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 March 31, 2019

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)

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 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 ☒ .

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 the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 38,612,447 shares of Common Stock, par value $0.0001 per share, were outstanding as of May 1, 2019.

PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- the commercialization of NERLYNX ® (neratinib);
- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the 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 licensees to obtain regulatory approval and commercialize NERLYNX in areas outside the United States;
- our ability to market any of our products;
- our history of operating losses;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our intention and ability to vigorously defend against any litigation to which we are or may become party;
- our estimates for damages that we may be required to pay in connection with the lawsuits to which we are a party;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report on Form 10-Q, 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, 2018 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 – FINANCI AL INFORMATION

Item 1. Financial Statements

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

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,786	$ 108,419
Marketable securities	101,617	57,002
Accounts receivable, net	80,984	20,773
Inventory	2,637	2,625
Prepaid expenses, current	11,979	12,397
Other current assets	10,155	1,787
Total current assets	256,158	203,003
Lease right-of-use assets	21,120	—
Property and equipment, net	3,718	3,963
Intangible assets, net	43,421	44,408
Restricted cash	4,321	4,319
Prepaid expenses and other, long-term	2,617	3,429
Total assets	$ 331,355	$ 259,122
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 28,878	$ 20,684
Accrued expenses	70,281	46,431
Lease liabilities	2,239	—
Total current liabilities	101,398	67,115
Deferred rent	—	5,815
Lease liabilities, long-term	24,645	—
Post-marketing commitment liability	9,000	—
Long-term debt	152,841	151,886
Total liabilities	287,884	224,816
Stockholders' equity:		
Common stock - $.0001 par value per share; 100,000,000 shares authorized; 38,573,118 shares issued and outstanding at March 31, 2019 and 38,325,037 issued and outstanding at December 31, 2018	4	4
Additional paid-in capital	1,255,586	1,236,355
Receivable from exercise of stock options	(11)	—
Accumulated other comprehensive loss	20	(12)
Accumulated deficit	(1,212,128)	(1,202,041)
Total stockholders' equity	43,471	34,306
Total liabilities and stockholders' equity	$ 331,355	$ 259,122

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 March 31,	
	2019	**2018**
Revenue:		
Product revenue, net	$ 45,567	$ 36,016
License revenue	53,500	30,500
Total revenue	99,067	66,516
Operating costs and expenses:		
Cost of sales	7,985	6,383
Selling, general and administrative	45,506	36,602
Research and development	35,728	46,925
Total operating costs and expenses	89,219	89,910
Profit (loss) from operations	9,848	(23,394)
Other (expenses) income:		
Interest income	872	174
Interest expense	(4,443)	(1,079)
Legal verdict expense	(16,350)	—
Other expenses	(14)	(46)
Total other expenses:	(19,935)	(951)
Net loss	$ (10,087)	$ (24,345)
Net loss applicable to common stockholders	$ (10,087)	$ (24,345)
Net loss per share of common stock—basic and diluted	$ (0.26)	$ (0.65)
Weighted-average shares of common stock outstanding—basic and diluted	38,481,824	37,699,024

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended March 31,	
	2019	**2018**
Net loss	$ (10,087)	$ (24,345)
Other comprehensive loss		
Unrealized (loss) gain on available-for-sale securities	32	—
Comprehensive loss	$ (10,055)	$ (24,345)

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

For the quarter ended March 31, 2019:

	Common Stock		Additional Paid-in	Receivables from Exercises	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	of Options	Income (Loss)	Deficit	Total
Balance at December 31, 2018	38,325,037	$ 4	$1,236,355	$ —	$ (12)	$ (1,202,041)	$ 34,306
Stock-based compensation	—	—	18,138	—	—	—	18,138
Shares issued or restricted stock units vested under employee stock plans	248,081	—	1,093	(11)	—	—	1,082
Unrealized loss on available-for-sale securities	—	—	—	—	32	—	32
Net loss	—	—	—	—	—	(10,087)	(10,087)
Balance at March 31, 2019	38,573,118	$ 4	$1,255,586	$ (11)	$ 20	$ (1,212,128)	$ 43,471

For the quarter ended March 31, 2018:

	Common Stock		Additional Paid-in	Receivables from Exercises	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	of Options	Income (Loss)	Deficit	Total
Balance at December 31, 2017	37,594,851	$ 4	$1,142,213	$ (449)	$ —	$ (1,088,466)	$ 53,302
Stock-based compensation	—	—	25,352	—	—	—	25,352
Shares issued or restricted stock units vested under employee stock plans	167,668	—	2,766	381	—	—	3,147
Net loss	—	—	—	—	—	(24,345)	(24,345)
Balance at March 31, 2018	37,762,519	$ 4	$1,170,331	$ (68)	$ —	$ (1,112,811)	$ 57,456

See Accompanying Notes to the Unaudited Consolidated Financial Statements

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

	For the Three Months Ended March 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (10,087)	$ (24,345)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,135	1,341
Stock-based compensation	18,138	25,352
Disposal of property and equipment	1	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(60,211)	(6,639)
Inventory	(12)	(713)
Prepaid expenses and other	1,230	(1,045)
Other current assets	(8,368)	—
Accounts payable	8,194	(4,217)
Accrued expenses	23,850	3,910
Post-marketing commitment liability	9,000	—
Deferred rent	—	103
Net cash used in operating activities	(16,130)	(6,253)
Investing activities:		
Purchase of property and equipment	—	(40)
Purchase of available-for-sale securities	(86,715)	—
Sale/maturity of available-for-sale securities	42,132	—
Net cash used in provided by investing activities	(44,583)	(40)
Financing activities:		
Net proceeds from shares issued under employee stock plans	1,082	3,147
Net cash provided by financing activities	1,082	3,147
Net decrease in cash, cash equivalents and restricted cash	(59,631)	(3,146)
Cash, cash equivalents and restricted cash, beginning of period	112,738	86,015
Cash, cash equivalents and restricted cash, end of period	$ 53,107	$ 82,869
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment purchases in accounts payable	$ —	$ 85
Receivables related to stock option exercises	$ 11	$ 68
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,228	$ 989

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Note 1—Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or the Company, is a biopharmaceutical company based in Los Angeles, California with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to three drug candidates—PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor recept ors HER1, HER2 and HER4. Currently, the Company is primarily focused on the U.S. commercialization of NERLYNX (neratinib), its first U.S. Food and Drug Administration, or FDA, approved product, and on the further development of the oral version of neratini b for additional indications in the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2.

In November 2012, the Company established and incorporated Puma Biotechnology Ltd., a wholly owned subsidiary, for the sole purpose of serving as the Company's legal representative in the United Kingdom and the European Union in connection with the Company's clinical trial activity in those countries. In December 2018, the Company established and incorporated Puma Biotechnology, B.V., a wholly owned subsidiary, for the sole purpose transferring the above mentioned marketing authorisation in preparation of the departure of the United Kingdom from the European Union. Puma Biotechnology, B.V., is currently the holder of the marketing authorisation for commercialization of NERLYNX in the European Union.

Basis of Presentation:

The Company is focused on developing and commercializing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive, breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. The Company has reported a net loss of approximately $10.1 million and negative cash flows from operations of approximately $16.1 million for the three months ended March 31, 2019. The Company believes that it will continue to incur net losses and negative net cash flows from operating activities through the drug development process and global commercialization.

The Company has incurred significant operating losses and negative cash flows from operations since its inception. On July 17, 2017, the Company received 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.

The Company in-licenses PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357, as well as certain related compounds, from Pfizer Inc., or Pfizer. The Company is required to make substantial payments to Pfizer upon the achievement of certain milestones and has contractual obligations for clinical trial contracts.

Additionally, the Company has entered into exclusive license agreements with Specialised Therapeutics Asia Pte Ltd., or STA, Medison Pharma Ltd., or Medison, CANbridgepharma Limited, or CANbridge, Pint Pharma International SA, or Pint, and, most recently, Knight Therapeutics Inc., or Knight, and Pierre Fabre Medicament SAS, or Pierre Fabre, to pursue regulatory approval and/or commercialize NERLYNX, if approved, in various specified regions outside of the United States. The Company plans to continue to pursue commercialization of NERLYNX in additional countries outside the United States, if approved, and is evaluating various commercialization options in those countries, including developing a direct salesforce, contracting with third parties to provide sales and marketing capabilities, or some combination of these two options. In September 2018, the European Commission, or EC, granted marketing authorisation for NERLYNX for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab based therapy.

The Company's commercialization, R&D, or marketing efforts may require funding in addition to the cash and cash equivalents totaling approximately $48.8 million and marketable securities totaling approximately $ 101.6 million available at March 31, 2019. The Company believes that its exi sting cash and cash equivalents and marketable securities as of March 31, 2019 and proceeds that will become available to the Company through product sales and upfront license payments are sufficient to satisfy its operating cash and needs for at least one year after the filing of the Quarterly Report on Form 10-Q in which these financial statements are included. The Company continues to remain dependent on its ability to obtain sufficient funding to sustain operations and continue to successfully commercia lize neratinib in the United States. While the Company has been successful in raising capital in the past, there can be no assurance that it will be able to do so in the future. The Company's ability to obtain funding may be adversely impacted by uncerta in market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time.

Since its inception through March 31, 2019, the Company's financing has primarily been proceeds from product and license revenue, public offerings of its common stock, private equity placements, and borrowings under its loan and security agreement with Silicon Valley Bank, or SVB and Oxford Finance LLC, or Oxford.

Note 2—Significant Accounting Policies:

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

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.

Use of Estimates:

The preparation of consolidated financial statements in conformity with Generally Accepted Accounting Principles, or GAAP, requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the balance sheet, and reported amounts of 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.

Principles of Consolidation:

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

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 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. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in the revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. 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.

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

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales of 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. The FDA approval of NERLYNX in July 2017 triggered a one-time milestone payment pursuant to the Company's license agreement with the Pfizer. The Company capitalized the milestone payment as an intangible asset and is amortizing the asset to cost of sales on a straight-line basis through 2030, the estimated useful life of the licensed patent. The Company recorded amortization expense related to its intangible asset of $1.0 million for the three months ended March 31, 2019, respectively. As of March 31, 2019, estimated future amortization expense related to the Company's intangible asset was approximately $2.9 million for the remainder of 2019, approximately $3.9 million for each year starting 2020 through 2029, and approximately $1.0 million for 2030.

Royalties:

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.

Leases:

In February 2016, the FASB issued an accounting standards update which requires lessees to recognize most leases on the balance sheet with a corresponding right-of-use asset. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Right-of-use 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. Leases will be classified as financing or operating which will drive the expense recognition pattern. For lessees, the income statement presentation and expense recognition pattern for financing and operating leases is similar to the current model for capital and operating leases, respectively. The Company has elected to exclude short-term leases. The update also requires additional disclosures that will better enable users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The Company adopted this guidance as of January 1, 2019, the required effective date, using the effective date transition method. As permitted under the effective date transition method, financial information and disclosure for periods prior to the date of initial application will not be updated. An adjustment to opening retained earnings was not required in conjunction with our adoption. For additional information, see Note 6 — Leases. We have elected not to reassess whether expired or existing contracts contain leases, nor did we reassess the classification of existing leases as of the adoption date.

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 renewals 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 the options to purchase the leased property. The depreciable life of assets and leasehold improvements are 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 presents the rate of interest that 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 le ase 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 l ease payments. The Company's average incremental borrowing rate, or IBR, for existing leases on the transition date (January 1, 2019) was calculated as 10.9%.

Inventory:

The Company values its inventories at the lower of cost and estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within the cost of sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of sales in the consolidated statements of operations and comprehensive loss.

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. The Company previously expensed $4.5 million of product prior to receipt of marketing approval, which was recorded as research and development expense at the time it was incurred. Inventory that can be used in either the production of clinical or commercial product is recorded as research and development expense when selected for use in a clinical trial. Starter kits, provided to patients prior to insurance approval, are expensed by the Company to sales and marketing expense as incurred.

As of March 31, 2019, the Company's inventory balance consisted primarily of raw materials purchased subsequent to FDA approval of NERLYNX.

Revenue Recognition:

The Company adopted ASC Topic 606 - Revenue from Contracts with Customers, or ASC 606, on January 1, 2017. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements, and financial instruments. Under ASC 606, when its customer obtains control of the promised goods or services, an entity recognizes revenue in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services. The Company had no contracts with customers until after the FDA approved NERLYNX in July 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.

To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identifies the contract(s) with a customer, (ii) identifies the performance obligations in the contract, (iii) determines the transaction price, (iv) allocates the transaction price to the performance obligations in the contract, and (v) recognizes revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under ASC 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product revenue, see *Product Revenue, Net* (below).

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 re serves for variable consideration, including discounts and allowances. The Company's payment terms range between 10 and 68 days.

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

If taxes should be collected from these 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 three months ended March 31, 2019.

Product revenue from customers who individually accounted for 10% or more of the Company's total revenue for the three months ended March 31, 2019 consisted of the following, shown as a percentage of total revenue:

	For the Three Months Ended March 31, 2019
CVS/Caremark	30%
Accredo/Acaria	25%
Diplomat	11%
Biologics	11%

License Revenue:

The Company also recognizes license revenue under certain of the Company's sub-license agreements that are within the scope of ASC Topic 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 Topic 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.

Knight Agreement

During the first quarter of 2019, the Company entered into a sub-license agreement, or the Knight Agreement, with Knight. Pursuant to the Knight Agreement, the Company granted to Knight, under certain of the Company's intellectual property rights relating to neratinib, an exclusive, sublicensable (under certain circumstances) license (i) to commercialize any product containing neratinib and certain related compounds in Canada, (ii) to seek and maintain regulatory approvals for the licensed products in Canada and (iii) to manufacture the licensed products anywhere in the world solely for the development and commercialization of the licensed products in Canada for human use, subject to the terms of the Knight Agreement and the related supply agreement. During the first quarter of 2019, a non-refundable, upfront license fee was received and recognized as license revenue in accordance with ASC Topic 606. The Company satisfied the necessary performance obligations to recognize this license revenue under the terms of the arrangement. This license agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. As a separate promise under the terms of the license agreement, the Company is obligated to supply Knight with the licensed product in accordance with the supply agreement entered in connection with the license agreement. The Company is also obligated to participate in a Joint Steering Committee, which was identified as a separate performance obligation. To determine the stand-alone selling price, the Company estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations based on similar

arrangements. When determining the transaction prices, the Company assumed that the goods or services will be transferred to the customer based on the terms of the existing contract, and did not take into consideration the possibility of a contract being canceled, renewed, or modified. The Company noted there was no additional variable consideration, significant financing components, non-cash consideration, or consideration payable to the customer in this agreement. This li cense agreement also includes potential future milestone and royalty payments due to the Company upon successful completion of certain separate, distinct performance obligations. Pursuant to the Knight Agreement, the Company will potentially receive upfro nt, regulatory and commercial milestone payments totaling up to $7.2 million. In addition, the Company is entitled to receive significant double-digit royalties calculated as a percentage of net sales of the licensed products in Canada. At this time, the Company cannot estimate when these milestone-related performance obligations are expected to be achieved.

Pierre Fabre Agreement

Additionally, during the first quarter of 2019, the Company entered into a sub-license agreement, or the Pierre Fabre Agreement, with Pierre Fabre Medicament SAS, or Pierre Fabre. The Pierre Fabre Agreement granted intellectual property rights and set forth the parties' respective obligations with respect to development, commercialization and supply of the licensed product in European countries excluding Russia and Ukraine, along with countries in North Africa and francophone countries of West Africa. During the first quarter of 2019, a non-refundable, upfront license fee of $51.0 million was recognized as license revenue in accordance with ASC Topic 606. The Company satisfied the necessary performance obligations to recognize this license revenue under the terms of the arrangement. The Pierre Fabre Agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. As a separate promise under the terms of the Pierre Fabre Agreement, the Company is obligated to supply Pierre Fabre with the licensed product in accordance with the related supply agreement. The Company is also obligated to participate in a Joint Steering Committee and Transition Plan, which were identified as separate performance obligations. To determine the respective stand-alone selling prices, the Company estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations based on similar arrangements. When determining the transaction prices, the Company assumed that the goods or services will be transferred to the customer based on the terms of the existing contract, and did not take into consideration the possibility of a contract being canceled, renewed, or modified. The Company noted there was approximately $9.0 million of additional variable consideration in this agreement related to a post-marketing commitment liability, while there were no significant financing components, non-cash consideration, or consideration payable to the customer. The Pierre Fabre Agreement also includes potential future milestone and royalty payments due to the Company upon successful completion of certain separate, distinct performance obligations. Pursuant to the Pierre Fabre Agreement, the Company will potentially receive additional regulatory and commercial milestone payments totaling up to $345 million. In addition, the Company will receive significant double-digit royalties on NERLYNX sales throughout the territory covered by the Pierre Fabre Agreement . At this time, the Company cannot estimate when these milestone-related performance obligations are expected to be achieved.

Reserves for Variable Consideration:

Revenue from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the related sales, and are classified as reductions of accounts receivable 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 Topic 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 material reversal of revenue would not occur in a future period for the estimates detailed below as of March 31, 2019 and, therefore, the transaction price was not reduced further during the quarter ended March 31, 2019. 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 trade receivables, 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 statement of operations and comprehensive loss through March 31, 2019.

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 revenue in the period the related product revenue is recognized, as well as a reduction to trade receivables, net on the consolidated balance sheets. The Company currently estimates product returns using available industry data and 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 that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues payments for such amounts within a few weeks of the customer's notification to the Company of the resale. Reserves for chargebacks consist of payments 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 and the establishment of a current liability, which is included in accrued expenses and other current liabilities 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 and the establishment of a current liability.

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 and other current liabilities on the consolidated balance sheets.

Assets Measured at Fair Value on a Recurring Basis:

ASC, 820, *Fair Value Measurement* , or ASC 820, provides a single definition of fair value and a common framework for measuring fair value as well as new 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 March 31, 2019 and December 31, 2018, 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):

March 31, 2019	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 42,592	$ —	$ —	$ 42,592
Commercial paper	—	52,503	—	52,503
Corporate bonds	—	28,296	—	28,296
U.S. government securities	20,818	—	—	20,818
Totals	$ 63,410	$ 80,799	$ —	$ 144,209

December 31, 2018	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 83,329	$ 2,987	$ —	$ 86,316
Commercial paper	—	35,941	—	35,941
Corporate bonds	—	18,077	—	18,077
U.S. government securities	2,984	—	—	2,984
Totals	$ 86,313	$ 57,005	$ —	$ 143,318

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 short-term investments (in thous ands):

March 31, 2019	Maturity (in years)	Amortized cost	Unrealized Gains	Losses	Estimated fair value
Cash equivalents		$ 42,592	$ —	$ —	$ 42,592
Commercial paper	Less than 1	52,503	—	—	52,503
Corporate bonds	Less than 1	28,282	15	(1)	28,296
U.S. government securities	Less than 1	20,812	6	—	20,818
Totals		$ 144,189	$ 21	$ (1)	$ 144,209

December 31, 2018	(in years)	cost	Gains	Losses	fair value
Cash equivalents		$ 86,316	$ —	$ —	$ 86,316
Commercial paper	Less than 1	35,941	—	—	$ 35,941
Corporate bonds	Less than 1	18,089	—	(12)	$ 18,077
U.S. government securities	Less than 1	2,984	—	—	$ 2,984
Totals		$ 143,330	$ —	$ (12)	$ 143,318

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents and accounts receivable. 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 March 31, 2019, were approximately $56.1 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 trade receivables and net product revenues. 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 our 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 with 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's success depends on its ability to effectively commercialize NERLYNX.

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.

Research and Development Expenses:

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

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

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

Stock-Based Compensation:

Stock option awards:

ASC 718, *Compensation-Stock Compensation* , or ASC 718, requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee 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 six years of publicly traded history. Beginning in 2018, the Company estimated its expected volatility based on its average volatilities using its past six years of publicly traded stock history, including industry, stage of life cycle, size and financial leverage. 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 calculated when the option is granted to reduce the option expense to be recognized over the life of the award and updated upon receipt of further information as to the amount of options expected to be forfeited. The option expense is "trued-up" upon the actual forfeiture of a stock option grant. Due to its limited history of stock option exercises, the Company uses the simplified method to determine the expected life of the option grants.

Restricted stock units:

Restricted stock units, or 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).

Income Taxes:

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

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of March 31, 2019, the Company has established a reserve of 20% of its research and development ("R&D") credit carryover balance.

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.

Net Loss per Common Share:

Basic net loss per share of common stock is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the periods presented, as required by ASC 260, *Earnings per Share* . For purposes of calculating diluted loss per share of common stock, the denominator includes both the weighted average number of shares of common stock outstanding and the number of dilutive common stock equivalents, such as stock options, 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. For the quarter ended March 31, 2019, potentially dilutive securities excluded from the calculations were 5,554,070 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 1,698,146 shares underlying RSUs that were subject to vesting and were antidilutive. For the quarter ended March 31, 2018, potentially dilutive securities excluded from the calculations were 6,163,307 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 1,612,321 shares underlying RSUs that were subject to vesting and were antidilutive.

Recently Adopted Accounting Standards:

In February 2016, the FASB issued ASU No. 2016-02, *Leases* . The amendments in ASU 2016-02 require organizations that lease assets, with lease terms of more than 12 months, to recognize on their balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily depends on its classification as a finance or operating lease. However, unlike previous GAAP that requires only capital leases to be recognized on the balance sheet, ASU No. 2016-02 requires both types of leases to be recognized on the balance sheet. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. For lessees, the income statement presentation and expense recognition pattern for financing and operating leases is similar to the current model for capital and operating leases, respectively. Companies may elect to exclude short-term leases. The update also requires additional disclosures that will better enable users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The Company adopted ASU No. 2016-02 in the first quarter of 2019 using the effective date transition method. As permitted under the effective date transition method, financial information and disclosure for periods prior to the date of initial application will not be updated. The adoption of ASU No. 2016-02 resulted in an increase in its assets and liabilities on its consolidated balance sheets related to recording right-of-use assets and corresponding lease liabilities of approximately $21.6 million and $27.4 million, respectively. The difference between the additional lease assets and lease liabilities represent deferred rent for leases that existed as of the date of adoption. As a result of the adoption there was no material impact to the consolidated statement of operations or statement of cash flows.

Note 3—Accounts Receivable:

Accounts receivable consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Accounts receivable	$ 20,984	$ 20,773
License revenue receivable	60,000	-
Less: allowance for doubtful accounts	-	-
Total accounts receivable, net	$ 80,984	$ 20,773

Accounts receivable consists entirely of amounts owed from our customers related to product sales. The license revenue receivable relates to amounts owed from Pierre Fabre relating to license revenue recognized during the first quarter of 2019.

Note 4—Prepaid Expenses and Other:

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

	March 31, 2019	December 31, 2018
Current:		
CRO services	$ 5,176	$ 5,824
Other clinical development	1,132	888
Insurance	1,762	2,446
Professional fees	1,069	272
Other	2,840	2,967
	11,979	12,397
Long-term:		
CRO services	1,063	1,073
Other clinical development	398	650
Other	1,156	1,706
	2,617	3,429
Totals	$ 14,596	$ 15,826

Other prepaid amounts consist primarily of deposits, licenses, subscriptions, software, and professional fees.

Note 5—Other Current Assets:

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

	March 31, 2019	December 31, 2018
Insurance receivable	$ 9,912	$ 1,175
Other	243	612
Totals	$ 10,155	$ 1,787

Other current asset amounts consist primarily of insurance reimbursements related to various lawsuits to which the Company is a party, and to a tenant improvement receivable.

Note 6—Leases:

Components of lease expense include fixed lease expense and variable lease expense of approximately $1.2 million and $0.1 million, respectively, for the three months ended March 31, 2019. 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. Our office and equipment leases generally have contractually specified minimum rent and annual rent increases are included in the measurement of the right-of-use asset and related lease liability. Additionally, under these lease arrangements, we 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 our Consolidated Statements of Income when they are incurred.

Supplemental cash flow information related to leases for the three months ended March 31, 2019:	
Operating cash flows from operating leases (in thousands)	$ 1,332
Right-of-use assets obtained in exchange for new operating lease liabilities	-
Weighted average remaining lease term (in years)	7.0
Weighted average discount rate	10.9%

The maturity of lease liabilities as of March 31, 2019 were as follows (in thousands):

	Amount
2019 (remaining)	$ 3,746
2020	5,196
2021	5,355
2022	5,477
2023	5,631
Thereafter	13,297
Total	**$ 38,702**
Less: imputed interest	(11,818)
Total lease liabilities	**$ 26,884**

The future minimum lease payments as of December 31, 2018 under ASC 840 were as follows (in thousands):

	Amount
2019	$ 4,924
2020	5,141
2021	5,300
2022	5,464
2023	5,631
Thereafter	13,296
Total	**$ 39,756**

Note 7—Property and Equipment:

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

	March 31, 2019	December 31, 2018
Leasehold improvements	$ 4,048	$ 4,048
Computer equipment	2,399	2,402
Telephone equipment	343	343
Furniture and fixtures	2,346	2,346
	9,136	9,139
Less: accumulated depreciation	(5,418)	(5,176)
Totals	$ 3,718	$ 3,963

Note 8—Intangible assets, net:

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

	March 31, 2019	Estimated Useful Life
Acquired and in-licensed rights	$ 50,000	13 Years
Less: accumulated amortization	(6,579)	
Total intangible asset, net	$ 43,421	

Note 9—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Accrued legal verdict expense	$ 31,350	$ 9,000
Accrued CRO services	10,332	10,187
Accrued royalties	6,845	9,162
Accrued variable consideration	5,788	3,818
Accrued compensation	4,113	4,435
Accrued professional fees	3,699	2,175
Accrued other clinical development	2,752	2,380
Accrued bonus	2,301	1,705
Accrued legal fees	1,074	1,379
Accrued manufacturing costs	626	788
Other	1,401	1,402
Totals	$ 70,281	$ 46,431

Accrued CRO services, accrued other clinical development expenses, and accrued legal fees represent the Company's estimates of such costs. Accrued compensation includes sales commissions and vacation. Accrued royalties represent royalties incurred in connection with the Company's license agreement with Pfizer. Accrued compensation includes accrued bonuses and accrued vacation, which is accrued at the rate the employee earns vacation and reduced as vacation is used by the employee.

Accrued variable consideration represents estimates of adjustments to net revenue for which reserves are established. Other accrued expenses consist primarily of accrued contractor/consultant costs, business license fees, taxes, insurance, and marketing fees.

