affiliates or its or their officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Takeda's prior written consent.

Section 10.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, not to be unreasonably withheld or delayed except that either Party shall be free to assign this Agreement (a) to an Affiliate of such Party (for so long as such Affiliate remains an Affiliate) *provided* that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any merger, consolidation or sale of such Party or sale of all or substantially all of the assets of the Party to which this Agreement relates, without the prior consent of the non-assigning Party but with written notice to such non-assigning Party. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the Parties hereto. Any assignment of this Agreement in contravention of this Section 10.8 shall be null and void.

Section 10.9 Waivers. A Party's consent to or waiver, express or implied, of any other Party's breach of its obligations hereunder shall not be deemed to be or construed as a consent to or waiver of any other breach of the same or any other obligations of such breaching Party. A Party's failure to complain of any act, or failure to act, by the other Party, to declare the other Party in default, to insist upon the strict performance of any obligation or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof, no matter how long such failure continues, shall not constitute a waiver by such Party of its rights hereunder, of any such breach, or of any other obligation or condition. A Party's consent in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance and in any event no consent or waiver shall be effective for any purpose hereunder unless such consent or waiver is in writing and signed by the Party granting such consent or waiver.

Section 10.10 No Third Party Beneficiaries. Except as expressly provided with respect to Takeda Indemnified Parties and Puma Indemnified Parties in Article 7, nothing in this Agreement shall be construed as giving any Person, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

Section 10.11 Headings; Exhibits. Article and Section headings used herein are for convenient reference only, and are not a part of this Agreement. All Exhibits are incorporated herein by this reference.

Section 10.12 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The term "including" (or cognates thereof) as used herein shall mean including (or the cognate thereof), without limiting the generality of any description preceding such term. The term "will" as used herein means "shall." All references to a "business day" or "business days" in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in New York, New York. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof.

Section 10.13 Equitable Relief. Each Party acknowledges that a breach by it of the provisions of Article 8 of this Agreement may not reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party is entitled to seek, in addition to any other remedies it may have under this Agreement or otherwise, preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of Article 8 of this Agreement by the other; *provided, however*, that no specification in this Agreement of a specific legal or equitable remedy will be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach.

Section 10.14 Force Majeure. Neither Party shall be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, embargoes, power shortage or failure, acts of war (whether war be declared or not), insurrections, riots, terrorism, civil commotions, strikes, lockouts or other labor disturbances, acts of God, or any acts, omissions, or delays in acting by any Governmental Authority or the other Party; *provided, however*, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect); and *provided further, however*, that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed.

Section 10.15 Further Assurances. Each Party shall execute, acknowledge, and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

Section 10.16 Counterparts. This Agreement may be executed in counterparts by a single Party, each of which when taken together shall constitute one and the same agreement, and may be executed through the use of facsimiles or.pdf or other electronically transmitted documents.

[**Signature page follows**]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

PUMA BIOTECHNOLOGY, INC.

By:/s/ Alan Auerbach
Name: Alan Auerbach
Title: CEO

MILLENNIUM PHARMACEUTICALS, INC.

By:/s/ Michael Martin
Name: Michael Martin
Title: Authorized Signatory

[Signature Page to Exclusive License Agreement]

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 September 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: November 3, 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 September 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: November 3, 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 September 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 September 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: November 3, 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 September 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 September 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: November 3, 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.