Accrued legal verdict expense represents an initial estimate of a range between $9.0 million and $18.0 million that may be owed to class action participants as a result of the recent jury verdict in *Hsu v. Puma Biotechnology, Inc.,* and an initial estimate of $22.4 million that may be owed to the plaintiff as a result of the recent jury verdict in *Eshelman v. Puma Biotechnology, Inc., et al*. The total amount of aggregate class-wide damages in *Hsu* is uncertain and will be ascertained only after an extensive claims process and the exhaustion of any appeals. It is also reasonably possible that the total damages will be higher than this estimate.

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

Note 10—Debt:

Long term debt consisted of the following at March 31, 2019 (dollars in thousands):

	March 31, 2019	Maturity Date
Long term debt	$ 155,000	May 1, 2023
Accretion of final interest payment	1,970	
Less: deferred financing costs	(4,129)	
Total long term debt, net	$ 152,841	

In October 2017, the Company entered into a loan and security agreement with SVB, as administrative agent, and the lenders party thereto from time to time, including Oxford and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement, the Company borrowed $50.0 million.

In May 2018, the Company entered into an amendment to the loan and security agreement. Under the amended credit facility, the lenders agre ed 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 borrowed under the original credit facili ty, and (ii) an aggregate amount of $ 30.0 million that the Company drew in December 2018, which was available to under the credit facility as a result of achieving a specified minimum revenue milestone. Proceeds from the term loans under the amended credit facility may be used for working capital and general business purposes. Upon entry into the amended credit facility, the Company was required to pay the lenders aggregate fees of $ 4.2 million , consisting of a first amendment facility fee of $ 0.4 million a nd a final payment of $ 3.8 million in connection with the repayment of the $50.0 million borrowed under the original credit facility. The amended credit facility is secured by substantially all of the Company's personal property other than its intellectual property. The Company also pledged 65 % of the issued and outstanding capital stock of its subsidiary, Puma Biotechnology Ltd.

The term loans under the amended credit facility bear 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 precedes the month in which the interest will accrue, plus (b) 3.5%. The Company is 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 will make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender, calculated pursuant to the amended credit facility. All unpaid principal and accrued and unpaid interest with respect to each term loan is due and payable in full on May 1, 2023. Upon repayment of the term loans, the Company is also required to make a final payment to the lenders equal to 7.5% of the original principal amount of term loans funded.

At the Company's option, the Company may 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 occurs through and including the first anniversary of the funding date of such term loan, 2.0% of any amount prepaid if the prepayment occurs 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 occurs after the second anniversary of the funding date of such term loan and prior to May 1, 2023.

The amended credit facility includes affirmative and negative covenants applicable to the Company, its current subsidiary and any subsidiaries the Company creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. In accordance with these covenants, the Company must also achieve certain product revenue targets, measured as of the last day of each fiscal quarter on a trailing 3-month basis that is greater than or equal to 50% of the Company's revenue target, set forth in its board-approved projections for the 2019 fiscal year. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of the Company, SVB as administrative agent, and the lenders. 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 amended credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide SVB, as collateral agent, with the right to exercise remedies against the Company and the collateral securing the amended credit facility, including foreclosure against the property securing the credit facilities, including its cash. These events of default include, among other things, the Company's failure to pay principal or interest due under the amended credit facility, a breach of certain covenants under the amended credit facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $0.5 million and one or more judgments against the Company in an am ount greater than $0.5 million individually or in the aggregate that remains unsatisfied, unvacated, or unstayed for a period of 10 days after its entry .

As of March 31, 2019, there was $155 million in term loans outstanding under the amended credit facility, and the Company was in compliance with all applicable covenants under the amended credit facility.

Note 11—Stockholders' Equity:

Common Stock:

The Company issued 56,125 and 72,571 shares of common stock upon exercise of stock options during the quarters ended March 31, 2019 and 2018, respectively. The Company issued 192,912 and 96,347 shares of common stock upon vesting of RSUs during the quarters ended March 31, 2019 and 2018 respectively.

Authorized Shares:

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

Warrants:

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

In connection with the closing of a public offering in October 2012, the exercise price and number of shares underlying the warrant issued to Mr. Auerbach were established and, accordingly, the final value of the warrant became fixed. Pursuant to the terms of the warrant, Mr. Auerbach may exercise the warrant to acquire 2,116,250 shares of the Company's common stock at $16 per share until October 4, 2021.

Stock Options and Restricted Stock Units:

The Company's 2011 Incentive Award Plan, as amended, or the 2011 Plan, was adopted by the Company's board of directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years. 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. Through March 31, 2019, a total of 12,529,412 shares of the Company's common stock had been reserved for issuance under the 2011 Plan.

As of March 31, 2019, 6,867,528 shares of the Company's common stock are issuable upon the exercise of outstanding awards granted under the 2011 Plan and 2,421,698 shares of the Company's common stock are available for future issuance under the 2011 Plan. The fair value of options granted to employees was estimated using the Black-Scholes Option Pricing Method (see Note 2) with the following weighted-average assumptions used during the three months ended March 31, 2019 and 2018:

	2019	2018
Dividend yield	0.0%	0.0%
Expected volatility	99.9%	95.5%
Risk-free interest rate	2.5%	2.5%
Expected life in years	5.83	5.85

The Company's 2017 Employment Inducement Incentive Award Plan, or the 2017 Plan, was adopted by the Company's Board of Directors on April 27, 2017. Pursuant to the 2017 Plan, the Company may grant stock options and restricted stock units, 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. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of such shares on the date of grant. As of March 31, 2019, a total of 1,000,000 shares of the Company's common stock have been reserved for issuance under the 2017 Plan. As of March 31, 2019, 374,688 shares have been awarded under the 2017 Plan.

Stock-based compensation was as follows for the three months ended March 31 (in thousands):

	2019	2018
Stock-based compensation:		
Options -		
Selling, general, and administrative	$ 2,986	$ 4,471
Research and development	2,333	10,072
Restricted stock units -		
Selling, general, and administrative	6,889	4,495
Research and development	5,930	6,314
Total stock-based compensation expense	$ 18,138	$ 25,352

The fair value of options granted to employees was estimated using the Black-Scholes Option Pricing Method (see Note 2 –Significant Accounting Policies) with the following weighted-average assumptions used during the three months ended March 31, 2019 and 2018.

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, 2018	5,708,544	$ 87.49	6.1	$ 7,762
Granted	129,734	$ 27.76	9.9	
Forfeited	(49,761)	$ 41.43		
Exercised	(56,125)	$ 19.46		$ 695
Expired	(188,322)	$ 112.65		
Outstanding at March 31, 2019	5,544,070	$ 86.34	5.8	$ 25,921
Nonvested at March 31, 2019	630,970	$ 43.07	8.6	
Exercisable	4,913,100	$ 91.90	5.5	$ 22,772

At March 31, 2019, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $16.9 million, which is expected to be recognized over a weighted-average period of 1.6 years. At March 31, 2019, the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately $73.3 million, which is expected to be recognized over a weighted-average period of 1.9 years. The weighted-average grant date fair value of options granted during the three months ended March 31, 2019 and 2018 was $21.82 and $56.46 per share, respectively. The weighted average grant date fair value of RSUs awarded during the three months ended March 31, 2019 was $28.69 and $72.43 per share, respectively.

Stock Option Rollforward

Stock options	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2018	779,292	$ 33.75
Granted	129,734	21.82
Vested/Issued	(228,295)	38.23
Forfeited	(49,761)	25.64
Nonvested shares at March 31, 2019	630,970	$ 30.31

Restricted Stock Unit Rollforward

Restricted stock units	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2018	1,838,670	$ 60.08
Granted	207,141	28.69
Vested/Issued	(192,912)	67.83
Forfeited	(154,753)	60.82
Nonvested shares at March 31, 2019	1,698,146	$ 55.30

Note 12—401(k) Savings Plan:

The Company maintains 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 $0.4 million and $0.5 million for the three months ended March 31, 2019 and 2018, respectively.

Note 13—Commitments and Contingencies:

Contractual Obligations:

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

License Agreement:

In August 2011, the Company entered into an agreement pursuant to which Pfizer agreed to grant it a worldwide license for the development, manufacture and commercialization of PB272 neratinib (oral), PB272 neratinib (intravenous) and PB357, and certain related compounds. The license is exclusive with respect to certain patent rights owned by or licensed to Pfizer. Under the agreement, the Company is obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and to use commercially reasonable efforts to complete clinical trials and to achieve certain milestones as provided in a development plan. From the closing date of the agreement through December 31, 2011, Pfizer continued to conduct the existing clinical trials on behalf of the Company at the Licensor'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 be responsible for completing 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. Should the Company commercialize any more of the compounds lic ensed 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 som e 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 gen eric competition for such licensed product reaching a certain level in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that the Company sublicenses the rights granted to the Company under the license agreement with Pfizer to a third party, the same milestone and royalty payments are required. The Company can terminate the license agreement at will, or for safety concerns, in each case upon specified advance notice.

Legal Proceedings

The Company and certain of its executive officers were named as defendants in the lawsuits detailed below. 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. Currently, the Company has accrued estimated losses of $9 million related to ***Hsu v. Puma Biotechnology, Inc.*** **and $22.4 million related to** ***Eshelman v. Puma Biotechnology, Inc., et al.*** **as detailed below.** . For certain legal expenses related to the verdicts listed below, the Company receives reimbursements from its insurers. Currently, the Company expects to receive $9.9 million in reimbursements, all of which have been deemed probable and estimable as of March 31, 2019.

Hsu v. Puma Biotechnology, Inc.

On June 3, 2015, Hsingching Hsu, individually and on behalf of all others similarly situated, filed a class action lawsuit against the Company and certain of its executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased the Company's securities between July 22, 2014 and May 29, 2015. A trial on the claims relating to four statements alleged to have been false or misleading was held from January 15 to January 29, 2019. At trial, the jury found that three of the four challenged statements were not false or misleading, and thus found in the defendants' favor on those claims. The jury found liability as to one statement and awarded a maximum of $4.50 per share in damages, which represents approximately 5% of the total claimed damages of $87.20 per share. The total amount of aggregate class-wide damages is uncertain and will be ascertained only after an extensive claims process and the exhaustion of any appeals. Trading models suggest that approximately ten million shares traded during the class period may be eligible to claim damages. Based on prior lawsuits, the Company believes that the number of stockholders who submit proof of claims sufficient to recover damages is typically in the range of 20% to 40% of the total eligible shares. Based on these assumptions, total damages after claims could range from $9 million to $18 million. It is also reasonably possible that the total damages will be higher than this estimate, however, at this time, the amount is not estimable. A final judgment has not been entered.

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 comp laint 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 plaintiff has since filed motions seeking attorneys' fees and prejudgment interest, which if granted could increase the judgment amount. The Company strongly disagrees with the verdict and, on April 22, 2019, filed a motion for a new trial or, in the alternative, a reduced damages award. If the verdict is upheld, pending the outcome of that motion, the Company intends to appeal the verdict.

Derivative Actions

On April 12 and April 14, 2016, stockholders filed two derivative lawsuits purportedly on behalf of the Company against certain of its officers and directors in the Superior Court of the State of California, Los Angeles, captioned *Xie* v. *Auerbach* , No. BC616617, and *McKenney* v. *Auerbach* , No. BC617059. The complaints asserted claims for breach of fiduciary duty, unjust enrichment, abuse of control, mismanagement and waste of corporate assets. *McKenney* was consolidated with *Xie* on June 21, 2016. The complaints sought an unspecified sum of damages and equitable relief.

Separately, on February 9, 2018, another purported stockholder filed a derivative lawsuit purportedly on behalf of the Company against certain of our officers and directors in the United States District Court, Central District of California, captioned *Van Der Gracht De Rommerswael* v. *Auerbach* , No. 8:18-cv-00236. The complaint asserted claims for violation of securities laws, breach of fiduciary duty, waste of corporate assets, and unjust enrichment.

On May 30, 2018, another stockholder filed a derivative lawsuit purportedly on behalf of the Company against certain of its officers and directors in the United States District Court, Central District of California, captioned *Duran v. Auerbach* , No. 2:18-cv-04802. The complaint asserted claims for violations of securities laws, breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets. The complaint seeks an unspecified sum of damages, declaratory judgment, corporate reforms, restitution, and costs and disbursements associated with the lawsuit.

On July 30, 2018, the parties reached a settlement in principle of the *Xie* , *Rommerswael* and *Duran* lawsuits. On January 7, 2019, the Court approved the settlement and entered final judgment in the *Rommerswael* case. On March 1, 2019, the Court approved the parties' stipulation and dismissed the *Duran* lawsuit with prejudice. On April 8, 2019, the Court approved the parties' stipulation and dismissed the *Xie* lawsuit with prejudice.

Note 14—Subsequent Events:

The Company noted no events or transactions subsequent to the balance-sheet date that would have a material effect on the financial statements.

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. 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, 2018.

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

Overview

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

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

We have entered into exclusive sub-license agreements with various partners to pursue regulatory approval, if necessary, and commercialize NERLYNX, if approved, in Europe (excluding Russia and Ukraine), Canada, South East Asia, Israel, greater China, Mexico, various countries in North Africa and West Africa, and various countries and territories in Central and South America, respectively. We plan to continue to pursue commercialization of NERLYNX in other countries outside the United States, if approved, and will evaluate various commercialization options in those countries, including developing a direct salesforce, contracting with third parties to provide sales and marketing capabilities, or some combination of these two options. We expect that our expenses will continue to increase as we continue commercialization efforts.

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 ou r credit facility and sales of our common stock in private placements.

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 three months ended March 31, 2019 from our accounting policies at December 31, 2018, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, with the exception of the sub-license agreements described below:

License Revenue:

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

Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a sig nificant 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 fo r 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.

Knight Agreement

On January 9, 2019, we entered into a sub-license agreement, or the Knight Agreement, with Knight. Pursuant to the Knight Agreement, we granted to Knight, under certain of our intellectual property rights relating to neratinib, an exclusive, sublicensable (under certain circumstances) license (i) to commercialize any product containing neratinib and certain related compounds in Canada, (ii) to seek and maintain regulatory approvals for the licensed products in Canada and (iii) to manufacture the licensed products anywhere in the world solely for the development and commercialization of the licensed products in Canada for human use, subject to the terms of the Knight Agreement and the related supply agreement. During the first quarter of 2019, we received a non-refundable, upfront license fee, which we recognized as license revenue in accordance with ASC Topic 606. We satisfied the necessary performance obligations to recognize this license revenue under the terms of the arrangement. The Knight Agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. As a separate promise under the terms of the Knight Agreement, we are obligated to supply Knight with the licensed product in accordance with the supply agreement entered in connection with the license agreement. We are also obligated to participate in a Joint Steering Committee, which was identified as a separate performance obligation. To determine the stand-alone selling price, we estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations based on similar arrangements. When determining the transaction prices, we assumed that the goods or services will be transferred to the customer based on the terms of the existing contract, and did not take into consideration the possibility of a contract being canceled, renewed, or modified. We noted there was no additional variable consideration, significant financing components, non-cash consideration, or consideration payable to the customer in this agreement. The Knight Agreement also includes potential future milestone and royalty payments due to us upon successful completion of certain separate, distinct performance obligations. Pursuant to the Knight Agreement, we will potentially receive upfront, regulatory and sales-based milestone payments totaling up to $7.2 million. In addition, we are entitled to receive significant double-digit royalties calculated as a percentage of net sales of the licensed products in Canada. At this time, we cannot estimate when these milestone-related performance obligations are expected to be achieved.

Pierre Fabre Agreement

Additionally, during the first quarter of 2019, we entered into a sub-license agreement, o r the Pierre Fabre Agreement, with Pierre Fabre Medicament SAS, or Pierre Fabre. The Pierre Fabre Agreement granted intellectual property rights and set forth the parties' respective obligations with respect to development, commercialization and supply of the licensed product in various countries in European countries excluding Russia and Ukraine, along with countries in North Africa and francophone countries of West Africa. During the first quarter of 2019, we recognized a non-refundable, upfront license fee of $51.0 million as license revenue in accordance with ASC Topic 606. We satisfied the necessary performance obligations to recognize this license revenue under the terms of the arrangement. The Pierre Fabre Agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. As a separate promise under the terms of the Pierre Fabre Agreement, we are obligated to supply Pierre Fabre with the licensed product in accordance with the related supply agreement. This supply arrangement has been identified as a separate promise. We are also obligated to participate in a Joint Steering Committee and Transition Plan, which were identified as separate performance obligations. To determine the respective stand-alone selling prices, we estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations based on similar arrangements. When determining the transaction prices, we assumed that the goods or services will be transferred to the customer based on the terms of the existing contract, and did not take into consideration the possibility of a contract being canceled, renewed, or modified. We noted approximately $9.0 million in additional variable consideration related to a post-marketing commitment liability , while no significant financing components, non-cash consideration, or consideration payable to the customer were noted. The Pierre Fabre Agreement also includes potential future milestone and royalty payments due to us upon successful completion of certain separate, distinct performance obligations. Pursuant to the Pierre Fabre Agreement, we will potentially receive additional regulatory and sales based milestone payments totaling up to $345 million. In addition, we will receive significant double-digit royalties on NERLYNX sales throughout the territory covered by the Pierre Fabre Agreement. At this time, we cannot estimate when these milestone-related performance obligations are expected to be achieved.

Summary of Income and Expenses

Product revenue, net:

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

License revenue:

License revenue consists of consideration earned for performance obligations satisfied pursuant to our 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 product sales also includes period costs related to royalty charges payable to Pfizer, the amortization of a milestone payment made to Pfizer after obtaining FDA approval of NERLYNX, certain inventory manufacturing services, inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Selling, general and administration expenses:

Selling, general and administrative, or SG&A, expenses consist primarily of salaries and related personnel costs, including stock-based compensation expense, professional fees, business insurance, rent, general legal activities, and other corporate expenses. Internal expenses primarily consist of payroll-related costs, but also include facilities and equipment costs, travel expenses and supplies. External expenses primarily consist of legal fees, insurance expenses and consulting for activities such as sales, marketing and software implementations to support corporate growth.

We expect overall SG&A expenses to remain higher in 2019 than 2018 due t o sales and marketing expenses relating to commercialization. Additionally , we are currently appealing the verdicts in two trials and may incur substantial legal expenses in connection with these appeals. However, we are currently unable to estimate the magnitude of such legal expenses and when these expenses will cease.

Research and development expenses:

R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for the manufacturing of clinical materials and clinical trials. During the three months ended March 31, 2019 and 2018, our R&D expenses consisted primarily of clinical research organization, or CRO, fees; fees paid to consultants; salaries and related personnel costs; and stock-based compensation. We expense our R&D costs as they are incurred. Internal expenses primarily consist of payroll-related costs, but also include equipment costs, travel expenses and supplies. External expenses primarily consist of clinical trial expenses and consultant and contractor expense, and also include costs such as legal fees, insurance costs and manufacturing expense.

While we expect clinical R&D expenses to decline in 2019 as compared to 2018, some areas of R&D are expected to increase, such as medical affairs, pharmacovigilance and regulatory affairs as we prepare to apply for global regulatory approval of NERLYNX both in the current and future indications.

Results of Operations

Three Months Ended March 31, 2019 Compared to Three Months Ended March 31, 2018

Total revenue:

For the three months ended March 31, 2019, total revenue was approximately $99.1 million, compared to $66.5 million for the three months ended March 31, 2018.

Product revenue, net:

Product revenue, net was approximately $45.6 million for the three months ended March 31, 2019, compared to $36.0 million for the three months ended March 31, 2018. The increase in product revenue, net was primarily attributable to an increase of 26% in sa les of NERLYNX and a 10% increase in gross selling price that occurred in the first quarter of 2019, partially offset by an increase in variable consideration of approximately 18.2% in the first quarter of 2019 as compared to approximately 10.6% in the first quarter of 2018.

License revenue:

License revenue was $53.5 million for the three months ended March 31, 2019, compared to $30.5 million for the three months ended March 31, 2018. The increase was primarily due to the satisfaction of performance obligations related to two license agreements as well as the satisfaction of a performance-based milestone.

Cost of sales:

For the three months ended March 31, 2019, cost of sales was approximately $8.0 million compared to $6.4 million for the three months ended March 31, 2018. The increase in cost of sales was primarily attributable to the increase in sales of NERLYNX the first three months of 2019 as compared to 2018.

Selling, general and administrative expenses:

For the three months ended March 31, 2019, SG&A expenses were approximately $45.5 million, compared to approximately $36.6 million for the three months ended March 31, 2018. SG&A expenses for the three months ended March 31, 2019 and 2018 were as follows:

Selling, general, and administrative expenses in thousands	**For the Three Months Ended March 31,**		**Change**	
	2019	**2018**	**$**	**%**
Professional fees and expenses	$ 19,115	$ 12,326	$ 6,789	55.1%
Payroll and related costs	11,177	10,512	665	6.3%
Travel and meetings	2,744	2,373	371	15.6%
Facilities and equipment costs	1,439	1,396	43	3.1%
Other	1,156	1,029	127	12.3%
Stock-based compensation	9,875	8,966	909	10.1%
	$ 45,506	$ 36,602	$ 8,904	24.3%

For the three months ended March 31, 2019, SG&A expenses increased by approximately $8.9 million compared to the same period in 2018, primarily attributable to the following:

- an increase in professional fees and expenses of approximately $6.8 million, comprised of an increase of approximately $5.4 million in legal fees in connection with various lawsuits and approximately $1.4 million for consultancy efforts related to marketing and commercialization support;
- an increase of approximately $0.7 million in payroll and payroll-related expenses primarily attributable to the increased payment of sales commissions to our salesforce, approximately $0.4 million in sales travel and meeting-related expenses, and approximately $0.1 million in other expenses such as office supplies and software; and
- an increase of approximately $0.9 million in employee stock-based compensation expense associated with additional headcount, primarily in support of the continued commercial launch of NERLYNX.

Research and development expenses:

For the three months ended March 31, 2019, R&D expenses were approximately $35.7 million, compared to approximately $46.9 million for the three months ended March 31, 2018. R&D expenses for the three months ended March 31, 2019 and 2018 were as follows:

Research and development expenses in thousands	For the Three Months Ended March 31,		Change	
			$	%
	2019	2018	2019/2018	2019/2018
Clinical trial expense	$ 13,758	$ 15,222	$ (1,464)	-9.6%
Internal R&D	10,144	12,206	(2,062)	-16.9%
Consultant and contractors	3,563	3,111	452	14.5%
Stock-based compensation	8,263	16,386	(8,123)	-49.6%
	$ 35,728	$ 46,925	$ (11,197)	-23.9%

For the three months ended March 31, 2019, R&D expenses decreased approximately $11.2 million compared to the same period in 2018, primarily attributable to the following:

- a decrease in clinical trial expenses of approximately $1.5 million, due primarily to a reduction of approximately $1.9 million in external clinical services, and a reduction of approximately $1.5 million in external manufacturing, testing and logistics, offset by an increase in CRO-related expenses of approximately $0.7 million, grant expenditures of approximately $0.7 million, and comparator drug usage of approximately $0.5 million;
- an increase in consultant and contractors expenses of approximately $0.5 million;
- a decrease in internal R&D expenses of approximately $2.1 million, due primarily to decreases of approximately $1.9 million in payroll and payroll related expenses due to reduction in headcount, and $0.2 million in other expenses such as office supplies, travel and software; and
- a decrease in employee stock-based compensation of approximately $8.1 million, due primarily to $6.0 million in stock options that fully vested in 2018 and a reduction in headcount, which reduced stock compensation expense by $2.1 million.

Other (expenses) income:

Other (expenses) income in thousands	For the Three Months Ended March 31,		Change	
			$	%
	2019	2018	2019/2018	2019/2018
Interest income	$ 872	$ 174	$ 698	401.1%
Interest expense	(4,443)	(1,079)	(3,364)	311.8%
Legal verdict expense	(16,350)	-	(16,350)	100.0%
Other (expenses) income	(14)	(46)	32	-69.6%
	$ (19,935)	$ (951)	$ (18,984)	1996.2%

Interest income:

For the three months ended March 31, 2019, we recognized approximately $0.9 million in interest income compared to approximately $0.2 million of interest income for the three months ended March 31, 2018. The increase in interest income reflects more cash in money market accounts and “high yield” savings accounts in 2019 compared to 2018.

Interest expense:

For the three months ended March 31, 2019, we recognized approximately $4.4 million in interest expense, compared to $1.1 million of interest expense for the three months ended March 31, 2018. The increase in interest expense was the result of drawing additional funds available to us under the terms of our loan and security agreement with Silicon Valley Bank, or SVB.

Legal verdict expense:

For the three months ended March 31, 2019, we recognized approximately $16.4 million in legal verdict expense related to the *Eshelman v. Puma Biotechnology, Inc., et al.* verdict. The legal verdict expense of $16.4 million is the result of a $22.4 million verdict, net of a $6.0 million anticipated insurance receivable.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2019 and December 31, 2018, and for the three months ended March 31, 2019 and 2018, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 48,786	$ 108,419
Marketable securities	101,617	57,002
Working capital	154,760	135,888
Stockholders' equity	43,471	34,306

	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Cash provided by (used in):		
Operating activities	$ (16,130)	$ (6,253)
Investing activities	(44,583)	(40)
Financing activities	1,082	3,147
Decrease in cash and cash equivalents	$ (59,631)	$ (3,146)

Operating Activities:

For the three months ended March 31, 2019, we reported a net loss of approximately $10.1 million, compared to approximately $24.3 million for the same period in 2018. Additionally, cash used in operating activities for the three months ended March 31, 2019 was approximately $16.1 million compared to approximately $6.3 million and for the same periods in 2018, respectively.

Cash used in operating activities for the three months ended March 31, 2019 consisted of a net loss of approximately $10.1 million, an increase in net accounts receivable of approximately $60.2 million, and an increase in other current assets of approximately $8.4 million, offset by an increase of $23.9 million in accrued expenses, an increase of approximately $9.0 million in a post-marketing commitment liability, an increase of approximately $8.2 million in accounts payable, and $1.2 million decrease in prepaid expenses and other and $20.3 million of non-cash items such as stock-based compensation and depreciation and amortization.

Investing Activities:

During the three months ended March 31, 2019, net cash used in investing activities was approximately $44.6 million, compared to net cash used by investing activities of $40,000 for the same period in 2018. Net cash used in investing activities during the three months ended March 31, 2019 was made up of approximately $86.7 million of cash invested in available-for-sale securities, offset by $42.1 million of sales or maturities of available-for-sale securities. This difference of approximately $44.6 million represents excess cash being invested in short-term investments according to our investment policy.

Financing Activities:

During the three months ended March 31, 2019, cash provided by financing activities was approximately $1.1 million, which consisted of approximately $1.1 million of net proceeds from the exercise of stock options. During the same period in 2018, cash provided by financing activities was approximately $3.1 million, comprised of net proceeds from the exercise of stock options.

Loan and Security Agreement:

In October 2017, we entered into a loan and security agreement with SVB, as administrative agent, and the lenders party thereto from time to time, including SVB and Oxford. Pursuant to the terms of the credit facility provided for by the original loan and security agreement, we borrowed $50 million in October 2017. In May 2018, we entered into an amendment to the loan and security agreement. Under the amended credit facility, the lenders agreed to make term loans available to us in an aggregate amount of $155 million, consisting of (i) a term loan in an aggregate amount of $125 million, the proceeds of which, in part, were used to repay the $50 million we borrowed under the original credit facility, and (ii) a term loan in an aggregate amount of $30 million that we drew in December 2018, which was available to us under the credit facility as a result of achieving a specified minimum revenue milestone. Proceeds from the term loans under the amended credit facility may be used for working capital and general business purposes. The amended credit facility is 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 subsidiary, Puma Biotechnology Ltd.

The term loans under the amended credit facility bear 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 precedes the month in which the interest will accrue, plus (b) 3.5%. We are 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, we will make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender, calculated pursuant to the amended credit facility. All unpaid principal and accrued and unpaid interest with respect to each term loan is due and payable in full on May 1, 2023. Upon repayment of the term loans, we are also required to make a final payment to the lenders equal to 7.5% of the original principal amount of term loans funded.

At our option, we may 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 occurs through and including the first anniversary of the funding date of such term loan, 2.0% of any amount prepaid if the prepayment occurs 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 occurs after the second anniversary of the funding date of such term loan and prior to May 1, 2023.

The amended credit facility includes affirmative and negative covenants applicable to us, our current subsidiary and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. We must also achieve product revenue, measured as of the last day of each fiscal quarter on a trailing three month basis, that is greater than or equal to 50% of our revenue target set forth in our board-approved projections for the 2019 fiscal year. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of us, SVB, as administrative agent, and the lenders. The negative covenants include, among others, restrictions on us 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 amended credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide SVB, as collateral agent, with the right to exercise remedies against us and the collateral securing the amended credit facility, including foreclosure against the property securing the credit facilities, including our cash. These events of default include, among other things, a failure by us to pay principal or interest due under the amended credit facility, a breach of certain covenants under the amended credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000 and one or more judgments against us in an amount greater than $500,000 individually or in the aggregate that remains unsatisfied, unvacated, or unstayed for a period of 10 days after its entry.

As of March 31, 2019, there was $155.0 million in term loans outstanding under the amended credit facility, and we were in compliance with all applicable covenants under the amended credit facility.

Current and Future Financing Needs:

We have incurred negative cash flows from operations since we started our business, and we did not receive or record any product revenues until the third quarter of 2017. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, our R&D efforts and our commercialization efforts. Given the current and desired pace of clinical development of our product candidates, over the next 12 months we estimate that our R&D spending will be approximately $120 million to $130 million, excluding stock-based compensation.

Additionally, we expect SG&A expenses to increase as we continue commercialization efforts.

We may choose to begin new R&D efforts or we may choose to launch additional marketing efforts. These efforts may require funding in addition to the cash and cash equivalents totaling approximately $48.8 million and $101.6 million in marketable securities available at March 31, 2019. 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 continue to remain dependent on our ability to obtain sufficient funding to sustain operations and successfully commercialize neratinib. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, 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 changes in and progress of our development activities, the imp act of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. We may seek to acc ess 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 o ur existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

Non-GAAP Financial Measures:

In addition to our operating results, as calculated in accordance with generally accepted accounting principles, or GAAP, we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net loss and net loss per share, as calculated in accordance with GAAP, as adjusted to remove the impact of stock-based compensation. For the three months ended March 31, 2019, stock-based compensation represented approximately 22.4 % of our operating expenses and 30.4% for the same period in 2018 , in each case excluding cost of sales. Our management believes that these non-GAAP financial measures are useful to enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

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

	For the Three Months Ended March 31,		
	2019	2018	
GAAP net loss	$ (10,087)	$ (24,345)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	9,875	8,966	(1)
Research and development	8,263	16,386	(2)
Non-GAAP adjusted net income	$ 8,051	$ 1,007	
GAAP net loss per share—basic	$ (0.26)	$ (0.65)	
Adjustment to net loss (as detailed above)	0.47	0.68	
Non-GAAP adjusted basic net income per share	$ 0.21	$ 0.03	(3)
GAAP net loss per share—diluted	$ (0.26)	$ (0.60)	
Adjustment to net loss (as detailed above)	0.46	0.62	
Non-GAAP adjusted diluted net income per share	$ 0.20	$ 0.02	(4)

(1) To reflect a non-cash charge to operating expense for selling, general, and administrative stock-based compensation.
(2) To reflect a non-cash charge to operating expense for research and development stock-based compensation.
(3) Non-GAAP adjusted basic net income per share was calculated based on 38,481,824 and 37,699,024 weighted-average shares of common stock outstanding for the three months ended March 31, 2019 and 2018, respectively.
(4) Non-GAAP adjusted diluted net income per share was calculated based on 39,281,714 and 40,642,311 weighted-average shares of common stock outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the three months ended March 31, 2019 and 2018, respectively.

Off-Balance Sheet Arrangements

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

Item 3. QUANTITATIVE AND QUALITATI VE 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 March 31, 2019. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our cash and cash equivalents without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

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

We also have interest rate exposure as a result of borrowings outstanding under our loan and security agreement with SVB. As of March 31, 2019, the outstanding principal amount of our borrowings was $155.0 million. Our borrowings under the loan and security agreement, as amended, bear 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 precedes the month in which the interest will accrue, plus (b) 3.5%. Changes in the prime rate may therefore affect our interest expense associated with our borrowings under the loan and security agreement.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of March 31, 2019. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective as of March 31, 2019.

Changes in Internal Control over Financial Reporting

Effective January 1, 2019, we adopted Accounting Standards Codification 842, Leases (Topic 842). As a result, we have made changes to certain internal controls over financial reporting to address risks associated with the required lease accounting and disclosure requirements. This includes the enhancement of our lease evaluation processes and the implementation of controls to address risks associated with the calculation of right-of-use assets and corresponding lease liabilities. There were no other changes in our internal control over financial reporting that occurred during the three months ended March 31, 2019 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.,

On June 3, 2015, Hsingching Hsu, individually and on behalf of all others similarly situated, filed a class action lawsuit against us and certain of our executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased our securities between July 22, 2014 and May 29, 2015. A trial on the claims relating to four statements alleged to have been false or misleading was held from January 15 to January 29, 2019. At trial, the jury found that three of the four challenged statements were not false or misleading, and thus found in the defendants' favor on those claims. The jury found liability as to one statement and awarded a maximum of $4.50 per share in damages, which represents approximately 5% of the total claimed damages of $87.20 per share. The total amount of aggregate class-wide damages is uncertain and will be ascertained only after an extensive claims process and the exhaustion of any appeals. Trading models suggest that approximately ten million shares traded during the class period may be eligible to claim damages. Based on prior lawsuits, we believe that the number of stockholders who submit proof of claims sufficient to recover damages is typically in the range of 20% to 40% of the total eligible shares. Based on these assumptions, total damages after claims could range from $9 million to $18 million. It is also reasonably possible that the total damages will be higher than this estimate, however, at this time, the amount is not estimable. A final judgment has not been entered.

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

In February 2016, Fredric N. E shelman filed a lawsuit against our Chief Executive Officer and President, Alan H. Auerbach, and us in the United States District Court for the Eastern District of North Carolina (Case No. 7:16-cv-00018-D). The complaint generally alleged that we and Mr. Auerbach made defamatory statements regarding Dr. Eshelman in connection with a proxy contest. In May 2016, Dr. Eshelman filed a notice of voluntary dismissal of the claims against Mr. Auerbach. A trial on the remaining defamation claims against us took place from March 11 to March 15, 2019. At trial, the jury found us liable and awarded Dr. Eshelman $15.85 million in compensatory damages and $6.5 million in punitive damages. Plaintiff has since filed motions seeking attorneys' fees and prejudgment interest, which if granted could increase the judgment amount. We strongly disagree with the verdict and, on April 22, 2019, filed a motion for a new trial or, in the alternative, a reduced damages award. If the verdict is upheld, pending the outcome of that motion, we intend to appeal the verdict.

Derivative Actions

On April 12 and April 14, 2016, stockholders filed two derivative lawsuits purportedly on behalf of us against certain of our officers and directors in the Superior Court of the State of California, Los Angeles, captioned *Xie* v. *Auerbach* , No. BC616617, and *McKenney* v. *Auerbach* , No. BC617059. The complaints asserted claims for breach of fiduciary duty, unjust enrichment, abuse of control, mismanagement and waste of corporate assets. *McKenney* was consolidated with *Xie* on June 21, 2016. The complaints sought an unspecified sum of damages and equitable relief.

Separately, on February 9, 2018, another purported stockholder filed a derivative lawsuit purportedly on behalf of us against certain of our officers and directors in the United States District Court, Central District of California, captioned *Van Der Gracht De Rommerswael* v. *Auerbach* , No. 8:18-cv-00236. The complaint asserted claims for violation of securities laws, breach of fiduciary duty, waste of corporate assets, and unjust enrichment.

On May 30, 2018, another stockholder filed a derivative lawsuit purportedly on behalf of us against certain of its officers and directors in the United States District Court, Central District of California, captioned *Duran v. Auerbach* , No. 2:18-cv-04802. The complaint asserted claims for violations of securities laws, breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets. The complaint seeks an unspecified sum of damages, declaratory judgment, corporate reforms, restitution, and costs and disbursements associated with the lawsuit.

On July 30, 2018, the parties reached a settlement in principle of the *Xie* , *Rommerswael* and *Duran* lawsuits. On January 7, 2019, the Court approved the settlement and entered final judgment in the *Rommerswael* case. On March 1, 2019, the Court approved the parties' stipulation and dismissed the *Duran* lawsuit with prejudice. On April 8, 2019, the Court approved the parties' stipulation and dismissed the *Xie* lawsuit with prejudice.

Ite m 1A. RIS K FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 1, 2019, 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 Form 10-Q. There has been no material change in our risk factors subsequent to the filing of our Annual Report. However, the risks described in our Annual Report are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations .

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

Recent Sales of Unregistered Securities

We did not sell any of our equity securities without registration under the Securities Act of 1933, as amended, during the three months ended March 31, 2019.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any "affiliated purchasers" within the definition of Rule 10b-18(a)(3) promulgated under the Exchange Act made any purchases of our equity securities during the quarter ended March 31, 2019.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

I tem 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	Second 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 8, 2017 and incorporated herein by reference)
10.1*	License Agreement, dated January 9, 2019, by and between the Company and Knight Therapeutics Inc. (filed as Exhibit 10.19 to the Company's Annual Report on Form 10-K filed with the SEC on March 1, 2019 and incorporated herein by reference)
10.2	Form Transition and General Release Agreement, by and between the Company and Charles R. Eyler (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 12, 2019 and incorporated herein by reference)
10.3+*	License Agreement, dated March 29, 2019, by and between the Company and Pierre Fabre Medicament SAS
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019
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+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Linkbase Document
+	Filed herewith
++	Furnished herewith
*	Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.
#	Management contract or compensatory plan or arrangement.

SIGNAT URES

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: May 10, 2019

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

Date: May 10, 2019

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

Exhibit 10.3

[***] 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.

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (" Agreement ") dated as of March 29 th , 2019 (" Effective Date ") is entered into between Puma Biotechnology, Inc., a corporation organized and existing under the laws of Delaware with its principal place of business at 10880 Wilshire Blvd, Los Angeles, CA 90024 (" Licensor ") and Pierre Fabre Medicament SAS, a company duly organized and existing under the laws of France, having offices and principal place of business at 45, Place Abel Gance 92100 Boulogne Billancourt, France (" Licensee ").

BACKGROUND

A. Licensor owns or controls certain patents, know-how and other intellectual property relating to the product known as Nerlynx® and has obtained marketing approval for such product in the European Union;

B. Licensee has experience in developing, marketing and distributing pharmaceutical products; and

C. Licensor is willing to grant to Licensee, and Licensee desires to obtain, certain exclusive rights and licenses with respect to the development, manufacture, registration and commercialization of Nerlynx® in certain countries.

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

ARTICLE I
DEFINITIONS

1.1 " Affiliate " shall mean, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" shall refer to: (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity.

1.2 " Annual Royalty Bearing Net Sales " shall mean the Royalty Bearing Net Sales generated (a) over any given Calendar Year, (b) the period comprised between the First Commercial Sale of the Product and December 31 of the year of the First Commercial Sale, or (c) the period comprised between January 1 and the date of expiration of the Royalty Term or termination of the Agreement, as applicable.

1.3 " Background Agreements " means the (i) Pfizer License Agreement and (ii) the License Agreement between The General Hospital Corporation d/b/a Massachusetts General Hospital and Wyeth, an Affiliate of Pfizer Inc., acting through its Wyeth Pharmaceuticals Divisions dated December 21, 2006.

1.4 " Business Days " shall mean any day other than Saturday, Sunday or any other day on which commercial banks in USA or France are authorized or required by law to remain closed.

1.5 " Calendar Quarter " shall mean the respective periods of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.

1.6 " Calendar Year " shall mean any twelve (12) month period commencing on January 1.

1.7 " Clinical Studies " shall mean any human clinical study of the Product, whether interventional or not, including without limitation Post-Approval Marketing Studies and PRAS .

1.8 " Combination Product " shall mean any pharmaceutical preparations, in any dosage strengths, formulations and methods of administration, that include the Compound and at least one (1) Other Active Ingredient, whether co-formulated or co-packaged.

1.9 " Commercialize " shall mean to market, promote, distribute, import, export, offer to sell and/or sell a product and/or conduct related commercialization activities. " Commercialization " and " Commercializing " shall have the correlative meanings.

1.10 " Commercially Reasonable Efforts " shall mean with respect to the Development or Commercialization of the Product, that level of efforts and resources commonly dedicated in the research-based pharmaceutical industry by a company to the development or commercialization, as the case may be, of a product of similar commercial potential at a similar stage in its lifecycle, 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, and other relevant scientific, technical and commercial factors.

1.11 " Compound " shall mean the compound known as "neratinib," and all stereoisomers, all salts, solvates, hydrates, and polymorphs, as well as solid forms of any of the foregoing.

1.12 " Control " (including any variations such as " Controlled " and " Controlling "), shall mean with respect to any Intellectual Property Rights, material or document, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense of or under such Intellectual Property Rights, or to provide or provide access to such material or document, to the other Party without breaching the terms of any agreement with a Third Party.

1.13 " Cover " shall mean with respect to any Patent and activity, that such Patent would be infringed by such activity in the absence of the licenses granted pursuant to this Agreement.

1.14 " CTA " shall mean a Clinical Study application (including any amendments thereto) as provided for in European Community Directive 2001/20/EC and the regulations promulgated thereunder, filed with a Regulatory Authority in the European Union before the commencement of Clinical Studies for the Product , or any comparable filing with any Regulatory Authority in any other jurisdiction within or outside the Licensee Territory (including any Investigational New Drug Application filed with a Regulatory Authority in the United States pursuant to 21 C.F.R. §321).

1.15 " Data " shall mean, subject to Article 4.2, any and all research data, pharmacology data, preclinical data, clinical data, including raw data, as well as marketing, market access, pharmacovigilance, and other data related to the Product, in each case to the extent Controlled by a Party or its Affiliates as of the Effective Date or during the term of this Agreement.

1.16 " Data Protection Law " means all applicable Laws , including the Health Insurance Portability and Accountability Act (" HIPAA "), the California Consumer Privacy Act of 2018 (" CCPA ") and any national legislation relating to privacy and data protection , direct marketing or the interception or communication of electronic messages, in each case as amended, consolidated, re-enacted or replaced from time to time, including European Data Protection Laws.

1.17 " Data Subject " means a natural person who is identified or identifiable natural person. An identifiable natural 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, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

1.18 " Development " or " Develop " shall mean development activities, including, with respect to drugs, research, preclinical activities, Clinical Studies, test method development and stability testing, assay development and audit development, toxicology, formulation, as the case may be.

1.19 " DMF " shall mean a drug master file and all equivalents in any country or jurisdiction for the Product, and any components of such Product, submitted by a Party and/or its applicable Subcontractor(s) to Regulatory Authorities. For the avoidance of doubt, DMF shall include any active substance master files.

1.20 " EC " shall mean the European Commission, or any successor entity thereto performing similar functions.

1.21 " EMA " shall mean the European Medicines Agency, or any successor entity thereto performing similar functions.

1.22 " Encumbered Territory " shall mean those countries within the Licensor Territory, excluding the Non- Encumbered Territory.

1.23 " European Data Protection Laws " means the General Data Protection Regulation 2016/679 (the "GDPR"), the e-Privacy Directive 2002/58/EC, the e-Privacy Regulation 2017/003 (once it takes effect), and any relevant Law, or other binding instrument which implements, replaces, adds to, amends, extends, reconstitutes or consolidates such laws from time to time, in each case as amended, consolidated, re-enacted or replaced from time to time.

1.24 " EU Standard Contractual Clauses " means those standard contractual clauses issued by the European Commission that offer sufficient safeguards on data protection for Personal Data to be transferred internationally, which presently consist of two sets of standard contractual clauses for transfers from data controllers in the European Union to controllers established outside the European Union or European Economic Area (Decision 2001/497/EC and Decision 2004/915/EC) and one set of standard contractual clauses for transfers of Personal Data from controllers in the European Union to processors established outside the European Union or European Economic Area (Decision 2010/87/EU), in each case as amended, consolidated, re-enacted or replaced from time to time.

1.25 " FDA " shall mean the US Food and Drug Administration, or any successor entity thereto.

1.26 " Field " shall mean all therapeutic and prophylactic indications for human or veterinary use.

1.27 " First Commercial Sale " shall mean the first sale for use or consumption by an end user of the Product following receipt of the first Marketing Approval of such Product in a country in the Licensee Territory.

1.28 " FTE " shall mean a commitment of time and effort to constitute full-time, which shall consist of [***] for a twelve (12) month period, equivalent person (i.e., one fully committed person or multiple partially committed persons aggregating to one (1) full time person), with appropriate Development, regulatory or other relevant capabilities and seniority employed by a Party or its Affiliates

assigned to directly perform specified activities with respect to the Shared Clinical Trial and/or the Post-Approval Marketing Studies, as applicable, pursuant to this Agreement.

1.29 " FTE Costs " means the product of: (a) that number of FTEs (proportionately, on a per-FTE basis) used by a Party or its Affiliates in directly performing the activities with respect to any Shared Clinical Trial and Post-Approval Marketing Studies, as applicable, multiplied by (b) the applicable FTE Rate.

1.30 " FTE Rate " means, unless otherwise agreed between the Parties, an annual rate per FTE of [***] per year, which may be prorated on a daily or hourly basis as necessary and as may be adjusted from time to time by mutual agreement of the Parties. This annual FTE Rate is "fully burdened" and will cover employee salaries, benefits, travel (e.g., airfare, mobile allowance, meal expenses, and hotel expenses) and other incidental expenses incurred by such personnel in the ordinary course of employment, and such facilities and equipment and other materials and services including ordinary laboratory and manufacturing consumables procured from distributors of relevant products as they may use.

1.31 " GAAP " shall mean, with respect to a Person, the generally accepted accounting principles in the United States as consistently applied to such Person, including with respect to Licensee, International Financial Reporting Standards.

1.32 " Generic Competitors " shall mean, with respect to the Product being sold in a country, one or more Generic Drugs therefor, where a " Generic Drug " is a generic pharmaceutical product (a) sold under a Marketing Approval granted by a Regulatory Authority to a Third Party (who is not a Sublicensee of Licensee or otherwise has been authorized by Licensee to sell such product), (b) that contains the same Compound as the relevant Product (whether or not in the same formulation or a similar formulation as the Product), and (c) is approved in reliance on a prior Marketing Approval of the Product granted to by the applicable Regulatory Authority, including for the avoidance of doubt the Marketing Approval to be transferred from Licensor to Licensee in accordance with Article 4.6(a). For purposes of the foregoing, different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of the Compound shall be considered to be the same Compound, unless they differ significantly in properties with regard to safety and/or efficacy from such Compound.

1.33 " Generic Market Share " means, with respect to the Product in a country, the total unit volume of Generic Competitors(s) of such Product sold in such country, as a percentage of the combined unit volume of such Product and such Generic Competitor(s), in the aggregate in such country. Such unit volumes shall be determined based on data provided by a reputable Third Party data source generally accepted in the pharmaceutical industry in the relevant country, such as IQVIA.

1.34 " Good Clinical Practice " or " GCP " shall mean the current standards for clinical studies for pharmaceuticals, as set forth in the ICH guidelines and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by the European Union and other organizations and governmental agencies in countries in which the Product is intended to be sold to the extent such standards are not less stringent than United States Good Clinical Practice.

1.35 **"** Good Laboratory Practice " or " GLP " shall mean the current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, as amended from time to time, and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which the Product is intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.36 " Good Manufacturing Practices " or " GMP " shall mean current good manufacturing practices and standards as provided for (and as amended from time to time) in European Community Directive 91/356/EEC (Principles and Guidelines of Good Manufacturing Practice for Medicinal Products), subject to any arrangements, additions, or clarifications agreed in writing from time to time between the Parties.

1.37 " Governmental Authority " means any domestic or foreign entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, including any governmental authority, agency, department, board, commission, court, tribunal, judicial body or instrumentality of any union of nations, federation, nation, state, municipality, county, locality or other political subdivision thereof.

1.38 " Indication " shall mean an initial, expanded or additional patient population for which use of the Product is indicated, as reflected or to be reflected in the approved label for the Product.

1.39 " Initial Indication " shall mean extended adjuvant treatment of an 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 trastuzamab based therapy.

1.40 " Inventions " means any and all inventions (whether or not patentable), that are conceived during the term of this Agreement and in the course of activities conducted pursuant to this Agreement by one or more employees, Affiliates, sublicensees (including Sublicensees) or independent contractors of Licensor and/or Licensee.

1.41 " Investigator Sponsored Clinical Study " shall mean a Clinical Study of the Product that is sponsored and conducted by a physician, physician group or other Third Party not acting on behalf of a Party or its Affiliate or Sublicensee and who does not have a license from a Party or its Affiliate or Sublicensee to Commercialize such Product, pursuant to a CTA owned by such Third Party, and with respect to which a Party or its Affiliate or Sublicensee provides clinical supplies of the Product, funding or other support for such Clinical Study.

1.42 " Intellectual Property Rights " shall mean all Patents, trade secrets, copyrights, Trademarks, moral rights, Know-How and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

1.43 " Know-How " shall mean any invention, discovery, Data, information, process, method, technique, material (including any chemical or biological material), technology, result, cell line, compound, probe, sequence or other know-how, whether or not patentable.

1.44 " Law " shall mean any applicable national, supranational, federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any Governmental Authority, including any rules, regulations, guidelines, directives or other requirements of Regulatory Authorities, including all GMP, GLP and GCP, and including all laws pertaining to the pharmaceutical industry or the healthcare industry, anti-trust or competition laws and all anti-bribery or anti-corruption laws, as applicable.

1.45 " Licensed Intellectual Property " shall mean the Licensed Patents and the Licensed Technology.

1.46 " Licensed Patents " shall mean any and all Patents Controlled by the Licensor or its Affiliates, including the Patents licensed to the Licensor under the Background Agreements, as of the Effective Date or at any time during the term of this Agreement that:

(a) are listed in EXHIBIT 1 ; or

(b) but for the license granted under this Agreement, would be infringed by the Development, Manufacture, registration or Commercialization of the Product in the Field in the Licensee Territory, in each case (a) and (b), including all additions, divisions, continuations, continuations-in-part, substitutions, re-issues, re-examinations, registrations, patent term extensions, supplemental protection certificates, inventors' certificates, substitutions, extensions and renewals of any the Patents listed on EXHIBIT 1 and of the Patents that satisfy the requirements of subsection (b) above. For the avoidance of doubt, to the extent included in the foregoing, "Licensed Patent" shall:

(i) include any Patent claim that claims the composition of matter of, or any method of making or method of using, a Compound Combination, where a " Compound Combination " is the combination of the Compound together with any one or more Other Active Ingredients as a Combination Product;

(ii) exclude any Patent claim that solely claims any composition of matter of, or method of making or method of using, any Other Active Ingredient or the composition of matter of, or any method of making or method of using, any combination of active ingredients other than a Compound Combination; and

(iii) include any Patent claim that claims, generically, the composition of matter of or the method of making or method of using both the Compound and an Other Active Ingredient.

1.47 " Licensed Technology " shall mean all Know-How or other information that is Controlled by Licensor or its Affiliates, including Know-How licensed to Licensor under the Background Agreements as of the Effective Date, or at any time during the term of this Agreement, that is not generally known and is necessary or reasonably useful for the conduct of the Development, Manufacture, Commercialization and otherwise the exploitation of the Compound and the Product in accordance with this Agreement.

1.48 " Licensee Territory " shall mean Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom, Switzerland, Albania, Bosnia-Herzegovina, Croatia, Kosovo, Republic of Macedonia, Montenegro, Serbia, Tunisia, Algeria, Morocco, Western African Countries and any other countries as may be added from time to time pursuant to Article 2.6 or by mutual agreement.

1.49 " Licensor Territory " shall mean all countries of the world other than the Licensee Territory.

1.50 " Major Markets " mean [***].

1.51 " Manufacture " shall mean all activities related to the production of the Product and any drug substance produced in bulk form for use as an active pharmaceutical ingredient, drug product, compounded or finished final packaged and labelled form, and in intermediate states, in each case, to the extent used in the Product, and includes without limitation reference standard preparation, purification,

formulation, scale-up, packaging, disposition of product, quality assurance oversight, quality control testing (including in-process release and stability testing), storage of product or any component or ingredient thereof and validation activities directly related to all of the foregoing, and data management and recordkeeping related to all of the foregoing.

1.52 " Manufacturing Agreements " shall mean that [***].

1.53 " Manufacturing Standards " shall mean all applicable specifications, GMP and any requirements of any Regulatory Authority.

1.54 " Market Access " shall mean any and all processes and activities conducted to establish, seek and maintain national country pricing and reimbursement, including Pricing and Reimbursement Approval, as well as country level, regional and local payor processes and activities to obtain and maintain local and regional patient access for the Product, including price setting, national mandatory rebate negotiations with applicable Governmental Authorities and preparing reimbursement and economic dossiers.

1.55 " Marketing Approval " shall mean such approvals, licenses, registrations or authorizations granted, provided or otherwise issued by the applicable Regulatory Authority(ies) in a country, that are necessary to Commercialize the Product in such country. Marketing Approval shall not include Pricing and Reimbursement Approval.

1.56 " Marketing Approval Application " shall mean an application requesting Marketing Approval for the Commercialization of the Product for a particular Indication in a particular jurisdiction filed with the relevant Regulatory Authorities in such jurisdiction.

1.57 " Materials " shall have the meaning set forth in Article 8.1(a) .

1.58 " Material Agreements " shall mean the Background Agreements and the Manufacturing Agreements.

1.59 [***].

1.60 " Net Sales " means the gross amount invoiced by or on behalf of Licensee, its Affiliates and their respective Sublicensees for sales of the Product in the Licensee Territory (other than sales among Licensee, its Affiliates or Sublicensees for subsequent resale in which case the first sale to a Third Party that is not a Sublicensee shall be used for calculation of Net Sales), less the following deductions if and to the extent they are (i) included in the gross invoiced sales price of the Product or otherwise directly incurred by Licensee, its Affiliates and their respective Sublicensees with respect to the sale of the Product, (ii) normal and customary for Licensee, its Affiliates or their respective Sublicensees as applicable, and (iii) not otherwise deducted in computing other amounts hereunder:

(a) rebates, quantity and cash discounts, and other discounts to customers,

(b) taxes (except income taxes) and tariffs or duties paid, absorbed or allowed which are directly related to the sale or promotion of the Product,

(c) credits, allowances, discounts and rebates to, and chargebacks for, spoiled, damaged, out-dated, rejected or returned Product (including in connection with Product withdrawals, expired Product and Product recalls),

(d) actual freight and insurance costs, including without limitation the costs of export licenses, shipping, postage and handling charges, incurred in transporting the Product to customers,

(e) discounts or rebates or other payments required by Law, including any governmental special medical assistance programs . For clarity, the foregoing shall [***] ,

(f) customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of the Product, and

(g) bad debts actually written off in connection with the Product.

In the case of any sale of the Product which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the Product is paid for, if paid for before shipment or invoice. In the case of any sale or other disposal of the Product for non-cash consideration, Net Sales shall be calculated as the fair market price of the Product in the country of sale or disposal. Notwithstanding the foregoing, provision of the Product for the purpose of conducting pre-clinical or clinical research shall not be deemed to be a sale. For clarity, any consideration received for the Product provided as free samples, as charitable donations, or for compassionate use shall not be included in the calculation of Net Sales.

Net Sales shall be determined in accordance with GAAP.

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

(i) If the 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 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 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 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 Compound contained in the Combination Product in such country, but the average gross selling price of such 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 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 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.

1.61 " Non-Encumbered Territory " means, with respect to any right granted by Licensor to Licensee hereunder, any country for which Licensor is not prevented, prohibited or inhibited by any Third Party agreement, entered into before or after the Effective Date, from granting that right, provided that the Non-Encumbered Territory shall in any event be deemed to include [***] .

1.62 " Option Territory " shall mean [***].

1.63 " Other Active Ingredient " means any therapeutically active pharmaceutical ingredient other than the Compound.

1.64 " Out-of-Pocket Costs " means reasonable amounts actually paid to Third Party vendors, consultants, suppliers or contractors, for services or materials, as applicable, provided by each such Third Party that is directly related to the Shared Clinical Trial or the Post-Approval Marketing Study, as applicable, to the extent such services or materials apply to the activities contemplated in this Agreement. For clarity, Out-of-Pocket Costs do not include payments for a Party's internal salaries or benefits for its employees; facilities (including leased facilities); utilities; general office or facility supplies; insurance; information technology, capital expenditures or the like; or items included in the determination of the FTE Rate.

1.65 " Party " shall mean Licensor or Licensee, individually; and " Parties " shall mean Licensor and Licensee, collectively.

1.66 " Patent(s) " shall mean (a) unexpired patents (including without limitation inventor's certificates), including without limitation any substitution, extension, registration, confirmation, reissue, re-examination, addition, renewal, supplemental protection certificate, or inventor's certificate, and (b) pending applications for patents, including without limitation any continuation, divisional, or continuation-in-part thereof, and any provisional or nonprovisional applications, and (c) all foreign or international equivalents of any of the foregoing in any country.

1.67 " Person " shall mean an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.68 " Personal Data ", " Process ", " Processed " and " Processing " will be construed in accordance with the GDPR.

1.69 " Pfizer License Agreement " shall mean the license agreement between Licensor and Pfizer Inc. (" Pfizer "), dated August 18, 2011 as amended by amendment n°1 dated July 18, 2014, pursuant to which, among other rights, Licensor received an exclusive, worldwide license with the right to grant sublicenses to develop and to commercialize the Compound.

1.70 " Post Regulatory Approval Study " (" PRAS ") means any Clinical Study sponsored by a Party, or any Investigator Sponsored Clinical Study (whether conducted as a phase I, II, III or IV clinical trial, as applicable) that is conducted after a Marketing Approval other than with the objective to seek an extension of the indication or label of the Marketing Approval, but excluding Post-Approval Marketing Studies.

1.71 " Post-Approval Marketing Study " means any non-clinical study or Clinical Study (other than PRAS) that is conducted as a commitment made to a Regulatory Authority as a condition of, or in connection with obtaining or maintaining, a Marketing Approval. Currently contemplated Post-Approval Marketing Studies are set forth in EXHIBIT 4 .

1.72 " Post-Approval Marketing Study Costs " shall mean FTE Costs and Out-of-Pocket Costs directly related to Post-Approval Marketing Studies conducted in accordance with Article 4.1(b) .

1.73 " Pricing and Reimbursement Approval " shall mean, with respect to any country or jurisdiction in the Licensee Territory in which one or more Governmental Authorities determine the pricing at which the Product will be reimbursed by public and/or private payors, the approval, agreement, determination or decision by such applicable Governmental Authority(ies) establishing the pricing and reimbursement status for such Product.

1.74 " Product " shall mean any product containing, as an active ingredient, the Compound. For the avoidance of doubt, each product containing the Compound irrespective of its dosage, formulation or indication shall be deemed to be the same Product.

1.75 " Product Trademarks " shall mean: (a) the product-specific Trademarks owned or Controlled by Licensor and designated by Licensor for use with the Product in the Licensee Territory, as reflected on EXHIBIT 5 ; and (b) any other product-specific Trademark(s) Controlled by Licensee in connection with the distribution, marketing, promotion and sale of the Product in the Licensee Territory, or accompanying logos, trade dress or indicia of origin.

1.76 " Regulatory Authority " shall means any governmental agency or authority responsible for granting Regulatory Filings for the Product.

1.77 " Regulatory Filing " shall mean, with respect to the Product, all approvals, licenses, registrations, submissions and authorizations made to or received from a Regulatory Authority in a jurisdiction necessary for or in connection with the development, manufacture and/or commercialization of a pharmaceutical product, including any CTAs, Marketing Approval Applications, Marketing Approvals, and Pricing and Reimbursement Approvals.

1.78 " Royalty Bearing Net Sales " shall mean the Net Sales generated in any given country of the Licensee Territory during the Royalty Term in such country.

1.79 " Royalty Term " shall mean, on country -by -country basis within the Licensee Territory, the period beginning on the date of the First Commercial Sale of the Product in such country and expiring upon the later of: (a) expiration or abandonment of the last Valid Claim of the Licensed Patents which Covers the Use of the Product Commercialized in such country and (b) the earlier of: (i) the time when Generic Competitors to the Product have achieved [***] percent ([***]%) or more market share in such country based on unit volume, and (ii) [***] years following the date of First Commercial Sale of the Product in such country. [***] percent ([***]%) or more market share means that the sales of all such Generic Competitors in such country equal or exceed, on a unit volume basis, [***] percent ([***]%) of the total combined unit sales of the Product and all such Generic Competitors in any Calendar Quarter.

1.80 " Senior Executives " shall mean the Chief Executive Officers of each of Licensee and Licensor.

1.81 " Shared Clinical Trial " shall have the meaning set forth in Article 4.3(c) .

1.82 " Shared Clinical Trial Costs " shall mean FTE Costs and Out-of-Pocket Costs directly related to Shared Clinical Trials conducted in accordance with this Agreement.

1.83 " Shared Development Budget " shall have the meaning set forth in Article 4.3(c) .

1.84 " Subcontractor " shall mean any Third Party to which a Party or its Affiliate may subcontract the performance of any activities undertaken in accordance with this Agreement in accordance with Article 17.9.

1.85 " Sublicensee " shall mean a Third Party that has been granted a right to sell, market, distribute and/or promote the Product in the Field and in the Licensee Territory pursuant to Article 2.3; and " Sublicense " shall mean an agreement or arrangement granting any such rights. As used in this Agreement, " Sublicensee " shall not include a wholesaler, distributor or reseller of such Product, to the extent that Licensee or its Affiliate sells to such Person the Product at only supply prices .

1.86 " Supply Agreement " shall have the meaning set forth in Article 8.2.

1.87 " Third Party " shall mean any person, corporation, joint venture or other entity, other than Licensor, Licensee and their respective Affiliates.

1.88 " Third Party Manufacturer " shall mean one or more Third Party manufacturers engaged by Licensor in connection with the Manufacture of the applicable Materials, including, [***].

1.89 " Trademark " shall mean any registered or unregistered trademark, service mark, trade dress, trade name, logo, insignia, domain name, symbol, design, or combinations thereof

1.90 " Transferred Data " shall mean any Data transferred, disclosed or provided by a Party to the other Party pursuant to this Agreement.

1.91 " Transition Plan " shall mean a transition plan established between Licensor and Licensee in order to transition in a smooth and efficient manner the ongoing activities currently handled by Licensor with respect to the Licensee Territory, including but not limited to [***]. The Transition Plan detailing each Party's responsibility for each activity and timelines is attached hereto as EXHIBIT 2 . In the event of any conflict between the Transition Plan and the terms of this Agreement, the terms of this Agreement shall govern.

1.92 " Use " means to Develop, Manufacture, Commercialize, use, sell, have sold, offer for sale, have offered for sale, import, and export.

1.93 " Valid Claim " shall mean (i) a claim of an issued and unexpired patent included within the Licensed Patents, which has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction, or (ii) a claim of a pending patent application included within the Licensed Patents which claim was filed in good faith, has not been pending for more than [***] ([***]) years from the priority date, and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

1.94 " Western African Countries " shall mean Burundi, Republic of the Congo (Brazzaville), Benin, Burkina Faso, Cameroon, Chad, Democratic Republic of the Congo, Ivory Coast, Gabon, Guinea, Libya, Madagascar, Mali, Mauritania, Mauritius, Niger, Senegal, Togo, Djibouti and Central African Republic.

ARTICLE II
GRANT OF LICENSE

2.1 License . Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee and its Affiliates an exclusive (even as to Licensor and its Affiliates), royalty bearing license under the Licensed Intellectual Property, with the right to sublicense (subject to Article 2.3) through multiple tiers:

(a) to Develop the Product in the Licensee Territory and any Non-Encumbered Territory for Commercialization of the Product in the Licensee Territory in the Field; and

(b) to Manufacture, or have Manufactured, Materials in or outside the Licensee Territory solely for Commercialization of the Product in the Licensee Territory in the Field in accordance with this Agreement and the Supply Agreement; and

(c) to seek approval of Regulatory Filings and Commercialize of the Product in the Licensee Territory in the Field.

2.2 Pfizer License Agreement . For clarity, Licensed Intellectual Property includes all Intellectual Property Rights licensed to Licensor under the Pfizer License Agreement, including any rights licensed to Licensor through the Pfizer License Agreement as a result of the sub-license provided for therein to Licensor of Pfizer's rights under the GHC License Agreement, to the extent claiming or constituting technology or inventions reasonably necessary or useful for the Development, Manufacture or Commercialization of the Product in the Licensee Territory. [***] . Licensor represents and warrants that the provisions provided under Schedule 2.2 as well as the other provisions included in this Agreement constitute all material obligations resulting from the Pfizer License Agreement which may materially impact Licensee's rights and obligations with respect to the Product as provided under this Agreement. For the avoidance of doubt, pursuant to the Pfizer License Agreement, Licensee acknowledges that Licensor will furnish to Pfizer a true and complete copy of this Agreement and any current and future amendments hereto in accordance with Article 9.4(b). To the extent reasonably requested by Licensor from time-to-time, Licensee will take reasonable steps to support Licensor's compliance with obligations under the Pfizer License Agreement that have been disclosed to Licensee prior to execution of this Agreement and provided that Licensee shall not be required to incur [***].

2.3 Sublicense . Licensee may sublicense the rights granted to it by Licensor under this Agreement to any of its Affiliates without notice to Licensor, and to any Third Party with Licensor's prior written consent, which shall not be unreasonably withheld or delayed, provided that any Third Party Sublicensee shall have the necessary financial, regulatory and technical capacity to carry out the portion of Licensee's obligations under this Agreement sublicensed to such Third Party, and further provided that if a Sublicense is granted to an Affiliate pursuant to the foregoing and such Affiliate becomes a non-Affiliate during the term of any such Sublicense, Licensee shall provide prompt written notice to Licensor of such change of such Sublicensee's status to non-Affiliate and such non-Affiliate shall only be permitted to continue performance under the applicable Sublicense if approved in writing by Licensor, such approval not to be unreasonably withheld. Any and all Sublicenses shall be subject to the following requirements:

(a) All Sublicenses shall be subject to and consistent with the terms and conditions of this Agreement. In no event shall any Sublicense relieve Licensee of any of its obligations under this Agreement.

(b) Licensee shall furnish to Licensor a true and complete copy of each Sublicense agreement entered into with a Third Party and each amendment thereto, which Sublicense agreement may be redacted to omit information not directly relevant to the performance of Licensee's obligations under this Agreement, within [***] ([***]) days after the Sublicense or amendment has been executed.

(c) Any Sublicense of the rights granted to a Sublicensee under this Article 2.3 shall be granted only in connection with a Sublicense of the rights granted to Licensee under Article 2.1.

2.4 Retained Rights .

(a) Licensee acknowledges and agrees that notwithstanding the exclusive rights granted to Licensee, Licensor retains the following rights:

(i) to conduct, as the sponsor, those Ongoing Clinical Studies identified in EXHIBIT 3 and any Post-Approval Marketing Studies described in Article 4.1(b), each in the Licensee Territory; and

(ii) to Manufacture or have Manufactured, or Develop or have Developed subject to Article 4.3, the Compound or the Product in the Licensee Territory for Commercialization of the Product by or on behalf of Licensor, its Affiliates or licensees in the Licensor Territory, or for Commercialization by or on behalf of Licensee in the Licensee Territory.

(b) Licensee acknowledges and agrees that Pfizer (i) retains the right for itself and its affiliates to make, have made, use, have used, import and export the Product for all research purposes and (ii) may use for any purpose (other than the Development, Manufacture or Commercialization of the Compound or the Product during the term of this Agreement) the Residuals resulting from Pfizer's access to or work with the Product related Know-How. As used herein, " Residuals " means information in non-tangible form which may be retained by persons who have had access to the Product or Know-How, including information relating to ideas, concepts, know-how or techniques.

2.5 Transfer of Licensed Technology .

(a) Initial Transfer. Licensor or its Affiliates will make available to Licensee all Licensed Technology as Licensee may reasonably request that exists as of the Effective Date in accordance with the Transition Plan, provided, the Data and such other documents set forth under the Transition Plan

shall be made available by Licensor to Licensee within the time set forth in the Transition Plan, but in any event no later than [***] ([***]) days from the Effective Date. Licensor shall implement the Transition Plan, including providing reasonable assistance to Licensee, to ensure an effective transfer of the Licensed Technology.

(b) Subsequent Transfers. During the term of the Agreement, Licensor shall promptly deliver any and all Licensed Technology, together with supporting documentation as each may become Controlled by Licensor, and provide reasonable assistance to Licensee which is necessary or reasonably useful for Licensee to Develop, Commercialize the Product in the Field and the Licensee Territory, provided, however that with respect to Licensed Technology that is not feasible for Licensor to deliver to Licensee in accordance with this Article 2.5(b), the Parties shall cooperate to enable Licensee to access such Licensed Technology in another manner, including by enabling Licensee to visit Licensor's facilities for such access or engage Licensor to perform analyses on such Licensed Technology on Licensee's behalf.

2.6 Right of First Negotiation in the Option Territory . [***].

2.7 Activities Outside the Respective Territory .

(a) Licensee covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate its licensees, Sublicensees and contractors [***].

(b) Licensor covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate its licensees, Sublicensees and contractors not to, [***].

2.8 No Other Rights . Except for the rights and licenses expressly granted in this Agreement, each Party retains all rights under its Intellectual Property Rights, and no additional rights shall be deemed granted to the other Party by implication, estoppel or otherwise.

ARTICLE III
GOVERNANCE

3.1 Joint Steering Committee .

(a) Duties . Within [***] ([***]) days following the Effective Date, Licensor and Licensee shall establish a joint steering committee (" Joint Steering Committee " or " JSC "). The Joint Steering Committee shall perform the functions and assume the responsibilities and have such authority only as set forth in this Agreement. The Joint Steering Committee shall have the following duties:

(i) Be responsible, directly or through Working Groups, for the overall coordination, follow-up, and oversight of the Transition Plan, the Ongoing Clinical Studies and the Post-Approval Marketing Studies, including (x) providing general oversight to the conduct of such Clinical Studies, (y) reviewing and approving any Regulatory Filings related to such Clinical Studies, and any amendments to such clinical plans and (z) overseeing data analysis and Clinical Studies completion activities related thereto;

(ii) Review and approve substantive amendments and updates with respect to any Shared Clinical Trial, including to the Shared Development Budget;

(iii) Review proposed study protocols and substantive amendments and updates in connection with Additional Clinical Studies in accordance with Article 4.3(a) ;

(iv) Be informed on a periodic basis of the Investigator Sponsored Clinical Study and PRAS authorized or supported by either Party in the Licensee Territory and the Non-Encumbered Territory, as applicable;

(v) Provide a forum of exchange and discussion with respect to regulatory and Market Access strategies, marketing and promotional activities, Patent and manufacturing strategies for the Product in the Licensee Territory and the Non-Encumbered Territory, as applicable; and

(vi) Perform such other duties as are specifically assigned to the JSC in accordance with this Agreement.

(b) Membership . The JSC shall each be composed of an equal number of representatives from each of Licensee and Licensor, selected by such Party. Unless the Parties otherwise agree, the exact number of representatives for each of Licensee and Licensor shall be three (3) representatives, each of whom shall be at a level which allows him/her to make decisions on behalf of the Party he/she represent with respect to the relevant matters. Either Party may replace its respective JSC representatives at any time with prior written notice to the other Party; provided that the criteria for composition of the JSC set forth in the preceding sentence continues to be satisfied following any such replacement of a Party's representative on any such Committee.

(c) Committee Meetings . The JSC shall meet at least twice each Calendar Year, or more or less often as otherwise agreed to by the Parties, provided that it shall meet within [***] ([***]) days after the formation of the JSC in accordance with Article 3.1(a) . JSC meetings may be conducted by telephone, video-conference or in person as determined by its members; provided that the JSC shall hold its first meeting in person at least once each Calendar Year. Unless otherwise agreed by the Parties, all in-person meetings of JSC shall be held on an alternating basis between Licensor's facilities and Licensee's facilities. [***]. With the consent of the Parties (not to be withheld unreasonably), other employee representatives of the Parties may attend any JSC meeting as non-voting observers at such Party's sole cost and expense.

(d) Decision -Making . Matters for which approval of the JSC is expressly required herein (i.e., pursuant to Articles 3.1(a)(i) and (ii)) shall be decided by unanimous vote, with at least one (1) representative from each Party participating in any vote. In the event that the JSC fails to reach unanimous agreement with respect to such matter for which approval of the JSC is expressly required herein , then either Party may, by written notice to the other Party, have such matter referred to the Senior Executives, who shall meet promptly and negotiate in good faith pursuant to Article 16.1 . If despite such good faith efforts, the Senior Executives are unable to resolve such dispute, then:

(i) if such dispute relates to substantive amendments and updates with respect to a Shared Clinical Trial or Post-Approval Marketing Study, all changes shall require mutual consent of the Parties, provided that no such consent shall be unreasonably withheld or delayed if the change is required to comply with any request of a Regulatory Authority, including the EMA or other Regulatory Authority in the Licensee Territory;

(ii) if such dispute relates to [***], Licensor shall be entitled to make the final determination, provided that such determination is not likely to have a material adverse impact [***]; or

(iii) if such dispute relates to the [***], Licensee shall be entitled to make the final determination, provided that such determination does not create a material obligation on [***] .

3.2 Working Groups .

(a) Establishment . From time to time, the JSC may establish and delegate duties to sub-committees or teams (each, a " Working Group ") to oversee particular projects or activities within their respective authority. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to the JSC. A Working Group shall be composed of an equal number of representatives from each of Licensor and Licensee, selected by such Party, and the total number of members of each Working Group will be determined by the JSC. Each Working Group shall meet at such times and in such places as directed by the JSC. In no event shall the authority of any Working Group exceed that specified for the JSC, as set forth in this Article 3 .

(b) Specific Working Groups . The Parties already agree to form the following Working Groups :

(i) a transition Working Group which will monitor and coordinate the conduct of the Transition Plan, including the transfer of the supply chain in accordance with Article 8.4;

(ii) a Working Group which will monitor and coordinate Patent strategies and prosecution, defense and enforcement procedures set out in Article 10 ;

(iii) a Working Group which will monitor and coordinate Development and regulatory activities in accordance with Article 4 ;

(iv) a Working Group which will monitor and coordinate the publication and communication strategy on the Product in accordance with Article 9.5 and which will establish an annual publication plan for submission to the JSC; and

(v) a Manufacturing and supply Working Group which will monitor and coordinate the Manufacture, supply and quality of the applicable Materials supplied to by each Party to the other Party in accordance with the applicable supply agreement and the quality agreement to ensure a continuous and reliable supply on a cost effective basis.

3.3 Alliance Managers . Within [***] ([***]) days following the Effective Date, each Party shall appoint a representative (" Alliance Manager ") to facilitate communications between the Parties (including, coordinating the exchange of Know-How of each Party as required under this Agreement) and to act as a liaison between the Parties with respect to such other matters as the Parties may mutually agree in order to maximize the efficiency of the collaboration. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Each Party's Alliance Managers shall be entitled to attend all JSC and Working Group meetings , as applicable, except if the other Party specifically requests the exclusion of Alliance Managers (including its own Alliance Managers) from a particular meeting. Each Alliance Manager may bring any matter to the attention of the JSC where such Alliance Manager reasonably believes that such matter requires attention of the JSC. Each Alliance Manager shall be responsible with creating and maintaining a collaborative work environment within the JSC. For clarity, an Alliance Manager may also be a member of the JSC and/or one or more Working Groups.

3.4 Scope of Governance . Notwithstanding the creation of the JSC and/or any Working Group, each Party shall retain the rights, powers and discretion granted to it hereunder, and neither JSC nor any Working Group shall be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly do so agree in writing. Neither JSC nor any Working Group shall have the power to amend or modify this Agreement, and their decisions shall not be in contravention of any terms and conditions of this Agreement. The Alliance Managers shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder and in no event shall the Alliance Managers have any power to modify or amend this Agreement. It is understood and agreed that issues to be formally decided by the JSC are only those specific issues that are expressly provided in this Agreement to be decided by the JSC.

3.5 Cost of Governance . The Parties agree that the costs incurred by each Party in connection with its participation at any meetings under this Article 3 shall be borne [***].

ARTICLE IV
DEVELOPMENT AND REGULATORY ACTIVITIES

4.1 Current Development Status .

(a) Ongoing Clinical Studies . [***] shall remain responsible for and shall complete [***] all ongoing Clinical Studies as of the Effective Date that are listed in EXHIBIT 3, including all analysis and reports that are reasonably necessary to obtain, extend or update the Marketing Authorization of the Product with the EMA, and shall remain responsible for contracting with and managing any Third Party that may be involved with such Clinical Studies (each, an " Ongoing Clinical Study ").

(b) Post-Approval Marketing Studies . In the event one or more Regulatory Authorities in the Licensee Territory, including the EMA, require [***] to conduct one or more Post-Approval Marketing Studies for the Product in the Indication(s) in which [***] acted as the sponsor of an Ongoing Clinical Study, then [***] shall pay for the Post-Approval Marketing Study Costs for such Post-Approval Marketing Study. Without limiting the foregoing, the sponsorship and the responsibility for conducting, as the sponsor, the following Post-Approval Marketing Studies shall be the responsibility of the following Party:

(i) [***]: The Clinical Studies designated as [***] and [***]; and

(ii) [***]: The Clinical Study designated as [***], provided that if [***] intends to subcontract the performance of [***] in [***], [***] shall consider [***] as a preferred partner to conduct such Clinical Study, and if [***] at its sole discretion selects [***] as such subcontractor, [***] shall be conducted [***].

(c) [***] shall reimburse [***] for all Post-Approval Marketing Study Costs incurred by Licensee for the conduct of such Post-Approval Marketing Studies pursuant to Article 4.1(b)(i), [***] , provided that in the event that any amounts are incurred in connection with such Post-Approval Marketing Studies in excess of such amount that arise from any circumstances arising beyond [***] reasonable control (including additional Regulatory Authorities' requirements), the Parties shall discuss in good faith on how to mitigate such excess amount, provided that [***].

4.2 Rights of Reference and Access to Data .

(a) Subject to Article 4.3 below, each Party shall have the right to cross-reference the Regulatory Filings Controlled by the other Party during the term of this Agreement that relates to the Product (including each other's, and their Affiliate's or Subcontractor's DMF), and to access such Regulatory Filings and any Data for the sole purpose of the performance of its obligations and exercise of its rights under this Agreement, including inclusion of such Data in its own Regulatory Filings for the Product; provided, however, that (i) with respect to Data obtained from new Clinical Studies conducted at the other Party's expense in accordance with Article 4.3 , the non-funding Party's right to cross-reference, or to include such Data in its Regulatory Filings for the Product, shall be subject to compliance with the corresponding reimbursement obligation set forth in that Article, and (ii) the definition of " Data " shall not include the closed portions of any DMF, nor any information contained in any such portions of a DMF and, notwithstanding any other provision of this Agreement, neither Party shall have any obligation to disclose to the other Party, or any of its Affiliates or Sublicensees, the closed portions of such DMFs or any information contained therein, but shall provide to the other Party all necessary or useful Right of Reference to such closed portion. Subject to Article 4.3 below, each Party hereby grants to the other Party, its Affiliates and Sublicensees, a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other country or region, to any Data, including such Party's or its Affiliate's clinical dossiers, Controlled by such Party or such Affiliates that relates to the Product for the sole purpose of the performance of its obligations and exercise of its rights under this Agreement, subject to the limitations set forth in this Article 4.2(a) . With respect to any country within the Non-Encumbered Territory, if during the term of this Agreement, one or more of such countries become an Encumbered Territory, Licensor shall structure any agreement with a Third Party that renders such country(ies) to be an Encumbered Territory so that Licensee has continued access and right to any Data generated with respect to the Product in such country(ies) while it was a Non-Encumbered Territory and for which Licensee had a right under this Article 4.2(a) prior to such country(ies) becoming an Encumbered Territory.

(b) Each Party or its Affiliates shall provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any country or region or otherwise provide appropriate notification of such right of the other Party to the applicable Regulatory Authority. Each Party will provide, and cause its Affiliates to provide, cooperation to the other Party to effect the foregoing.

4.3 New Clinical Trials .

(a) In the event a Party (the " Additional Development Party ") proposes to perform a Clinical Study (other than a PRAS) (any such Clinical Study, an " Additional Clinical Study ") of the Product in the Field as a sponsor, it shall provide the other Party (" non-Additional Development Party ") an opportunity to review a proposed study protocol and related budget to such protocol (together, the " Protocol ") as well as the publication plan in accordance with Article 9.5 , if available, through the JSC, provided, however, that with respect to Licensor, this Article 4.3 shall only apply to those Clinical Studies that are being conducted or proposed to be conducted in the Non-Encumbered Territory, unless Licensor, in its sole discretion, offers to Licensee the opportunity to participate in such Clinical Studies.

(b) The non-Additional Development Party shall have [***] ([***]) days upon receipt of the Protocol to elect whether to participate in such Additional Clinical Study.

(c) In the event the non-Additional Development Party provides a written notice to the Additional Development Party within such [***] ([***])-day period expressing its intent to participate in the Additional Clinical Study by establishing Clinical Study sites for such study within its respective

territory, then such Additional Clinical Study will be designated as a shared Clinical Study (" Shared Clinical Trial "). Within [***] ([***]) days after such election by such non-Additional Development Party to participate, the Parties will discuss and agree to a budget related to such Shared Clinical Trial (the " Shared Development Budget "). Licensee shall bear [***] ([***]) of the costs of the applicable Shared Development Budget and Licensor shall bear [***] ([***]) of the applicable Shared Development Budget.

(d) If the non-Additional Development Party declines to participate in the Additional Clinical Study, either expressly or by failing to provide the written notice within the [***] ([***])-day period as provided under Article 4.3(c) , then the Additional Development Party shall be free to conduct such Additional Clinical Study at its sole cost and expense, by itself or with or through a Third Party within its respective territory.

(e) If upon completion of an Additional Clinical Study by the Additional Development Party, the non-Additional Development Party wishes to use any Data arising out of such Additional Clinical Study in a substantive manner by filing the same with a Regulatory Authority (either directly or by reference) in the non-Additional Development Party's territory as the basis for obtaining new or expanded Marketing Approval for the Product for the same Indication that was the subject of such Additional Clinical Study, the non-Additional Development Party shall [***].

(f) Notwithstanding anything to the contrary herein, no payments shall be required to use (i) the safety Data arising out of any Additional Clinical Study, which shall be available to both Parties at all times free of charge in accordance with the Safety Data Exchange Agreement, or (ii) by Licensee of the Data arising out of any Post-Approval Marketing Studies that are described in Article 4.1(b) .

(g) In the event either Party undertakes new Development activities comprising material non-Clinical Studies of the Product, the Parties will apply the sharing and reimbursement principles set forth in Articles 4.3(c) and (e) above should the other Party wish to use such Data and such Data is Controlled by the Party conducting such new Development activities, provided, with respect to such Data Controlled by Licensor, this Article 4.3 shall only apply to those non-Clinical Study Data that are being conducted or proposed to be conducted in the Non-Encumbered Territory, unless Licensor, in its sole discretion, offers to Licensee the opportunity to use such non-Clinical Studies in accordance with this Article 4.3(g) .

(h) For the avoidance of doubt, if Licensee does not elect to use the Data from any new Development activities, such election shall not in and of itself be deemed in breach of its Commercially Reasonable Efforts obligations pursuant to this Agreement.

(i) Prior to the commencement of each Shared Clinical Trial, the JSC shall define the common database format to be used, the owner of such database, the access of the other Party to the database, the relevant clinical information to be contained within, in a manner designed to address both FDA and EMA requirements, and whether any amendment or addendum to this Agreement is required in accordance with Article 9.26 to ensure the Parties' compliance with Data Protection Law in relation to any Processing of Personal Data by or on behalf of the Parties as joint controllers in connection with such Shared Clinical Study.

(j) Generally, for purposes of the above, each Party shall calculate and maintain records of any Shared Clinical Trial Costs incurred by such Party and its Affiliates in accordance with procedures to be established by the JSC. The procedures for reporting of actual results, review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to such Shared Clinical Trial Costs will be determined by the JSC. Such procedures will provide the ability to comply with financial reporting requirements of each Party.

4.4 Notwithstanding anything to the contrary in this Agreement, neither Party shall initiate after the Effective Date an Additional Clinical Study or a PRAS within the other Party's territory (i.e., Licensee in the Licensor Territory or Licensor in the Licensee Territory) or authorize or contribute to any Investigator Sponsored Clinical Study within the other Party's territory, in each case, without the prior written approval of the other Party to be given in its sole discretion. Licensor represents and warrants that Exhibit 3 contains an exhaustive list of all Ongoing Clinical Studies, Investigator Sponsored Clinical Study or other Clinical Studies that Licensor has initiated as of the Effective Date in the Licensee Territory.

4.5 Development Efforts; Manner of Performance; Reports .

(a) Development Efforts . Each Party and its Affiliates shall conduct its Development activities for the Product in the Field in good scientific manner and in compliance with applicable Law, including Laws regarding environmental, safety and industrial hygiene, Good Manufacturing Practice, Good Laboratory Practice and Good Clinical Practice, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects such as Data Protection Law.

(b) Day-to-Day Responsibility . Each Party shall be responsible for the day-to-day implementation of the Development activities of the Product in the Field and shall keep the other Party reasonably informed as to the progress of such activities.

(c) Development Reports . At each meeting of the JSC, each Party will report on its Development activities of the Product in the Field that such Party and its Affiliates has performed or caused to be performed since the last meeting of the JSC, and evaluate the work performed with respect to any Ongoing Clinical Studies, and Post-Approval Marketing Studies, and provide such other information as may be reasonably requested by the JSC with respect to such Development activities.

(d) Compliance Audits . With respect to any facility or site at which a Party, its Affiliates or its Subcontractor conducts Development activities pursuant to this Agreement, the other Party shall have the right, [***], upon reasonable written notice to such Party (and if applicable, such Affiliate or as described below, Subcontractor), and during normal business hours, to inspect such site and facility and any records relating thereto once per year, or more often with cause, to verify such Party's compliance with the terms of this Agreement relating to all applicable Laws, including Good Manufacturing Practice, Good Laboratory Practices, Good Clinical Practices and current standards for pharmacovigilance practice. Such inspection shall be subject to the confidentiality provisions set forth in Article 9 . With respect to Licensor, prior to initiation of the transfer of Licensed Technology in connection with the Materials to Licensee in accordance with Article 8.4, Licensor shall have the right, [***], upon reasonable written notice to Licensee and/or its Affiliates, as applicable, and during normal business hours, to inspect such site and facility and any records relating thereto to verify Licensee's and/or its Affiliate's compliance with all applicable Laws with respect to any facility or site at which Licensee and/or its Affiliates intends to conduct Manufacturing activities pursuant to this Agreement. Each Party agrees to use commercially reasonable efforts to include in any contract or other written arrangement with its Subcontractors a clause permitting the other Party to exercise its rights under this Article 4.5(d) . In the event a Party is unable to secure such inspection rights from any of its Subcontractors, such Party agrees to secure such rights for itself and, if requested by the other Party , shall exercise such rights, [***], on behalf of the other Party and fully report the results thereof to the other Party . If Licensee desires to conduct such an audit of Licensor's manufacturing Subcontractors, the Parties will reasonably cooperate to minimize the number of separate audits being conducted by Licensor of such Subcontractor by, for example, allowing Licensee to participate in an audit being conducted for Licensor or one of its other licensees.

(e) Quality Assurance Audits . Licensee's quality assurance department will be responsible for establishing audit plans for the Development activities assigned to Licensee with respect to any Shared Clinical Trial, and Post- Approval Marketing Studies according to Licensee's internal SOP. Licensor's quality assurance department will be responsible for establishing audit plans for the Development activities assigned to Licensor with respect to any Shared Clinical Trial, ongoing Clinical Trials and Post-Approval Marketing Studies according to Licensor's internal SOP. The JSC shall form a joint Oversight/Quality Working Group (the " Oversight/Quality Working Group ") and such Oversight/Quality Working Group may review and provide comments on the audit plans established by Licensee's and Licensor's quality assurance personnel. Licensee's and Licensor's quality assurance personnel will each consider in good faith all such comments submitted by the Oversight/Quality Working Group, but Licensee's and Licensor's quality assurance personnel shall each have final decision-making authority with respect to the audit plans it develops.

(f) If Licensor is conducting any activities that could be deemed to fall within the scope of this Article 4.5 with or through its Third Party licensees in the Encumbered Territory, such Third Party licensees and their subcontractors shall not be deemed to be Subcontractors of Licensor, and , except as set forth in Article 4.2 , the foregoing provisions of this Article 4.5 shall not apply to any activities conducted by, or Data or other Know-How controlled or owned by, such Third Party licensee unless and until Licensor, in its sole discretion, agrees to extend this Article 4.5 thereto and Licensee agrees in writing to do so.

4.6 Submissions and Marketing Approvals .

(a) Regulatory Responsibilities . Licensor shall transfer to Licensee or its Affiliates all Regulatory Filings and Marketing Approvals for the Product in the Field in the Licensee Territory existing as of the Effective Date and thereafter during the term of this Agreement, as applicable for Shared Clinical Trials, in accordance with the terms of this Agreement and the Transition Plan, subject to subclause (c) below. Before the transfer of the applicable Marketing Authorization in the Licensee Territory to Licensee, Licensor shall (i) not take or omit to take any material action or make any material communication with respect to any Regulatory Filings or such Marketing Authorization for the Product in the Licensee Territory without Licensee's prior written consent and (ii) promptly transmit to Licensee any communication received from or draft of any planned communication or submission to the Regulatory Authorities with respect to any such Marketing Authorization.

(b) Ownership of Marketing Approvals . Upon completion of the Transition Plan and subject to Article 4.6(a) with respect to Ongoing Clinical Studies and Post-Approval Marketing Studies to be sponsored by Licensor in accordance with Article 4.1(b) , Licensee or its Affiliates (or if required by applicable Law, its Sublicensees) shall own all regulatory submissions, including all applications, for Marketing Approvals for the Product in the Field in the Licensee Territory.

(c) CTAs and Temporary Use Authorizations .

(i) Each Party shall own the CTAs of the Clinical Studies for which it is the sponsor. With respect to any Ongoing Clinical Studies or Post-Approval Marketing Studies to be performed in accordance with Article 4.1(b) , the Parties and their Affiliates shall cooperate fully so that the Party which is the sponsor of such Ongoing Clinical Study or Post-Approval Marketing Study, as applicable, in the Licensee Territory, may make the necessary and appropriate Regulatory Filings and submissions and undertaking such regulatory interactions.

(ii) Licensor shall maintain named patient, temporary use, or similar programs, Regulatory Filings or approvals, for the Product as existing on or prior to the Effective Date in each country of the Licensee Territory and supply all Product requirements thereunder, [***], in consultation with Licensee, provided that no named patient, temporary use, or similar program shall be initiated by Licensor after the transfer of the Marketing Authorization to Licensee.

(d) Regulatory Cooperation . The JSC shall review the overall regulatory strategy and positioning for the Product in the Licensee Territory and the Non-Encumbered Territory . In connection with such review, each Party shall provide to the JSC such information regarding a proposed filing as either Party may reasonably request. Each Party shall provide to the JSC, copies of all material submissions it makes to, and all material correspondence it receives from the EMA or the FDA pertaining to the Product, and the other Party may provide comments regarding such documents and correspondence prior to their submission, which comments shall be considered in good faith.

(e) Regulatory Audits . The Parties shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility where Clinical Studies, manufacturing or pharmacovigilance activities with respect to the Product are conducted by or on behalf a Party pursuant to this Agreement, whether such site or facility is such Party's or its Affiliate's or Subcontractor's (each an " Audited Site "), subject to terms and conditions of Third Party agreements (provided that each Party shall use reasonable efforts to ensure that Third Party agreements do not prevent the exercise of such rights) . Each Party shall be given a reasonable opportunity (taking into account the timing and notice provided by the applicable Regulatory Authority) to assist in the preparation of the other Party's Audited Sites for inspection, where appropriate, and to attend any inspection by any Regulatory Authority of the other Party's Audited Sites, and the summary, or wrap-up, meeting with a Regulatory Authority at the conclusion of such inspection. If such attendance would result in the disclosure to the other Party of Confidential Information unrelated to the subject matter of this Agreement, the Parties shall enter into a confidentiality agreement covering such unrelated subject matter. In the event that any Audited Site is found to be non-compliant with one or more Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice or current standards for pharmacovigilance practice, the non-compliant Party shall submit to the other Party a proposed recovery plan or Corrective and Preventative Actions (" CAPA ") within a reasonable period after such non-compliant Party, its Affiliate or its Subcontractor receives notification of such non-compliance from the relevant Regulatory Authority and such non-compliant Party shall use commercially reasonable efforts to implement such recovery plan or CAPA promptly after submission. Each Party shall use commercially reasonable efforts to secure for the other Party the rights set forth in this Article 4.6(e) from its Subcontractors. In the event a Party is unable to secure such inspection rights from any of its Subcontractors, such Party agrees to secure such rights for itself and, if requested by the other Party, shall exercise such rights, [***], on behalf of the other Party and fully report the results thereof to the other Party. If Licensee desires to conduct such an audit of Licensor's manufacturing Subcontractors, the Parties will reasonably cooperate to minimize the number of separate audits being conducted by Licensor of such Subcontractor by, for example, allowing Licensee to participate in an audit being conducted for Licensor or one of its other licensees.

4.7 Pricing and Reimbursement Approvals . As between the Parties, after completion of the transfer of the Marketing Authorization to Licensee in the Licensee Territory in accordance with the Transition Plan, Licensee shall be solely responsible for and have the exclusive right to seek and attempt in accordance with Article 5.1 to obtain Pricing and Reimbursement Approval for the Product in the Field in the Licensee Territory, provided that Licensee shall keep the JSC reasonably informed with regard to any Pricing and Reimbursement Approval proceedings for the Product in the Field in the Licensee Territory. Prior to the transfer of such Marketing Authorization to Licensee, Licensor shall not submit any application for the Pricing and Reimbursement Approval to a Regulatory Authority or any update thereto, or

communication with a Regulatory Authority, in each case with respect to the Product in the Licensee Territory, without Licensee's prior written consent and shall promptly transmit to Licensee any communication received from or draft of any planned communication or submission to the Regulatory Authorities in Licensee Territory with respect to the Product in the Licensee Territory. As between the Parties, Licensor shall be responsible for and have the exclusive right to seek and attempt to obtain Pricing and Reimbursement Approvals for the Product in the Field in the Licensor Territory and Licensor shall keep the JSC reasonably informed with regard to any Pricing and Reimbursement Approval proceedings for the Product in the Non-Encumbered Territory. Neither Party shall be obliged to provide information in violation of applicable Law.

4.8 Reporting; Adverse Drug Reactions .

(a) Licensor shall be responsible for maintaining the global safety database (" Global Safety Database ").

(b) The Parties shall use good faith efforts to elaborate and execute, prior to the transfer of the Marketing Approval by Licensor to Licensee in accordance with the Transition Plan, a safety data exchange agreement (" Safety Data Exchange Agreement "), which shall provide that Licensor shall be responsible for maintaining the Global Safety Database and shall delineate the specific rights and responsibilities of each Party with respect to the management and the exchange of safety information for the Product within and outside of the Licensee Territory, provided, that for purposes of this Article 4.8 and notwithstanding any other provision to the contrary, (i) all safety Data generated by or on behalf of Licensor, its Affiliates and their respective licensees anywhere in the world and (ii) all Regulatory Filings (and related Data) of Licensor, its Affiliates and their respective licensees filed in the United States, shall be deemed Controlled by Licensor and available to Licensee in accordance with the Safety Data Exchange Agreement.

4.9 Recalls . Without prejudice to Licensee's right to indemnity pursuant to this Agreement or the Supply Agreement, to the extent that: (a) any Regulatory Authority in the Licensee Territory issues a directive or order that any Product be recalled or withdrawn in any country within the Licensee Territory; (b) a court of competent jurisdiction orders a recall or withdrawal of any Product in any country within the Licensee Territory, or (c) Licensee determines the Product should be recalled or withdrawn voluntarily in any country within the Licensee Territory, Licensee will recall or withdraw the Product. Either Party shall advise the other Party of any Regulatory Authority-initiated mandatory recall of the Product in its respective territory. Neither Party shall initiate any voluntary recall of the Product in its respective territory without the prior written notice to the other Party.

ARTICLE V
COMMERCIALIZATION AND PROMOTION

5.1 Licensee Commercialization .

(a) Licensee shall, itself or through its Affiliates or Sublicensees, be responsible for, and shall control the conduct of, the Commercialization of the Product in the Licensee Territory, [***], and shall use Commercially Reasonable Efforts to Commercialize the Product in the Initial Indication in the Major Markets and in any other indication for which Marketing Approval of the Product is obtained in such Major Markets. For clarity, it is understood and agreed that nothing in this Agreement shall require Licensee to conduct any Development activities with respect to the Product. The Parties acknowledge that under appropriate circumstances it may fall within Commercially Reasonable Efforts in Commercializing the Product for Licensee to decide not to advance to the next stage of Commercialization depending on the outcomes of prior stages of Commercialization, including Market Access in the Licensee Territory.

(b) Licensor shall supply to Licensee representative forms of Marketing, advertising and promotional core materials (together " Core Marketing Materials "), training manuals and educational materials for the Product used by Licensor in the Licensor Territory, which Licensee, its Affiliates and Sublicensees may adapt, in Licensee's reasonable discretion and subject to any Third Party copyright, for use with respect to the Product in the Licensee Territory.

(c) Licensee shall use Commercially Reasonable Efforts to develop and launch a patient support program for the Product in the Field and in the Licensee Territory [***], provided, in the event such patient support program is required under applicable Law in the countries of the Licensee Territory where the Licensed Product is Commercialized, Licensee shall develop and launch such patient support program [***].

(d) Licensee shall supply to Licensor final approved forms of the Core Marketing Materials, training manuals and educational materials for the Product used by Licensee, its Affiliates and Sublicensees in the Licensee Territory, which Licensor, its Affiliates and sublicensees may adapt, subject to Licensor's reasonable discretion and subject to any Third Party copyright, for use with respect to the Product in the Licensor Territory. Upon Licensor's reasonable request, Licensee shall also provide Licensor with all other marketing materials other than Core Marketing Materials developed, generated or otherwise prepared by or on behalf of Licensee.

ARTICLE VI
PAYMENTS

6.1 License Fee . In consideration for the exclusive rights and licenses granted by Licensor to Licensee hereunder, Licensee shall pay to Licensor a license fee equal to sixty million USD (US $60,000,000) within [***] ([***]) days following the Effective Date in accordance with the payment provisions of Article 7 . Payment made in accordance with this Article 6.1 shall be non-refundable, non-creditable and non-cancellable.

6.2 Milestone Payments .

(a) Development Milestone Payments . In further consideration for the exclusive rights and licenses granted by Licensor to Licensee hereunder, Licensee shall pay to Licensor the milestone payments set out below following the first achievement by Licensee, and/or any of its Affiliates or Sublicensees, of the corresponding milestone events set out below with respect to the Product, in accordance with this Article 6.2 and the payment provisions in Article 7 :

Milestone Event	Milestone Payment
[***]	[***]
[***]	[***]

Total development milestones payable under this Article 6.2(a) shall not exceed [***] ([***]).

(b) Sales Milestone Payments . In further consideration for the exclusive rights and licenses granted by Licensor to Licensee hereunder, Licensee shall pay to Licensor the milestone payments set out below following the first time that the Annual Royalty Bearing Net Sales of the Product reach the following thresholds, in accordance with this Article 6.2 and the payment provisions in Article 7 :

Sales Milestone Events	Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(c) With respect to the Sales Milestones, each such Sales Milestone payment shall be payable only once, provided that if two (2) or more Sales Milestones are due and payable during the same Calendar Year, then Licensee may pay only the higher Sale Milestone payment due and payable during such Calendar Year and the payment of the lower Sales Milestone(s) would be deferred to the subsequent Calendar Year (any such deferred Sales Milestone payment amount, collectively, " Deferred Sales Milestone Amount ").

(d) Licensor acknowledges and agrees that, the Development Milestones and Sales Milestones set forth in this Article 6 are conditional and nothing in this Agreement shall be interpreted to impose on Licensee any obligation to reach any such Development Milestones and Sales Milestones or to make the corresponding payments, provided Licensee complies with its obligations under this Agreement. Licensor further acknowledges and agrees that the sales levels set forth in Articles 6.2(b) and 6.4 shall not be construed as representing an estimate or projection of anticipated sales of the Product or implying any level of diligence or Commercially Reasonable Efforts, in the Licensee Territory but are merely intended to define Licensee's royalty and other payment obligations, as applicable, in the event such sales levels are achieved.

6.3 Reports and Payments . Licensee shall notify Licensor in writing within [***] ([***]) days after Licensee first learns of the achievement of each milestone set out in Article 6.2 (and with respect to sales related milestones, following [***]) by Licensee, or any of its Affiliates or Sublicensees . The corresponding milestone payment shall be due within [***] ([***]) days of receipt by Licensee of an invoice from Licensor and issued no earlier than the notice of achievement of the corresponding milestone event. Any payment made in accordance with Article 6.2 shall be non-refundable, non-creditable and non-cancellable, subject to Section 12.6(ii).

6.4 Royalties .

(a) During the Royalty Term, Licensee shall pay to Licensor, on a [***] basis, a royalty on the Annual Royalty Bearing Net Sales of the Product in the Licensee Territory by Licensee, its Affiliates or Sublicensees. Such royalty shall be paid [***], at the applicable rates set forth below, based on the Annual Royalty Bearing Net Sales of the Product, subject to the adjustments set forth in Article 6.6 (the " Royalty Payments ").

Annual Royalty Bearing Net Sales in a Given Calendar Year	**Royalty Rate**
With respect to the portion of Annual Royalty Bearing Net Sales [***]	[***]%
With respect to the portion of Annual Royalty Bearing Net Sales [***]	[***]%
With respect to the portion of Annual Royalty Bearing Net Sales [***]	[***]%

(b) Consequences of Expiration of the Royalty Term . Licensee shall not owe royalty on any Product sold in a country after expiration of the Royalty Term for such Product in such country. Upon expiration of the Royalty Term with respect to the Product Commercialized in a country, Licensee shall have a fully paid up , perpetual license under the rights granted in this Agreement with respect to the Product in such country.

(c) Royalty Payments and Reports . Within [***] after the end of each [***], commencing with the [***] in which the First Commercial Sale occurs, Licensee shall deliver to Licensor a report (each, a " Royalty Report ") setting out in compliance with the template attached in EXHIBIT 8 all details necessary to calculate the payments due under this Article 6.4 , including Royalty Bearing Net Sales in the relevant [***] on a country-by-country basis, all relevant exchange rate conversions in accordance with Article 7.3 and the amount of any payment due from Licensee to Licensor, calculated in accordance with this Article 6 . Licensee shall provide preliminary estimated Royalty Report within [***] of the end of each [***]. The royalty payment shall be due within [***] of receipt by Licensee of an invoice from Licensor and issued no earlier than the date of receipt of the Royalty Report by Licensor.

6.5 Reduction for Generic Competition . If during the Royalty Term, the Generic Competitors have achieved a Generic Market Share of more than [***]% within the Licensee Territory, in lieu of the royalty rate specified in Article 6.4(a) above, the royalty rate applicable to Annual Royalty Bearing Net Sales of the Product shall be reduced to [***] percent ([***]%), irrespective of the level of Net Sales.

6.6 Third Party Licenses . If Licensee or any of its Affiliates or Sublicensee determines in its good faith judgment that it is necessary or reasonably advisable to obtain a license from any Third Party in order to Use the Product for any given country of the Licensee Territory then Licensee may deduct [***] percent ([***]%) of any such Third Party payments from the payment set forth in Article 6 , provided that in no event shall the royalty rate payable to Licensor for the Annual Royalty Bearing Net Sales in a given Calendar Year (" Royalty Rate ") be reduced to a number that is less than [***] percent ([***]%) by application of such deduction, and any excess amount shall be carried forward to the subsequent Calendar Year(s).

6.7 Third Party Payments . [***] shall be solely responsible for all Third Party license payments, milestones and royalties owed with respect to the Product, or Intellectual Property Rights that are owned or licensed by [***] on or prior to the Effective Date (including for the avoidance of doubt any Third Party license payments owed under the Background Agreements).

6.8 [***] shall reimburse [***]'s any Post-Approval Marketing Study Costs to be conducted in accordance with Article 4.1(b) on a [***] basis within [***] from receipt of an invoice from [***]. Such invoice shall be accompanied by documentation supporting the calculation of such reimbursement amounts.

ARTICLE VII
PAYMENTS; BOOKS AND RECORDS

7.1 Payment Method . All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated with at least [***] ([***]) Business Days' notice by the Party to which such payments are due, which account shall be opened in the name of such Party in the book of a bank in the European Union or the United States of America, as applicable. Each Party undertakes to provide to the other Party all information and documents required by such other Party in connection with the relevant provisions of Laws relating to anti-money laundering / KYC and any existing related internal policies and which are satisfactory to it and allow it to comply with such Laws and policies.

7.2 Interest . Any payments or portions thereof due under this Agreement that are not paid by the date such payments are due under this Agreement shall bear interest at a rate equal [***] applicable on the date the payment becomes due with respect to payments in US Dollars, or the [***] with respect to payments in other currencies, plus in each case [***] percent ([***]%) per year, calculated on the number of days such payment is delinquent , compounded monthly and computed on the basis of a three hundred sixty five (365) day year. This Article 7.2 shall in no way limit any other remedies available to the Parties.

7.3 Currency Conversion . Unless otherwise expressly stated in this Agreement, all amounts specified in this Agreement are in US Dollars, and all payments by one Party to the other Party under this Agreement shall be paid in US Dollars. If any currency conversion shall be required in connection with the payment of royalties or other amounts under this Agreement, such conversion shall be calculated by the paying Party using the applicable average daily mid foreign exchange rates published in the Reuters pages over the period in which the payment obligation arises.

7.4 Taxes .

(a) If Laws or regulations require withholding of any taxes imposed upon a payee on account of any royalties or other payments paid under this Agreement, such taxes shall be deducted by the payor of such royalties or other payments as required by Law from such payment and shall be paid by the payor to the proper taxing authorities. The payor shall use Commercially Reasonable Efforts to (i) secure official receipts of payment of any withholding tax and shall send them to the payee as evidence of such payment and (ii) give advance notice to payee of the intention to withhold or deduct such taxes. Any such amounts deducted by the payor in respect of such withholding or similar tax shall be treated as having been paid by the payee for purposes of this Agreement . Notwithstanding the foregoing, if (i) the payor redomiciles, assigns its rights or obligations or delegates (including to an Affiliate pursuant to Article 17.8(c)) its rights under this Agreement, (ii) as a result of such redomiciliation, assignment or delegation, the payor (or its assignee or delegate) is required by applicable Law to withhold taxes from or in respect of any amount payable under this Agreement, and (iii) such withholding taxes exceed the amount of withholding taxes that would have been applicable but for such redomiciliation, assignment or delegation, then any such amount payable shall be increased to take into account such withholding taxes as may be necessary so that, after making all required withholdings (including withholdings on the additional amounts payable), the payee (or its assignee) receives an amount equal to the sum it would have received had no such increased withholding been made, provided however that if the payee receives, in the year of such withholding or the following year , a cash tax benefit from a refund of any such withholding taxes (or a credit in lieu of a refund), the payee shall pay to the payor an amount equal to such cash tax benefit, net of all reasonable out-of-pocket expenses incurred by the payee and its Affiliates in connection with the obtaining or receipt of such refund (or credit), it being specified that the payee shall use its commercially reasonable efforts to secure such refund (or credit) in the year of the relevant withholding or the following year. Solely for purposes of this Article 7.4(a) , a Party's "domicile" shall include its jurisdiction of incorporation or tax residence and a "redomiciliation" shall include a reincorporation or other action

resulting in a change in tax residence of the applicable Party or its assignee. Each Party shall cooperate with the other and furnish the other with appropriate documents, including Tax Documentation, to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). " Tax Documentation " means any certificate or documentary evidence necessary to alleviate withholding on payments made by payor to payee under this Agreement, which includes, as applicable, French tax forms number 5000 and 5003, as such forms may be amended from time to time in accordance with applicable Law duly stamped and validated by the relevant governmental entity with responsibility for taxes in connection with any tax reduction or exemption under any applicable international tax treaty between France and USA. Notwithstanding anything to the contrary in this Article 7.4(a) , the Parties acknowledge and agree that Licensee will not , absent a change in Law or relevant circumstance between the date of this Agreement and the applicable date of payment, deduct or withhold from the amounts payable pursuant to Articles 6.1 , 6.2 , 6.4 or 6.5 any amount in respect of any taxes provided that Licensor provides Licensee with applicable Tax Documentation establishing an exemption from withholding under Article 12 of the 1994 income tax treaty between the government of the United States and the French Republic (as amended by the 2006 protocol and the 2009 protocol).

(b) Indirect Taxes . All payments under Articles 6.1 , 6.2 , 6.4 , and 6.5 of this Agreement are stated exclusive of Indirect Taxes. Any Indirect Taxes required to be paid in connection with such payments due to Licensor shall [***]. " Indirect Tax " means any sales tax (including any consumption tax or value added tax), use tax, transfer taxes, duties or similar governmental charges.

7.5 Records; Inspection . Licensee shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to Licensor pursuant to this Agreement and, if applicable, Licensee's prosecution, maintenance and enforcement of Licensed Patents (" **Records** "). Such Records shall be kept for the longer of (a) the period of time required by applicable Law in the Licensee Territory and (b) at least [***] ([***]) years following the expiration or termination of this Agreement. Licensee shall require its Sublicensees to provide to Licensor (so that Licensor may provide the same to Pfizer) copies of all Records relating to such Sublicensees' sale of the Product as necessary to allow Licensor or, if applicable, Pfizer (under the Pfizer License Agreement) to review such Records when conducting an audit of Licensee or Licensor, as applicable, pursuant to this Article 7.5 . Notwithstanding Article 9 , pursuant to the Pfizer License Agreement, Pfizer will be allowed to review such Records. Such Records will be open for inspection by an independent auditor chosen by Licensor and reasonably acceptable to Licensee for the purpose of verifying the amounts payable by Licensee hereunder. Such inspections may be made [***] each Calendar Year, at reasonable times and on reasonable prior written notice. Such Records for any particular Calendar Quarter shall be subject to [***]. The independent auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Article 7.5 shall be at the expense of Licensor, unless a variation or error producing an underpayment in amounts payable exceeding [***] of the amount paid for a period covered by the inspection is established, in which case all reasonable costs relating to the inspection for such period and any unpaid amounts that are discovered shall be paid by Licensee, together with interest on such unpaid amounts at the rate set forth in Article 7.2 above. The Parties will endeavor in such inspection to minimize disruption of Licensee's normal business activities to the extent reasonably practicable. Licensor's right to inspect under this Article 7.5 shall survive the expiration or termination of this Agreement for a term of [***] ([***]) years.

ARTICLE VIII
PRODUCT MANUFACTURING AND SUPPLY

8.1 General .

(a) Subject to the terms and conditions of this Agreement, Licensor shall supply, or secure supply of, Licensee's requirements for Drug Substance, Drug Product, Finished Product and Brite Stock (collectively, the " Materials ") for the Licensee Territory pursuant to a supply agreement to be entered into by the Parties as set forth below.

(b) For purposes of this Article 8 :

(i) " Brite Stock " shall mean Drug Product in un-labelled bottles for commercial supply;

(ii) " Cost of Goods Sold " means, with respect to any Materials, the amount equal to the price paid by Licensor for the Materials to the Third Party as such Materials are ordered by Licensee (but excluding any costs relating to the maintenance of a safety stock), plus [***];

(iii) " Drug Product " shall mean a finished dosage form containing Drug Substance that is not fully packaged and labelled;

(iv) " Drug Substance " shall mean the active ingredient of the Product consisting of the Compound in bulk form meeting the applicable specifications therefor that, but does not include intermediates used in the synthesis of such ingredient; and

(v) " Finished Product " shall mean finished (i.e., fully packaged and labelled) Drug Product for commercial supply.

8.2 Supply Agreement . Within [***] ([***]) days after the Effective Date, the Parties will enter into a commercial supply agreement (a " Supply Agreement ") pursuant to which Licensor shall supply Licensee's requirements of the applicable Materials for the Licensee Territory in accordance with the Manufacturing Standards, and the provisions set forth in EXHIBIT 6 and the terms of this Agreement.

8.3 Quality Agreement . The Parties shall enter into separate quality agreement regarding supply of the Materials by Licensor to Licensee, incorporating provisions that are standard in the pharmaceutical field within [***] ([***]) days after Effective Date, and in any event prior to any delivery of Materials, as set forth in more details in EXHIBIT 6 .

8.4 Licensed Technology Transfer and Transfer of the Supply Chain .

(a) Notwithstanding anything in this Agreement, from the Effective Date, Licensee shall have the right (but not the obligation) to Manufacture or package or have Manufactured and or packaged by its Affiliates, Licensee's requirements of the Finished Product, as well as, Licensee's requirements of Drug Product and Drug Substance for the Licensee Territory, as set forth in more detail in EXHIBIT 6 .

(b) For the purposes of subclause (a), upon Licensee's written request, Licensor shall cooperate with Licensee, [***], to transfer, or cause to be transferred, to Licensee or its Affiliate within mutually agreed reasonable timelines the Know-How Controlled by Licensor that is necessary or actually used for the Manufacture, packaging and/or testing and release of the Materials, and shall make personnel of Licensor reasonably available to assist Licensee and its Affiliate in practicing the Know-How so transferred in accordance with this Article 8.4(b). With respect to any Brite Stock or Drug Substance Manufactured by Licensee or its Affiliate, Licensee shall have the option to terminate the Supply Agreement or to keep Licensor and the Third Party Manufacturer as second manufacturer.

(c) Upon completion of technology transfer of any Material in accordance with Article 8.4(b) and validation of Licensee's or Licensee's Affiliate Manufacture of such Material and qualification of the applicable facility, if Licensor so requests, Licensee shall act a secondary manufacturer of Licensor with respect to the supply of the Materials and the Parties shall discuss in good faith the terms and conditions of supply of such Materials by Licensee to Licensor, provided that Licensee shall have no obligation to supply Licensor in any country in which Licensee's facilities for Manufacturing the Materials are not yet qualified, and Licensee shall not be required to make any investment or obtain any new authorizations or permits to Manufacture and supply such Material for any such country.

ARTICLE IX
CONFIDENTIALITY AND DATA PROTECTION

9.1 Definition.

(a) " Confidential Information " shall mean this Agreement and the terms and provisions of this Agreement and other proprietary information and data of a financial, commercial or technical nature (including such information or data of or relating to a Third Party) that the disclosing Party or any of its Affiliates have supplied or otherwise made available to the other Party or its Affiliates, which are disclosed, whether orally, visually or in writing.

(b) Confidential Terms . The terms of this Agreement shall be deemed Confidential Information of both Licensee and Licensor.

9.2 Obligations . During the term of this Agreement and for [***] ([***]) years thereafter, the receiving Party will:

(a) protect all Confidential Information of the disclosing Party against unauthorized disclosure to Third Parties;

(b) not use the Confidential Information of the disclosing Party except as permitted by or in furtherance of exercising rights or carrying out obligations hereunder. Each receiving Party will treat Confidential Information provided by the other Party with the same degree of care as if it were the receiving Party's own confidential information (but under no circumstances less than reasonable care); and

(c) The receiving Party may disclose the Confidential Information of the disclosing Party to its Affiliates, and their respective directors, officers, employees, subcontractors, sublicensees, consultants, attorneys, accountants, banks, acquirers and investors (collectively, " Recipients ") who have a need-to-know such information for purposes related to this Agreement, provided that the receiving Party shall hold such Recipients to written obligations of confidentiality and non-use with terms and conditions at least as restrictive as those set forth in this Agreement.

9.3 Exceptions . The obligations under this Article 9 shall not apply to any information to the extent the receiving Party can provide convincing evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information;

(b) was known to, or was otherwise in the possession of, the receiving Party prior to the time of disclosure by the disclosing Party other than under obligations of confidentiality;

(c) is disclosed to the receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation; or

(d) is independently developed by or on behalf of the receiving Party or any of its Affiliates, as evidenced by its written records, without use or access to the Confidential Information.

9.4 Permitted Disclosures .

(a) The restrictions set forth in this Article 9 shall not prohibit the receiving Party from disclosing or using (as specified below) any Confidential Information of the disclosing Party (i) that the receiving Party is required to disclose under Laws, a court order or other governmental order, or the rules and regulations of the Securities and Exchange Commission (" SEC ") or any national securities exchange, (ii) that the receiving Party needs to disclose or use to file, prosecute or enforce any Licensed Patents or Patents on jointly-owned inventions under Article 10 , or (iii) that the receiving Party needs to disclose or use for purposes of obtaining or maintaining Regulatory Filings of the Product; provided that the receiving Party (A) as to subsection (i), provides the disclosing Party at least [***] ([***]) Business Days prior written notice of such disclosure (and the right to review and comment on the proposed disclosure)[***] (B) as to subsection (i) afford the disclosing Party an opportunity to review and comment on the confidential treatment for such required disclosure required by the SEC or national securities exchange and use reasonable efforts to secure confidential treatment for such required disclosure, (C) as to subsection (i) discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose in the receiving Party's legal counsel opinion and (D) as to subsections (ii) and (iii), the receiving Party provides reasonable advance notice to the other Party where reasonably practicable and discloses only that portion of the Confidential Information that it is reasonably necessary to disclose for such purpose and maintain confidential treatment for the longest possible period.

(b) A receiving Party hereto may also disclose the disclosing Party's Confidential Information to its Affiliates, licensees (with respect to Licensor), permitted Sublicensees (with respect to Licensee), investors and lenders and any other Third Parties to the extent such disclosure is reasonably necessary to exercise the rights granted to it, or reserved by it, under this Agreement, including granting a sublicense or obtaining any Marketing Approvals. Notwithstanding anything to the contrary herein, Licensee acknowledges and hereby agrees that Licensor shall furnish to Pfizer a true and complete copy of this Agreement and each amendment thereto, subject to redactions that are not directly relevant to the performance of Licensor's obligations under the Pfizer License Agreement, within [***] ([***]) days of the Effective Date and any Sublicense and amendments thereto, subject to redactions in accordance with this Article 9.4(b) .

9.5 Scientific Papers and Scientific Meetings . The Parties through a dedicated Working Group pursuant to Article 3.2(b) shall discuss their projected publications and elaborate an annual publication plan which will address all planned Scientific Papers and Scientific Presentations in scientific meetings on an annual basis.

9.6 Scientific Papers . Each Party may present, disclose or publish any information, data (including Data), and other results related to the Compound and the Product that have not previously been presented, disclosed or published (" Compound and Product Information ") through scientific publications in accordance with this Article 9.6 and subject to any obligations set forth under Licensor's agreements with Third Party licensees.

(a) Each Party shall provide to the other Party, prior to submission for publication, a draft of the proposed submission concerning the Compound and Product Information which have been prepared by or on behalf of such Party (or by a Clinical Study site contracted by such Party as sponsor of the relevant Clinical Study) or through any Investigator Sponsored Clinical Studies (each a " Scientific Paper ") to be published in indexed medical and scientific journals and similar publications (" Medical Journals ").

(b) Commencing with the receipt of such draft Scientific Paper, the receiving Party shall have [***] ([***]) Business Days to notify the sending Party of its consent or denial with respect to the publication of such Scientific Paper (it being understood that, during such [***] ([***]) Business Day period, no submission for publication thereof shall take place).

(c) In the event the receiving Party consents to the publications, but has comments thereto, the Party proposing to publish such Scientific Paper shall, in good faith, consider the comments made by the receiving Party, particularly if such publication may be prejudicial to the receiving Party's opportunity to obtain any Patent rights.

(d) The receiving Party may require that the publication of such Scientific Paper be suspended for a period of time not exceeding [***] ([***]) days to permit a Patent to be filed using the Know-How covered in the proposed Scientific Paper.

(e) Neither Party will publish or present any Confidential Information of the other Party without such other Party's prior written consent.

(f) The sending Party shall provide to the receiving Party copies of any final Scientific Paper accepted by a Medical Journal within [***] ([***]) Business Days after the approval thereof, subject to applicable Medical Journal publisher's rules, guidelines and any other health care compliance guidelines.

(g) To enable free exchange of copyrighted material between the Parties, each Party agrees that it has or shall (i) obtain and maintain, at its own expense, an annual copyright license or equivalent license from the copyright clearance center and (ii) list the other Party as a collaborator in an agreement with the copyright clearance center if required by such agreement.

(h) Notwithstanding anything to the contrary in this Article 9.6 , Licensor retains the right to publish, subject to subsections (a), (d), (e), (f) and (g), Compound and Product Information arising from the Ongoing Clinical Studies.

(i) Notwithstanding anything to the contrary in this Article 9.6 , with respect a Scientific Paper containing Compound and Product Information arising from an Investigator Sponsored Clinical Study supported by a Party, each Party will use reasonable efforts to follow the process described in subsections (a), (d), (e), (f) and (g), subject to compliance with best practices guidelines in the pharma industry and the provisions of such Party's agreement with the Third Party sponsor.

9.7 Abstracts , Posters and Slide Decks . Each Party may present any Compound and Product Information through publications, presentations, lectures, symposia or other meetings of healthcare professionals, or international congresses, conferences or meetings organized by a professional society or organization anywhere in the world (any such occasion, a " Presentation ") in accordance with this Article 9.7 , and subject to Licensor's obligations under Licensor's agreements with Third Party licensees.

(a) Each Party shall provide to the other Party, prior to presentation and through a dedicated working group, an initial draft of the proposed presentation concerning the Compound and Product Information which has been prepared by or on behalf of such Party (or by a Clinical Study site contracted by such Party as sponsor of the relevant Clinical Study) (each a " Scientific Presentation ") to be presented at a Presentation. The presenting Party shall make reasonable efforts to provide to the other Party the initial draft of such Scientific Presentation within [***] ([***]) Business Days prior to the Presentation.

(b) Commencing with the receipt of any such draft Presentation, the receiving Party shall have [***] ([***]) Business Days to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during such review period, as applicable, no Presentation thereof shall take place) and the Parties shall discuss such observations and suggestions in good faith , particularly if such Presentation may be prejudicial to the other Party's opportunity to obtain any Patent rights.

(c) The receiving Party may require that the Presentation be suspended for a period of time not exceeding [***] ([***]) days to permit a Patent to be filed using the Know-How covered in the proposed Presentation.

(d) Neither Party will present any Confidential Information of the other Party without such other Party's prior written consent.

(e) The sending Party shall provide to the receiving Party copies of all final versions of the Presentation presented at a Scientific Presentation within [***] ([***]) Business Days after the presentation thereof, subject to applicable publisher's rules, guidelines and any other health care compliance guidelines.

(f) Notwithstanding anything to the contrary in this Article 9.7 , Licensor retains the right to publish, subject to subsections (a), (b), (d) and (e) Data and information arising from the Ongoing Clinical Studies .

(g) Notwithstanding anything to the contrary in this Article 9.7 , with respect to a Scientific Presentation containing Compound and Product Information arising from an Investigator Sponsored Clinical Study supported by a Party, each Party will use reasonable efforts to follow the process described in subsections (a), (b), (d), and (e), subject to compliance with best practices guidelines in the pharma industry and the provisions of such Party's agreement with the Third Party sponsor .

9.8 Clinical Trial Website Registries . Each Party shall be free to register the Clinical Studies it is sponsoring with respect to the Product on ClinicalTrials.gov, clinicaltrialsregister.eu or in similar clinical trial registries. Neither Party shall disclose or publish any Compound and Product Information on any website registries unless required by applicable Law or by such Party's policies as consistently applied (provided that if either Party's policies change so that they require disclosing or publishing any Compound and Product Information, such Party shall inform the other Party of such policy change), in which case the Party proposing to make such disclosure shall provide the other Party a detailed description of such required disclosure at least [***] ([***]) days prior to such registration or disclosure and shall, in good faith, consider the comments made by the other Party regarding the proposed registration or disclosure and the protection of any Intellectual Property Rights contained therein.

9.9 Press Releases . Notwithstanding anything to the contrary in Article 9.2 , the Parties have agreed on a mutual press release to announce the execution of this Agreement in the form attached in EXHIBIT 7 , together with a corresponding Question & Answer outline for use in responding to inquiries about this Agreement. The Parties agree to consult with each other reasonably and in good faith with respect to the text of any subsequent press releases or other disclosures and obtain the approval of the other Party, no later than within [***] ([***]) Business Days prior to the issuance thereof; provided, however, that a Party may not unreasonably withhold or delay consent to such releases unless such release would adversely affect the rights or interests of such Party.

9.10 Prior Non-Disclosure Agreements . Upon execution of this Agreement, the terms of this Article 9 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties, including the Confidentiality Agreement between the Parties dated January 9, 2018 and amended December 19, 2018. Any information disclosed under such prior agreements shall be deemed disclosed under this Agreement.

9.11 Disclosing Party Obligations . To the extent a Party (the " Disclosing Party ") discloses, transfers or otherwise makes available any Transferred Data (which may include Personal Data) to the other Party (the " Receiving Party ") in connection with this Agreement, the Disclosing Party:

(a) shall, notwithstanding any other provision of this Agreement, use commercially reasonable efforts to: (i) ensure that the Transferred Data cannot be used by the Receiving Party to identify a Data Subject and (ii) not provide the Receiving Party with any additional information (if any), including any key codes or any other mechanism or data, that may enable the Receiving Party to attribute the Transferred Data to any identifiable Data Subjects; and

(b) has, to the best of its knowledge, complied with all applicable Data Protection Laws from time to time relating to the Processing of the Transferred Data.

9.12 Independent Data Controllers . Unless otherwise agreed between the Parties in accordance with Article 9.26 (for example in relation to any Processing of Personal Data by or on behalf of the Parties as joint controllers in connection with an Additional Clinical Study), the Receiving Party and the Disclosing Party agree that (to the extent that any Personal Data contained within the Transferred Data is disclosed to the Receiving Party), for the purposes of Data Protection Law, each of the Receiving Party and the Disclosing Party is an independent data controller .

9.13 Fair Processing Notices . The Receiving Party further agrees that the Disclosing Party (to the extent that any Personal Data contained within the Transferred Data is disclosed to the Receiving Party) may delay the disclosure of specific Personal Data to the Receiving Party until the Disclosing Party has provided such additional fair processing information to Data Subjects in relation to the Receiving Party's Processing of such Personal Data or taken such other actions as the Disclosing Party reasonably believes to be required by Data Protection Law to enable the Disclosing Party to comply with its obligations thereunder. If a Party reasonably believes that additional fair processing information or actions are required to ensure either Party's compliance with Data Protection Law from time to time, such Party shall notify the other Party and the Parties shall discuss in good faith what action, if any, is required to be taken provided that the Receiving Party agrees that, as between the Parties, the Disclosing Party shall have the sole right (but not the obligation) to communicate or procure the communication of fair processing information (including updating such fair processing information during the term of this Agreement) to Data Subjects, in a manner and form to be reasonably determined by the Disclosing Party in accordance with Data Protection Law, with any and all reasonable costs incurred by the Disclosing Party arising from such support to be borne by the Receiving Party.

9.14 Personal Data Transfers . The Receiving Party shall, other than to countries approved, from time to time, as having equivalent protection for Personal Data as under European Data Protection Laws by the EC, not Process such Personal Data outside the EEA unless where the Receiving Party complies with the data importer's obligations set out in the EU Standard Contractual Clauses for transfers from data controllers in the European Union or European Economic Area to controllers established outside the European Union or European Economic Area pursuant to EU Commission Decision 2004/915/EC (as amended or replaced from time to time) (the " Controller to Controller Clauses ") which are hereby incorporated into and form part of this Agreement (and for the purposes of Annex B of such Controller to Controller Clauses, categories of Data Subjects , purpose of transfer, types of Personal Data , recipients and categories of sensitive Personal Data shall be as set out in Articles 9.15 to 9.20 below .

9.15 Nature and Purpose of Sharing . Unless otherwise agreed between the Parties in accordance with Article 9.26 (for example in relation to any Processing of Personal Data by or on behalf of the Parties as joint controllers in connection with an Additional Clinical Study), the Personal Data is shared, on a controller to controller basis, solely for the purpose of the Development, Manufacture, Regulatory Filings and Commercialization of the Products by the Parties in connection with this Agreement. The sharing of the Personal Data is necessary for the purpose of the legitimate interests pursued by the Parties in Developing, Manufacturing, Regulatory Filings and Commercializing the Product as contemplated by this Agreement.

9.16 Categories of Recipients . the Personal Data may only be onward transferred by the receiving Party as permitted by and on the terms of this Agreement.

9.17 Duration of Sharing . As set forth in this Agreement.

9.18 Types of Personal Data Shared . The Personal Data will include:

(a) identification information, such as name, address, contact information and qualifications, relating to each Party's personnel and those working on such Party's behalf in connection with the Development, Manufacture, Regulatory Filings and Commercialization of the Products by the Parties in connection with this Agreement; and

(b) identification information, such as name, address, contact information and qualifications on healthcare professionals and on investigators involved in Clinical Studies, each to the extent included in the Transferred Data.

9.19 Special Category Personal Data Shared . The Personal Data will include any special categories of Personal Data included in the Transferred Data including but not limited to identification patient number, medical records, ethnic or racial background, test results, results of physical examinations, samples, adverse effects and any other health information relating to the Data Subjects listed in (c) and (d) of Article 9.20 below.

9.20 Categories of Data Subjects . The Personal Data will relate to data subjects including: (a) each Party's personnel and those working on such Party's behalf in connection with a Clinical Study; (b) healthcare professionals and investigators involved in Clinical Studies; (c) Clinical Study subjects and/or patients; and (d) end users of and/or patients using the Product;

9.21 Data Minimization . Each Party acknowledges that, pursuant to European Data Protection Laws, each Party is under an obligation to ensure that the Personal Data they Process and which the Disclosing Party discloses is limited to only that which is necessary for the purposes of the Processing, therefore the Disclosing Party shall (to the extent that any Personal Data contained within the Transferred

Data is disclosed to the Receiving Party), notwithstanding any other provision of this Agreement, use commercially reasonable efforts to transfer only that Personal Data which is required to facilitate the performance of this Agreement. If the Receiving Party reasonably believes that additional Personal Data is required to be disclosed to enable the performance of this Agreement, the Receiving Party shall notify the Disclosing Party and the Parties shall discuss in good faith whether such additional Personal Data will be disclosed by the Disclosing Party, taking into account the Disclosing Party's obligations under applicable European Data Protection Laws, the potential for the provision of anonymized data in place of the requested Personal Data, and any actions which are required to be taken by either Party in connection with such requested disclosure.

9.22 Receiving Party Obligations . The Receiving Party shall, and shall cause its officers, employees, agents, attorneys, consultants, advisors and other representatives to:

(a) Process any Personal Data contained within the Transferred Data in accordance with Data Protection Law and solely for the purposes disclosed and purposes compatible under applicable Data Protection Law with the purposes disclosed to the relevant Data Subjects from time to time or as otherwise permitted by applicable Data Protection Law;

(b) implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk, taking into account the state of the art, the costs of implementation and the nature, scope, context and purpose of processing and promptly notify the Disclosing Party if any Personal Data is subject to any unauthorized or unlawful access, loss, destruction or damage; and

(c) not further disclose the Personal Data to any Third Party (including, for clarity, any subcontractors) in a manner incompatible with the fair processing information provided to the relevant Data Subjects.

9.23 Data Subject Requests . In the event that either Party directly receives a request from a Data Subject for the rectification or erasure of such Personal Data (or any other request regarding Data Subjects exercising rights under any European Data Protection Law) (a " Data Subject Request "), the party receiving the request shall where appropriate pass on the details of the request to the other Party; and each Party shall provide the other any reasonable assistance as is required for the purposes of responding to the Data Subject Request in accordance with any European Data Protection Law especially in terms of time limit to respond to a Data Subject, which may involve contacting clinical sites, investigators or other subcontractors of the disclosing Party and providing additional information.

9.24 Governmental Authority Requests. In the event that either Party receives a request from a Governmental Authority in relation to any Personal Data comprised within the Transferred Data, the other Party agrees to provide reasonable assistance to such Party to enable it to respond to the Governmental Authority's request which may involve contacting any clinical sites, investigators or other subcontractors of the other Party and providing additional information, with any and all reasonable costs incurred by the other Party arising from such support to be borne by the Party which has received the request from the Governmental Authority.

9.25 CCPA . To the extent that the CCPA is applicable to either Party: (a) such Party agrees to comply with all of its obligations under the CCPA; and (b) to the extent that the Transferred Data involves any communication of "personal information" (as defined by the CCPA) from one Party to the other Party pursuant to this Agreement, the Parties agree that no monetary or other valuable consideration is being provided for such personal information and therefore neither Party is "selling" (as defined by the CCPA) personal information to the other Party.

9.26 Changes . If a Party reasonably believes that any changes are required to this Agreement to ensure a Party's compliance with Data Protection Law or to address the legal interpretation of Data Protection Law, including in relation to the respective roles of the Parties with regard to any Personal Data Processed under this Agreement, that Party may notify the other and the Parties shall negotiate in good faith appropriate amendments or addenda to this Agreement to the extent required to ensure both Parties' compliance with Data Protection Law from time to time. Without prejudice to the generality of the foregoing, if a Party reasonably believes that the Parties may be joint controllers in respect of certain Processing of Personal Data in connection with this Agreement, in particular, in the event of the Parties jointly conducting Shared Clinical Trial or of one Party requesting the other to perform a Clinical Study, regardless of the country where such Clinical Studies are performed, the Parties shall negotiate in good faith whether to amend or enter into an addendum to this Agreement in order to reflect such joint controller relationship and to allocate the Parties' respective responsibilities as joint controllers in respect of such Processing.

ARTICLE X
PATENT PROSECUTION AND ENFORCEMENT

10.1 Ownership of Inventions .

(a) Pre-existing IP . Subject only to the rights expressly granted to the other Party under this Agreement, each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned by, or licensed or sublicensed to, such Party prior to the Effective Date or independent of this Agreement.

(b) Inventorship of Inventions shall be determined in accordance with the rules and regulations of the U.S. Patent and Trademark Office.

(c) All Inventions made solely by employees, agents and independent contractors of Licensor or its Affiliates pursuant to this Agreement and all Intellectual Property Rights therein, shall be owned, as between the Parties, solely by the Licensor (" Licensor Inventions ").

(d) All Inventions made solely by employees, agents and independent contractors of Licensee or its Affiliates or Sublicensees, pursuant to this Agreement and all Intellectual Property Rights therein, shall be owned, as between the Parties, solely by Licensee (" Licensee Inventions ").

(e) All Inventions made jointly by employees, agents and independent contractors of each Party or its Affiliates or sublicensees (including Sublicensees as applicable) pursuant to this Agreement, and all Intellectual Property Rights therein, shall be owned jointly by the Parties such that each Party shall have an undivided interest therein (" Joint Inventions ").

(f) All Patents claiming patentable, jointly owned Joint Inventions shall be referred to herein as " Joint Patent Rights ." Except to the extent either Party is restricted by the licenses granted to the other Party and covenants set forth herein, each Party shall be entitled to practice and exploit the Joint Inventions and the Intellectual Property Rights therein, for all purposes on a worldwide basis and to grant licenses thereunder, without any duty of accounting or obligation to seek consent from the other Party with respect thereto. Each Party will: (i) grant and hereby does grant all permissions, consents and waivers with respect to, and all licenses under, the Joint Inventions, and Intellectual Property Rights therein, throughout the world, (ii) execute documents as reasonably necessary to accomplish the foregoing, and (iii) reasonably cooperate with the other Party to transfer to such other Party physical embodiments (or copies thereof) of any Joint Inventions, [***].

(g) Each Party shall, and shall cause its sublicensees and Affiliates, and all independent contractors, employees and agents of such Party, to cooperate with the other Party and take all reasonable actions and execute such agreements, declarations, assignments, legal instruments and documents as may be reasonably required to perfect the other Party's right, title and interest in and to Inventions, and Patents thereon, and other Intellectual Property Rights as set forth in this Article 10.1 . Each Party shall also include provisions in its relevant agreements with Third Parties that affect the intent of this Article 10.1 .

(h) During the term of this Agreement, Licensee shall and hereby does grant to Licensor a royalty free, fully paid up, perpetual, irrevocable, non-exclusive, license, with the right to sublicense through multiple tiers, under Licensee Inventions and all Intellectual Property Rights therein, solely to Develop, Manufacture and Commercialize the Compound and/or the Product in the Licensor Territory , provided, that the license under Licensee Inventions and all Intellectual Property Rights therein covering or claiming any new uses of the Product outside of the Initial Indication shall be exclusive in the Licensor Territory solely to Develop, Manufacture and Commercialize the Compound and/or the Product. This license shall be superseded by the license granted under Article 13.2(d) upon the expiration or termination of this Agreement .

10.2 Prosecution and Maintenance of Licensed Patents .

(a) Prosecution of Licensed Patents .

(i) As between Licensee and Licensor, Licensor shall have the sole right but not the obligation for the filing, prosecution and maintenance of all Licensed Patents in the Licensor Territory at Licensor's sole discretion and [***].

(ii) As between Licensee and Licensor, Licensor shall have the first right, but not the obligation, for the filing, prosecution and maintenance of all Licensed Patents (including the Joint Patent Rights) in the Licensee Territory [***], provided that if Licensor intends to abandon, or not to file a patent application covering, any such Licensed Patents (including Joint Patent Rights) that is not sublicensed to Licensee under the Pfizer License Agreement in any country in the Licensee Territory (a " Non-Pfizer Puma Patent Right "), Licensor shall provide Licensee with a written notice of such intent at least [***] ([***]) days in advance of the relevant deadline. In such case: (X) Licensee will provide a written response to Licensor at least [***] ([***]) days in advance of the relevant deadline if Licensee wishes to, file, prosecute and maintain (in its sole discretion) such Non-Pfizer Puma Patent Right in such country; (Y) if Licensee provides the affirmative notice under clause (X) above, Licensor shall promptly provide all files related to filing, prosecuting and maintaining such Non-Pfizer Puma Patent Right to counsel designated by Licensee; (c) upon completion of the transfer of such files under clause (Y), Licensor shall no longer be responsible for the costs and expenses relating to filing, prosecuting and maintaining (as applicable) such Non-Pfizer Puma Patent Right in such country; and (d) solely for the purpose of determining the Royalty Term for the Product, the term "Licensed Patent" automatically shall be modified to exclude such Non-Pfizer Puma Patent Right in such country as of the date Licensee provides such written request to Licensor.

(iii) Licensor agrees to inform with sufficient advance notice and coordinate with Licensee through the Patent Working Group with respect to patent prosecution or other proceedings with respect to the Licensed Patents in the Licensee Territory. Licensor shall provide Licensee with copies of each draft patent application to be filed as well as copies of each office action received from the relevant patent offices in each country of the

Licensee Territory, in each case with enough lead time where reasonably practicable, to enable Licensee to review and comment on such application or action, which comments shall be taken into account by Licensor.

(iv) Licensor shall consider in good faith Licensee's comments and feedback with respect to strategic patent prosecution decisions, including extension countries, patent term extension (or similar additional or supplementary protection), and Unitary Patent court opt-out. Subject to the above good faith consideration, Licensor is not required to incorporate Licensee's comments and, subject to the provisions of this Agreement, retains final decision-making authority with respect to prosecution and maintenance of such Licensed Patents .

(v) Licensor shall not decide to not file a patent or to discontinue prosecution, maintenance or defense of any Licensed Patents (other than Non-Pfizer Puma Patent Right) or otherwise abandon any such Licensed Patents without Licensee's written consent, which shall not be unreasonably withheld or delayed. Without limiting the foregoing, Licensee may withhold consent if Licensor has not obtained a permission from Pfizer to assign to Licensee the right to undertake or continue such prosecution, maintenance or defense at its sole cost and expense. If responsibility for prosecution, maintenance or defense of any of the Licensed Patents (other than Non-Pfizer Puma Patent Right) are assigned to the Licensee in accordance with this Article , then [***]. Licensee shall hold all information disclosed to it under this Article 10.2 as confidential. If such responsibility is so assigned to the Licensee, then Licensee shall be responsible for providing information required to be provided to Pfizer pursuant to the Pfizer License Agreement in connection with such activities as provided in Article 7.5 thereof.

(b) Patent Term Extensions .

(i) The Parties shall determine the strategy with respect to patent term extension or similar additional or supplemental protection in the Licensee Territory, including the Patent(s) to be extended in order to maximize the sales of the Product in the Licensee Territory (the " **Patent Extension Strategy** "). If the Parties cannot agree on the Patent Extension Strategy at least [***] ([***]) months before the applicable deadline to file the patent term extension or similar additional or supplemental protection in the Licensee Territory, the Parties shall designate an independent patent counsel (" Expert ") by mutual agreement no later than [***] ([***]) months before the applicable filing deadline (and in the absence of such agreement by such time, such Expert shall be selected by the ICC International Centre for ADR in accordance with the Rules for the Appointment of Experts and Neutrals of the International Chamber of Commerce, which procedure shall only apply to such selection) . Within [***] ([***]) days after such expert has been selected, Licensor will provide to the expert and to Licensee copies of the EP Patents in EXHIBIT 1 along with the Summary of Product Characteristics ("SumPC") issued by the EMA for the Product. Within [***] ([***]) days after receiving the EP Patents in EXHIBIT 1 and the SumPC, the Expert shall make a recommendation as to which of the EP Patents to choose for Supplemental Protection Certificate (" SPC ") protection. The decision of the Expert will be [***] on the Parties, provided that in the event that neither Party agrees with the Expert's recommendation as to the EP Patents to choose for SPC , [***] will [***] the final decision making right regarding the same. [***].

(ii) After the Patent Extension Strategy has been determined, Licensor shall implement such strategy and file all applications and take actions necessary to obtain patent term extensions, or similar additional or supplemental protection [***], with respect to the Product under statutes in any country within the Licensee Territory, which extensions shall be owned, as between the Parties, by Licensor. The Parties shall fully cooperate to obtain such extensions and additional protection.

10.3 Notice . Each Party will promptly notify the other Party in writing of (a) any actual or threatened infringement, misappropriation, other violation, or challenge to the validity, scope or enforceability by a Third Party of any Licensed Intellectual Property in the Non-Encumbered Territory or the Licensee Territory of which it becomes aware (" Third Party Infringement "), (b) any allegation by a Third Party that any Intellectual Property Right owned by it is infringed, misappropriated, or otherwise violated by the Development, Manufacturing or Commercialization of the Product in the Licensee Territory or the Non-Encumbered Territory, each of which it becomes aware (" Defense Action ").

10.4 Third Party Infringement Claims .

(a) Licensee Control . Subject to this Article 10.4(a) , Licensee shall have the first right (but not the obligation), [***], to control enforcement of the Licensed Intellectual Property against any Third Party Infringement in the Licensee Territory. Prior to commencing involvement in any such suit, action or proceeding, Licensee shall consult with Licensor and shall consider Licensor's timely recommendations regarding the proposed suit, action or proceeding, except to the extent delay may reasonably result in the loss of rights by or otherwise adversely impact Licensee. Licensee shall give Licensor timely notice of any proposed settlement of any such suit, action or proceeding that Licensee controls and [***]. Notwithstanding anything to the contrary herein, Licensor shall have the sole right, [***], to control enforcement of [***] against any Third Party Infringement in the Licensee Territory.

(b) Licensor's Control . Licensor shall have the right (but not the obligation) to control enforcement of the Licensed Intellectual Property against any Third Party Infringement if Licensee provides Licensor with written notice that it is not exercising its right to control such enforcement, or if Licensee fails to timely initiate or file the relevant response to (as applicable), a suit, action or proceeding with respect to such Third Party Infringement prior to the expiration of the [***] ([***]) day period following first receipt by either Party of notice from the other Party of such Third Party Infringement.

(c) Rights of Non-Controlling Party . Notwithstanding anything to the contrary herein, the Party that is not controlling the suit, action or proceeding pertaining to enforcement of the Licensed Intellectual Property against Third Party Infringement as described in this Article 10.4 shall join as a party to such suit, action or proceeding upon the reasonable request and expense of the Party controlling such action if necessary for standing purposes. The Party that is not controlling such a suit, action or proceeding shall have the right to be represented by counsel (which shall act in an advisory capacity only, except for matters solely directed to such Party) of its own choice and [***] (subject to subsection (d) below) in any such suit, action or proceeding.

(d) Recovery . After giving effect to any applicable allocation of recoveries pursuant to the Pfizer License Agreement, recoveries shall be allocated as follows: [***].

(e) Defense Actions . Licensee shall have all authority with respect to any such Defense Action in the Licensee Territory, including the right to exclusive control of the defense of any such suit, action or proceeding and the exclusive right to compromise, litigate, settle or otherwise dispose of any such suit, action, or proceeding; provided that Licensee shall keep Licensor timely informed of the proceedings and filings, and provide Licensor with copies of all communications pertaining to each such Defense Action and [***].

10.5 Recordation . In those countries where Licensee wishes to record its patent licenses, promptly following Licensee's request, Licensor shall record the Pfizer License Agreement at Licensor's expenses, and will provide to Licensee, a separate license for the Licensed Patents so that Licensee can arrange for the recordation of its license with the appropriate governmental agency, [***]. The Parties shall cooperate in the preparation and execution of such documents and Licensor shall provide all reasonable assistance to Licensee in this respect. Notwithstanding anything to the contrary herein, in the event the recording of the Pfizer License Agreement requires the consent, approval or other execution of signature(s) by Pfizer or its Affiliates, then Licensor shall use its commercially reasonable efforts to obtain such consent, approval or signature, as applicable, and if Pfizer or its Affiliate does not consent, approve or otherwise provide with its signature, then Licensor shall not be in breach of this Article 10.6 .

10.6 Patent Marking . To the extent required by applicable Laws, Licensee agrees to mark, and have its Affiliates and Sublicensees mark, all patented Product they sell or distribute pursuant to this Agreement in accordance with the applicable patent statutes or regulations in the country or countries of sale thereof.

ARTICLE XI
TRADEMARKS

11.1 Display .

(a) All packaging materials, labels and Marketing Materials for the Product shall display the Product Trademarks and no other product-specific trademarks or branding.

(b) Each Product shall be sold in the Licensee Territory under the trade name of Licensee or other trade name chosen by Licensee and the logo of Licensee. Licensee shall use Licensor's registered trademark Nerlynx®. The trademarks of Licensee, trade dress, style of packaging and the like with respect to Products in the Licensee Territory may be determined by Licensee in a manner that is consistent with Licensee's standard trade dress and style, but shall be subject to the review by the JSC to ensure the same are consistent with Licensor's global trademark guidelines.

11.2 Grant of License . Subject to the terms and conditions of this Agreement, Licensor hereby grants, and shall cause its Affiliates to grant, to Licensee a royalty-free, fully paid up, exclusive license to use the Product Trademark(s) solely for the purpose of Commercializing the Product in the Field and in the Licensee Territory in accordance with this Agreement. Licensor shall [***] and use its commercially reasonably efforts to otherwise maintain the registered Product Trademark(s) throughout the Licensee Territory [***]. If the Product Trademark(s) is not registered in any country of the Licensee Territory, Licensor shall file and [***], and use its commercially reasonable efforts to register, and maintain such Product Trademark(s) in such country as reasonably requested by Licensee, [***], and such Product Trademark(s) shall be deemed to be included in EXHIBIT 5 .

11.3 Recordation of Licenses . In those countries where Licensee wishes to record its trademark license, Licensor will provide to Licensee, on Licensee's written request, a separate trademark license for the Product Trademarks licensed by Licensor to Licensee, and Licensee will arrange for the recordation of such trademark license with the appropriate Governmental Authority, [***], promptly following receipt of such license from Licensor. The Parties shall cooperate in the preparation and execution of such documents and Licensor shall provide all reasonable assistance to Licensee in this respect [***].

11.4 Enforcement .

(a) If either Party becomes aware of any actual or threatened infringement of any Product Trademarks in the Licensee Territory, such Party shall promptly notify the other Party in writing. Licensee shall have the first right, [***], to initiate infringement proceedings or take other appropriate actions against an infringement of any Product Trademarks in the Licensee Territory and/or to defend any actions or proceedings involving the Product Trademarks in the Licensee Territory, as the case may be.

(b) If Licensee does not initiate proceedings or take other appropriate action within [***] ([***]) days of receipt of a request by Licensor to do so, then Licensor shall be entitled, [***], to initiate infringement proceedings or take other appropriate action against an infringement of the Product Trademark in the Licensee Territory, or to defend any actions or proceedings involving or affecting a Product Trademarks in the Licensee Territory, as the case may be.

(c) The Party conducting such action shall have full control over the conduct of such action, including settlement thereof; provided, however, that [***].

(d) In any event, the Parties shall keep one another informed of the status of their respective activities regarding any litigation in the Licensee Territory involving a Product Trademarks or settlement thereof and shall assist one another and cooperate in any such litigation at the other's reasonable request (including joining as a party plaintiff to the extent necessary and requested by the other Party). [***].

11.5 Domain Names . Licensor shall own rights to, and shall be responsible, [***], for registering and maintaining, the Internet domain names listed on EXHIBIT 5 (each of the foregoing, a " Domain Name ") and agrees to grant, and hereby grants to Licensee a royalty-free, fully paid-up non-exclusive license to use those particular Domain Names in connection with its Commercialization of the Product in the Licensee Territory in accordance with this Agreement. In the event Licensee would like to use an available Internet domain name that includes any Product Trademarks Controlled by Licensor and not previously registered in the Licensee Territory as a country-level Internet domain name, Licensor grants Licensee its consent to register and maintain such Internet domain names in Licensee's name and [***].

ARTICLE XII
TERM AND TERMINATION

12.1 Term . This Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to this Article 12 , shall expire upon the last-to-expire Royalty Term.

12.2 Termination for Material Breach . Either Party shall have the right to terminate this Agreement in the event the other Party has materially breached or defaulted in the performance of any of its material obligations hereunder and in the overall context of the Agreement, and such breach continues for ninety (90) days after written notice thereof was provided to the breaching Party by the non-breaching Party which clearly mentions the remedies that the non-breaching Party intends to apply should the breach remain uncured (the " Notice of Termination ") . Any such termination shall become effective at the end of such ninety (90) day period if, prior to the expiration of the ninety (90) day period, the breaching Party has not disputed or cured any such breach or default. Such ninety (90) day period may be extended if the breaching party communicates to the non-breaching Party a written remediation plan reasonably designed to cure such breach or default within a reasonable additional time period, not to exceed an additional ninety (90) days following expiration of the foregoing ninety (90) day period . If the allegedly breaching Party disputes in good faith the material breach set forth in a Notice of Termination provided by the non-breaching Party in accordance with this Article 12.2 and provides written notice of such dispute to the non-breaching

Party within thirty (30) of the Notice of Termination, this Agreement shall not be terminable by the non-breaching Party until it has been determined by arbitration under Article 16.3 (" Arbitration Period ") that this Agreement was materially breached by the breaching Party and then only if the breaching Party has not cured the material breach set forth in the Notice of Termination within thirty (30) days following such arbitration determination . [***]

12.3 Termination for Bankruptcy . Either Party shall have the right to terminate this Agreement upon written notice to the other Party: (a) if such other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against such other Party and such petition is not dismissed within ninety (90) days after filing; (c) if such other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors; or (d) substantially all of the assets of such other Party are seized or attached and not released within ninety (90) days thereafter. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to intellectual property as defined in Section 101 of such Code. The Parties agree that Licensee may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets. The Parties further agree that, in the event Licensee elects to retain its rights as a licensee under such Code, Licensee shall be entitled to complete access to any Licensed Intellectual Property and all embodiments of such technology.

12.4 Termination for Convenience . Licensee shall be permitted to terminate the Agreement at will with six (6) months' prior written notice.

12.5 Termination for Safety Reasons . Licensee shall be permitted to terminate the Agreement for safety reasons upon sixty (60) days written notice to Licensor if Licensee has evidence of safety issues on the basis of which a reasonable investigator would conclude that such issues will prevent the successful Development and Commercialization of the Product hereunder. Licensee shall provide such evidence to Licensor together with such notice and shall discuss such evidence as reasonably requested by Licensor. If Licensee determines, in its reasonable judgement, that it has evidence of safety issues that are likely to prevent the successful Development and Commercialization of the Product hereunder, Licensee may so notify Licensor in writing. In such event, whether or not the situation is determined to trigger Licensee's right to terminate the Agreement for safety reasons pursuant to the first sentence of this Article 12.5 , Licensee's obligations under Article 5.1 shall be suspended for a reasonable time period to enable the Parties to understand whether such issues exist and if so, address such issues (such suspension period not to be longer than ninety (90) days).

12.6 Alternative to Termination for Material Breach . If Licensor has materially breached or defaulted in the performance of any of its material obligations hereunder, including its representations and warranties pursuant to Article 14 , and such breach is not curable or has not been cured within ninety (90) days after written notice thereof was provided by Licensee, then, without limiting any other remedies of Licensee, Licensee may elect to continue the Agreement, provided that (i) Licensee shall be released of its diligence obligations pursuant to Article 5.1(a) to the extent such obligations are impacted by Licensor's breach and (ii) the payments to be made hereunder by Licensee to Licensor shall be reduced by [***] until such time as the resulting aggregate reduction equals the damages Licensee suffered as a result of Licensor's breach as will be finally determined by mutual agreement or pursuant to Article 16 [***]; provided that in no event shall a Royalty Rate under this Agreement be reduced to a number that is less than [***] by reason of such offset and/or through the application of Article 6.5 .

12.7 No Partial Termination . This Agreement may not be terminated by Licensee under Article 12.4 , 12.5 or by either Party for cause under Article 12.2 or for bankruptcy under Article 12.3 on a country-by-country or other partial basis.

ARTICLE XIII
EFFECT OF TERMINATION

13.1 Accrued Obligations . The expiration or termination of this Agreement for any reason shall not release either Party from any liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination, nor will any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement, provided that any milestone payment that is achieved under Article 6.2 during the termination notice period shall be reduced by [***] percent ([***]%). For clarity, any Deferred Sales Milestone Amount shall not be subject to the foregoing reduction.

13.2 Rights on Termination of Agreement . In case of termination of this Agreement by either Party, this Article 13.2 shall apply:

(a) Wind -down Period.

(i) Licensee shall use commercially reasonable efforts to effect a smooth termination of the Agreement, including by performing the activities set forth in Articles 13.2(a)(iii) , (iv) or (v) , for a period not exceeding six (6) months following the termination of the Agreement (" **Transition Period** ").

(ii) Licensee shall have the right to sell its remaining inventory of the Product in the Licensee Territory following the termination of this Agreement during the Transition Period.

(iii) In the event Licensee is the sponsor of or conducting any on-going Clinical Studies of the Product and/or any ongoing pre-clinical studies and/or formulation studies (e.g., stability studies) of the Product following the date a notice of termination has been issued by Licensor or Licensee, as applicable, Licensee shall be entitled to complete or wind down such activities, unless Licensor requests that they be transitioned to Licensor, in which case Licensee shall use commercially reasonable efforts to support such transition to Licensor, at Licensor's costs.

(iv) Each Party shall use commercially reasonable efforts to cooperate with the other and /or its designee to effect a smooth and orderly wind down or transition in of the activities related to the Product in the Licensee Territory during the Transition Period .

(v) Licensee shall provide Licensor with country specific Marketing Materials for use limited to the Product and subject to Third Party copyrights.

[***].

(b) Each Party shall pay to the other Party all amounts due to the other Party with respect to the Shared Development Budget, Post-Approval Marketing Study Costs and any Deferred Sales Milestone Amount accrued and unpaid as of the effective date of termination or expiration, within sixty (60) days following the effective date of termination or expiration.

(c) Subject to Article 13.2(a)(i) , upon termination of this Agreement all licenses granted by Licensor to Licensee shall terminate.

(d) Effective automatically upon any expiration or termination of this Agreement, Licensee shall and hereby does grant to Licensor a non-exclusive, worldwide, transferable, perpetual and irrevocable license, with the right to sublicense through multiple tiers, under any Intellectual Property Rights Controlled by Licensee claiming Inventions that are necessary or reasonably useful for the Development, Manufacture, Commercialization or other Use of the Product as they exist at the time of such termination of this Agreement solely to Develop, Manufacture, Commercialize and otherwise Use the Product, provided , that in case of termination of this Agreement (as opposed to expiration) , the license under Licensee Inventions and all Intellectual Property Rights therein covering or claiming any new uses of the Product outside of the Initial Indication shall be exclusive to Develop, Manufacture and Commercialize the Compound and/or the Product.

(i) Within sixty (60) days following any expiration or termination of this Agreement, the Parties shall meet and discuss in good faith the appropriate compensation payable to Licensee, if any, in consideration for such license (" Termination License Compensation "). In determining Termination License Compensation, relevant factors including but not limited to the value of the intellectual property involved, the jurisdictions in which any relevant Patents have been filed, whether Licensee is a sole or joint inventor and the nonexclusive nature of the license shall be considered. If the Parties do not, within such sixty (60) day time period, agree upon the Termination License Compensation, then either Party may submit for resolution pursuant to subsection (ii) whether any Termination License Compensation should be paid, and if so, the amount of the Termination License Compensation (a " Termination License Dispute ").

(ii) Any Termination License Dispute that remains unresolved after the discussions conducted pursuant to subsection (i), but no other issues arising under this Agreement, shall be submitted for resolution by expedited arbitration pursuant to this Article 13.2(d) . Any arbitration under this Article 13.2(d) shall be decided by a single arbitrator appointed pursuant to the Expedited Procedure Provisions of the Rules of Arbitration of the International Chamber of Commerce, irrespective of the amount in dispute. The place and language of the arbitration shall be those provided for in Article 16.3 herein. In such expedited arbitration, the arbitrator shall select an independent expert with significant experience relating to the valuation of intellectual property licenses in the life sciences industry, at a senior executive level, to advise the arbitrator with respect to the subject matter of the dispute. The Parties agree that the arbitrator shall have the power to resolve any disputes to be resolved pursuant to this Article 13.2(d) based on principles of fairness and equity. [***]. Notwithstanding the foregoing, Licensor shall have the right to decline or terminate a license under one or more Licensee Inventions and Intellectual Property Rights therein by written notice to Licensee, in which case the foregoing license shall not include the declined or terminated Licensee Inventions and Intellectual Property Rights therein and Licensor shall not have any payment obligations with respect thereto.

(e) Assignment of Regulatory Filings and Marketing Approvals . Licensee shall assign (or cause to be assigned) to Licensor or its designee, [***] (or to the extent not so assignable, Licensee shall take all reasonable actions to make available to Licensor or its designee the benefits of) all Regulatory Filings for the Product in the Licensee Territory, including any such Regulatory Filings made or owned by its Affiliates and/or Sublicensees. In each case, unless otherwise required by any applicable Law or regulation or requested by Licensor, the foregoing assignment (or availability) shall be made within a period of time agreed upon and consistent with the Wind-Down Period.

(f) Return of Confidential Information . Within thirty (30) days after the end of the Wind-down Period upon request by Licensor, Licensee shall either return to Licensor or destroy all tangible items comprising , bearing or containing Confidential Information of Licensor, that is in Licensee's possession, subject to Licensee's right to keep one copy for archiving purposes.

(g) Trademarks .

(i) Effective upon the end of the Wind-down Period, Licensee shall cease to use all Trademarks of Licensor (including the Product Trademarks) in the Licensee Territory, and all rights granted to Licensee hereunder with respect to the Product in the Licensee Territory shall terminate.

(ii) Effective upon the effective date of termination, Licensee agrees to assign on reasonable commercial terms to be agreed by the Parties all worldwide rights in and to any Product Trademarks, other than Product Trademarks of Licensor, specific to one or more Product that Licensee or any of its Affiliates used in connection with Product(s). It is understood that such assignment shall not include the name of Licensee or any of its Affiliates, nor the corporate logo, service mark, or trademark for Licensee or for any of its Affiliates as a corporate entity.

(iii) Sublicensees . Any contracts with Sublicensees in the Licensee Territory engaged by Licensee shall, at the request of Licensee in its discretion, be assigned to Licensor to the furthest extent possible. Licensee shall use commercially reasonable efforts , and cause its Affiliates to use Commercially Reasonably Efforts, to waive any exclusive dealing obligations of such Third Party with respect to such Third Party agreement, and to provide to Licensor information relevant to the Third Party agreement and make introductions to such Third Party so that Licensor may enter into direct discussions with such Third Party to secure the relevant items or services.

(h) Miscellaneous. The grant by Licensee to Licensor of the rights set forth in Articles 13.2(a)(i) , (d) , (e) and (g)(ii) is conditioned upon the grant by Licensor of the indemnity set forth in Article 15.2 with respect to the Third Party Claims resulting from Licensor (or its designee's) Development, registration, Manufacture and Commercialization of the Product in the Licensee Territory following termination of this Agreement.

13.3 Survival . Upon the expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate except those which are expressly or by their nature set to survive termination as well as those described in the following Articles : 1 , 2.2 , 2.3(a) , 2.4 , 2.8 , 7 , 9 , 10.1 , 12.7 , 13 , 15 (solely to the extent Third Party Claims were incurred during the term of this Agreement), 17.2 through 17.8 (inclusive), 17.10 through 17.13 (inclusive).

ARTICLE XIV
REPRESENTATIONS, WARRANTIES AND COVENANTS

14.1 Mutual Covenants, Representations and Warranties . Each Party covenants, represents and warrants to the other Party that, as of the Effective Date:

(a) it is a corporation duly organized, validly existing and is in good standing under its Laws or incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement;

(b) this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by such Party has been duly authorized by all necessary corporate action and does not and will not: (i) require the consent or approval of such Party's stockholders; (ii) to its knowledge, violate any Law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over it; nor (iii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound;

(c) it, its subsidiaries, and its Affiliates are in compliance with, and at all times during the term of this Agreement shall remain in compliance with, all applicable antibribery or anticorruption Laws. Neither such Party nor any of its subsidiaries, or Affiliates has, or will, authorize, offer, promise, or make payments or otherwise provide anything of value directly or indirectly to: (i) an executive , official, employee or agent of a government, governmental department, agency or instrumentality, (ii) a director, officer, employee or agent of a wholly or partially government-owned or controlled entity, (iii) a political party or official thereof, or candidate for political office, or (iv) an executive, official, employee or agent of a public international organization (e.g., the International Monetary Fund or the World Bank) (" Government Official ") for purposes of (A) (i) improperly influencing any act or decision of such Government Official in his or her official capacity, (ii) inducing such Government Official to do or omit to do any act in violation of the lawful duty of such Government Official, or (iii) securing any improper advantage; or (B) inducing such Government Official improperly to use his or her influence in order to assist the Company or any of its subsidiaries in obtaining or retaining business or to direct business to any person. Neither Party shall, during the term of this Agreement, provide anything of value to any person that may be considered a bribe, kickback, an illegal influence payment, or other illegal payment;

(d) all necessary consents , approvals and authorizations of all Regulatory Authorities, other Governmental Authorities and other persons or entities required to be obtained by it in order to enter into this Agreement have been obtained; and

(e) it is not subject to a corporate integrity agreement or equivalent thereof, or a comparable obligation to a Governmental Authority, in each case that is relevant to this Agreement or the Supply Agreement.

14.2 Representations and Warranties of Licensor . Licensor represents, warrants to Licensee that, as of the Effective Date:

(a) Licensor has the right and authority to grant the rights and licenses granted herein;

(b) Licensor has not previously granted any right, license or interest in or to the Licensed Intellectual Property that would interfere with the exercise of the licenses granted under this Agreement;

(c) As of the Effective Date, with the exception of proceedings with respect to Licensed Patents set forth in Schedule 14.2(c) , there are (i) no actual, pending, or, to the Licensor's knowledge, alleged, threatened, action, suits, claims, interference or governmental investigations involving the Product (including with respect to the Manufacturing of the Product), the Licensed Intellectual Property or the Product Trademarks by or against Licensor, or any of its Affiliates in the Licensee Territory, and (ii) to the Licensor's knowledge, there is no circumstances that may lead to any such action, suit, claims, interference or investigations;

(d) Licensor has not brought a claim alleging an infringement by a Third Party of any of the Licensed Intellectual Property in the Licensee Territory, and to Licensor's knowledge, as of the Effective Date, with the exception of proceedings with respect to Licensed Patents set forth in Schedule 14.2(d) , there is no circumstances that may lead to any such claim;

(e) To Licensor's knowledge, as of the Effective Date, the Use of the Product does not infringe the Intellectual Property Rights of any Third Party and Licensor has not received any claim alleging such any infringement. To Licensor's knowledge, none of the Licensed Patents are invalid or unenforceable;

(f) the Licensed Patents in the Licensee Territory listed on EXHIBIT 1 constitute a true, accurate and complete list of all Patents in existence as of the Effective Date Controlled by Licensor in the Licensee Territory relating to the Product in the Licensee Territory , and Licensor Controls such Licensed Patents in the Field and in the Licensee Territory, free of security interest;

(g) To Licensor's knowledge, all individuals who participated in the invention of any of the inventions claimed in the Licensed Patents have made effective assignments of all ownership rights either pursuant to written agreement or by operation of applicable Law;

(h) To Licensor's knowledge, all application and registration fees that have become due in respect of the Licensed Patents listed on EXHIBIT 1 and the Product Trademarks listed on EXHIBIT 5 have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of registering such Licensed Patents and such Product Trademarks;

(i) Licensor has taken reasonable precautions to preserve the confidentiality of the Licensed Technology;

(j) All Data with respect to Product that was provided or is intended to be provided to a Regulatory Authority, as of the Effective Date, has been generated and provided in compliance with applicable Laws, including applicable with GLP, GCP and GMP, in all material respects;

(k) Licensor has disclosed or made available to Licensee in writing, on the electronic diligence datasite, all copies of: (i) material study reports and Data from Clinical Studies or GLP preclinical studies of the Product in its possession that relate or is relevant to the Licensee Territory, and (ii) all material filings and correspondence between Licensor and its Affiliates, on the one hand, and any Regulatory Authority, on the other hand, relating to clinical or preclinical studies of the Product, in each case that are relevant to the rights granted to Licensee pursuant to this Agreement.

(l) No information or documentation provided by Licensor to Licensee contain, any untrue or misleading statement of a material fact or to Licensor's knowledge omit to state a material fact, with respect to the efficacy, side effects, formulation, stability, or preclinical or clinical testing or manufacturing of the Product;

(m) To Licensor's knowledge, in the course of the Development of the Product, Licensor has not used any employee or consultant who has been debarred by any Regulatory Authority, or was the subject of debarment proceedings by a Regulatory Authority, and to Licensor's knowledge, no such employees or consultants have been used by any Third Party contractor of Licensor in connection with the Development of the Product;

(n) The documents containing Data and Licensed Technology disclosed or made available to Licensee by Licensor are true and accurate copies of such documents in Licensor's possession;

(o) Licensor has the right to grant to Licensee the right to refer to and use any data and technology that has been generated by the manufacturers of the Product engaged by Licensor or its Affiliates for the use and registration of the Product as provided for in this Agreement and the Supply Agreement.

(p) With the exception of those proceedings relating to the Licensed Patents set forth in Schedule 14.2(p) , Licensor is not engaged in any litigation, opposition or arbitration affecting or relating to the Product, excluding oppositions before Patent authorities .

(q) To Licensor's knowledge, Licensor and its Affiliates are in material compliance with each Material Agreement, and have performed all material obligations required to be performed by them to date under the Material Agreement, except such non-compliance would not have a material impact on Licensor. To Licensor's knowledge, neither Licensor nor its Affiliates are in material breach under the Material Agreement and, to the knowledge of Licensor, no other party to any Material Agreement is in material breach in any respect thereunder, in each case, except such breach would not have a material impact on Licensor.

14.3 Representations and Warranties of Both Parties Related to Future Activities . Each Party represents, warrants to the other Party that:

(a) to the extent material to Use of the Compounds and the Product in the Licensee Territory, such Party shall, and shall ensure all Third Parties that it engages with respect to activities directed to the Compounds and the Product pursuant to this Agreement shall, comply in all material respects with all applicable Laws with respect to the performance of activities and obligations under this Agreement and the Supply Agreement;

(b) it will not knowingly utilize, in conducting Development, Manufacturing or Commercialization of the Product, any Person or entities that at such time are debarred by FDA, or that, at such time, are, to such Party's knowledge, under investigation by FDA for debarment action pursuant to the provisions of the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335);

(c) all employees, officers, contractors, and consultants of such Party or its Affiliates performing activities in connection with this Agreement shall execute or have executed agreements requiring assignment to such Party of all right, title and interest in and to their inventions and discoveries invented or otherwise discovered or generated during the course of and as a result of such activities, whether or not patentable, if any, prior to commencing such activities;

(d) such Party currently has, and will maintain during the term of this Agreement, directly or through Affiliates or Third Party subcontractors (i) sufficient qualified and trained personnel and resources, and (ii) necessary financial and technical capacity to effectively fulfill its obligations related to the Product as contemplated in this Agreement; and

(e) each Party represents and warrants to the other Party that as of the Effective Date, other than the Product, such Party is not, directly or with or through an Affiliate or Third Party, Developing, Manufacturing or Commercializing in or for the Licensee Territory, any product that targets the HER-2 receptor and that is intended for use, or approved for use, for the Initial Indication, provided that Licensee shall give no representation as to the activities of Pierre Fabre Médicament Production, its contract manufacturing Affiliate.

14.4 Certain Rights and Obligations under the Material Agreements .

(a) To the extent that any Background Agreement does not, as of the Effective Date, allow upon any termination of such Background Agreement, for the licenses granted to Licensor and sublicensed to Licensee to continue on substantially the same terms as were granted to Licensor, then, where requested by Licensee, Licensor shall use reasonable efforts to enable Licensee to secure such a separate agreement between Licensee and the applicable Third Party to provide for the grant of such rights to Licensee. In particular, within [***] ([***]) Business Days of the Effective Date, Licensor shall [***].

(b) To the extent that a Third Party is obligated to indemnify sublicensees of Licensor under a Material Agreement, and Licensee desires to assert a claim for indemnification, Licensor shall use reasonable efforts to cooperate with Licensee (at Licensee' expense) to permit Licensee to assert such claim against such Third Party.

(c) To the extent relating to the Product in the Licensee Territory, whenever Licensor receives any written report, notice or other communication from a Third Party with respect to the corresponding Material Agreement, Licensor shall promptly provide a copy of such report, notice or other communication to Licensee, in each case solely if such report, notice or communication would materially adversely affect the Product in the Licensee Territory or Licensee's rights under such Material Agreement with respect to the Product in the Licensee Territory.

(d) To the extent relating to the Product in the Licensee Territory, Licensor shall, if reasonably requested by Licensee and subject to obligations and limitations as provided under Third Party agreements, take reasonable efforts to exercise any of Licensor's rights or enforce any material obligation of a Third Party, [***], under the applicable Material Agreement. In addition, [***].

(e) To the extent relating to the Product in the Licensee Territory, Licensor shall not agree or consent to any substantive amendment , supplement or other modification to the Material Agreement or exercise any other right of agreement or consent thereunder, in each case to the extent that such amendment, supplement, modification, exercise or consent could adversely affect Licensee's rights under this Agreement, unless Licensee shall have consented in writing to the same, which consent may not be unreasonably withheld or delayed (and which agreement or consent of Licensee shall be provided within [***] ([***]) Business Days after a request therefor if such amendment, supplement or other modification would not adversely affect Licensee's rights under this Agreement).

(f) Licensor shall not terminate any Material Agreement and shall not take or fail to take any action that would reasonably permit the Third Party to terminate , (either unilaterally or by mutual agreement with the applicable Third Party), or any right thereunder relating to the Product in the Licensee Territory , without the prior written consent of Licensee, which consent may not be unreasonably withheld or delayed.

(g) Licensor shall not during the term of this Agreement (i) grant any lien, pledge, encumbrance, mortgage, or security interest (excluding any license rights or equivalents thereof) (collectively " Liens ") with respect to this Agreement or any of the Licensed Patents or Licensed Technology in the Licensee Territory or (ii) permit such a Lien, to attach to this Agreement or any of such rights, in each case if such Lien would conflict with the rights granted to Licensee hereunder.

(h) Licensor shall at all times comply with the terms of the Material Agreements. Licensor shall promptly notify Licensee of any actual or threatened breach of any Material Agreements of which Licensor becomes aware. Without limiting the foregoing, within [***] ([***]) Business Days after Licensor's receipt of any written notice , or otherwise becoming aware that such a notice may be

forthcoming, relating to any alleged breach by Licensor under such Material Agreements, Licensor shall notify Licensee thereof, specifying the basis for the alleged breach, as set out in the notice or otherwise known to Licensor . Without prejudice to any of Licensee's other rights under the Agreement or other remedies available to it, Licensee shall have the right to take step to cure an actual breach of the Material Agreements or prevent a termination of the Material Agreements, [***]. [***]

(i) If any Intellectual Property Right becomes Controlled by Licensor after the Effective Date that is subject to the licenses granted to Licensee under this Agreement, Licensor shall not revise, terminate or enter into any Third Party agreement related to or involving such Intellectual Property Right on terms that will cause such Intellectual Property Right to be no longer Controlled by Licensor for purposes of this Agreement.

14.5 Except as otherwise expressly set forth in this Agreement, neither Party makes any representation or extends any warranties of any kind either express or implied, including, but not limited to, warranties of merchantability, fitness for a particular purpose, noninfringement or validity of any Patents issued or pending.

ARTICLE XV
INDEMNIFICATION

15.1 Indemnification of Licensor . Licensee shall indemnify and hold harmless each of Licensor, its Affiliates and the directors, officers, shareholders and employees of such entities and the successors and assigns of any of the foregoing (the " Licensor Indemnitees "), from and against any and all liabilities, damages, penalties, fines, costs, expenses (including, reasonable attorneys' fees and other expenses of litigation) (" Liabilities ") from any claims, actions, suits or proceedings brought by a Third Party (a " Third Party Claim ") incurred by any Licensor Indemnitee, arising from, or occurring as a result of: (a) the Development, Manufacturing, Commercialization or other Use of any Compounds and Product by Licensee, its Affiliates or Sublicensees in the Licensee Territory or otherwise pursuant to this Agreement, including any products liability claim arising therefrom; (b) any Clinical Studies sponsored by or on behalf of Licensee in the Licensee Territory (other than Post-Approval Marketing Studies sponsored by Licensor in the Licensee Territory in accordance with Article 4.1(b)), including any products liability claim arising therefrom, (c) the gross negligence or wrongful intentional acts or omissions of Licensee, its Affiliates, subcontractors or Sublicensees; (d) breach by Licensee of any representation, warranty, obligation or covenant as set forth in this Agreement, or (e) the practice by Licensee of the Licensee Technology outside the scope of the licenses granted to Licensee as set forth in this Agreement; except, in each case (a), (b), (c) and (d), to the extent such Third Party Claims arises from the circumstances for which Licensor shall indemnify Licensee Indemnities pursuant to Article 15.2 .

15.2 Indemnification of Licensee . Licensor shall indemnify and hold harmless each of Licensee, its Affiliates and Sublicensees and the directors, officers and employees of Licensee, its Affiliates and Sublicensees and the successors and assigns of any of the foregoing (the " Licensee Indemnitees "), from and against any and all Liabilities from any Third Party Claims incurred by any Licensee Indemnitee, arising from, or occurring as a result of: (a) the Development, Manufacturing, Commercialization or other Use of any Compounds and Product by Licensor, its Affiliates or Sublicensees in the Licensor Territory, including any products liability claim arising therefrom (or following termination of this Agreement, anywhere in the world); (b) any Post-Approval Marketing Studies sponsored by Licensor in the Licensee Territory in accordance with Article 4.1(b) , (c) the gross negligence or wrongful intentional acts or omissions of Licensor, its Affiliates, subcontractors or Sublicensees; (d) Clinical Studies sponsored by or on behalf of Licensor in the Licensee Territory, including any products liability claim arising therefrom, (d) breach by Licensor of any representation, warranty, obligation or covenant as set forth in this Agreement, or (e) the practice by Licensor of the intellectual property rights licensed to Licensor by Licensee outside the scope of the licenses granted to Licensor as set forth in this Agreement.

15.3 Procedure . A Party that intends to claim indemnification under this Article 15.3 (the " Indemnitee ") shall promptly notify the other Party (the " Indemnitor ") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement, provided the Indemnitor may not settle the Third Party Claim without the Indemnitee's prior written consent, which shall not be unreasonably withheld or delayed, in the event such settlement materially adversely impacts the Indemnitee 's rights or obligations, and further provided that the Indemnitor shall keep the Indemnitee regularly informed of the status of the defense of the Third Party Claim and shall take into consideration the Indemnitee's reasonable comments thereon. The Indemnitee shall have the right to participate (but not control) and be represented in any suit or action by advisory council of its selection and [***]. [***]. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 15.3 , but the omission to so deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Article 15.3 . The Indemnitee under this Article 15.3 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

15.4 Disclaimer of Liability for Consequential Damages . UNLESS EXPRESSLY PROVIDED HEREUNDER, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS AND EMPLOYEES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUFFERED BY THE OTHER PARTY UNDER THIS AGREEMENT, OF ANY KIND WHATEVER AND HOWEVER CAUSED, AND WHETHER BASED ON AN ACTION OR CLAIM IN CONTRACT, TORT (INCLUDING NEGLIGENCE), BREACH OF STATUTORY DUTY OR OTHERWISE, AND EVEN IF FORESEEABLE OR SUFFERED IN CIRCUMSTANCES WHERE A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSSES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS ARTICLE 15.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE AMOUNTS PAYABLE TO THIRD PARTIES UNDER THE INDEMNITIES PROVIDED PURSUANT TO ARTICLES 15.1 AND 15.2 ABOVE.

15.5 During the term of the Agreement as set forth in Article 12.1 and thereafter for a period of [***] ([***]) years, each Party shall procure and maintain adequate insurance coverage with international reputable company(ies) or a program of self-insurance (which shall be of types and amounts sufficient to cover the liabilities hereunder, contingent or otherwise of such Party and its Affiliates). It is understood that such insurances shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 15. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] ([***]) days prior to the cancellation, non-renewal or material change in such insurance.

ARTICLE XVI
DISPUTE RESOLUTION

16.1 Referral to Senior Executives . The Parties recognize that a dispute arising out of or in connection with this Agreement (" **Dispute** ") may from time to time arise during the term of this Agreement. Any such Dispute which cannot be resolved by good faith negotiations shall be referred, by written notice from either Party to the other, to the Senior Executives (or their respective designees) for resolution. The Senior Executives (or their respective designees) shall negotiate in good faith to resolve such Dispute through discussions promptly following such written notice. If the Senior Executives cannot resolve the Dispute within [***] ([***]) days of such written notice, or either Party concludes that the matter will not be so resolved, then, the provisions of Article 16.2 shall apply. If the Parties should resolve such Dispute pursuant to the procedures in this Article 16.1 , a memorandum setting forth their agreement will be prepared and signed by both Parties, if requested by either Party.

16.2 Mediation . If the Senior Executives (or their respective designees) cannot resolve the Dispute during the [***] ([***]) day period pursuant to Article 16.1 , the Parties shall first refer the dispute to proceedings under the ICC Mediation Rules. Such mediation shall take place in Paris , France and shall be attended on behalf of each Party for at least one session by a senior business person with authority to resolve the Dispute.

16.3 Arbitration . Any Dispute not resolved under the procedures in Article 16.2 within [***] ([***]) days following the filing of a Request for Mediation or within such other period as the parties may agree in writing, such Dispute shall thereafter be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators. The President of the Tribunal shall be nominated by the two-party nominated arbitrators within [***] ([***]) days of the second arbitrator's appointment. The seat, or legal place, of arbitration shall be Paris, France. The language of the arbitration shall be English. The final award shall be rendered within [***] ([***]) months of the constitution of the tribunal, unless the tribunal determines that the interest of justice requires that such limit be extended. Except as may be required to confirm or enforce a final award, or as may be required by applicable Law, neither a Party nor an arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.

16.4 Non -Disclosure of Communications with Internal Counsel . Notwithstanding any rights to the contrary under applicable procedural or substantive rules of Law, any communications exchanged between members of each Party's respective legal department and directors, employees or agents in connection with any disputes, investigations, administrative or other proceedings, shall not be requested, produced or otherwise used, to the extent such communications would have been covered by legal privilege and not discloseable, had these communications been exchanged between such Party and its external attorneys.

ARTICLE XVII
GENERAL PROVISIONS

17.1 Force Majeure . If the performance of any part of this Agreement (except for any payment obligation under this Agreement) by either Party is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of such Party (including, fire, flood, earthquake, tsunami, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance, acts of God or any acts, omissions or delays in acting of the other Party), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its reasonable efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

17.2 Governing Law . This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with , the laws of France , without reference to conflict of law principles. The Parties hereby agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and are strictly excluded.

17.3 Waiver of Breach . The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

17.4 Modification . No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

17.5 Severability . In the event any provision of this Agreement should be held invalid, illegal, or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

17.6 Entire Agreement; Amendments . This Agreement (including the Exhibits attached hereto), together with the Pharmacovigilance Agreement, the Quality Agreement, and the Supply Agreement (in each case, when executed) constitute the entire agreement between the Parties relating to the subject matter hereof and supersede all prior and contemporaneous agreements, representations and/or understandings, including the Confidentiality Agreement between the Parties dated January 9, 2018 and amended on December 19, 2018. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

17.7 Notices . Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice required or permitted under this Agreement shall be in writing in the English language, and (a) delivered personally, (b) sent by air mail or express courier service providing evidence of receipt, postage pre-paid where applicable, or (c) by electronic transmission or facsimile (complete transmission confirmed and a copy promptly sent by another permissible method of providing notice described in paragraph (a) or (b) above), to the following addresses of the Parties (or such other address for a Party as may be specified by like notice):

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

To Licensee:
Pierre Fabre Medicament SAS
45 place Abel Gance
92100 Boulogne Billancourt, France
Attn: Chief Executive Officer

With a copy to (which shall not constitute notice):

Latham & Watkins LLP
140 Scott Drive
Menlo Park, CA 94025, USA
Attn: [***]

With a copy to (which shall not constitute notice):

Pierre Fabre Medicament SAS

Parc Industiel La Chartreuse

81106 Castres, France

Attn: General Counsel

Any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the Party to whom it is addressed.

17.8 Assignment.

(a) Except as provided in Article 17.8(b) , neither Party may assign or transfer this Agreement or any rights or obligations hereunder to a Third Party without the prior written consent of the other Party.

(b) A Party may assign this Agreement without the other Party's consent (i) with respect to Licensor, to a Third Party that acquires substantially all of the business or assets of Licensor, or (ii) with respect to Licensee, to a Third Party that acquires all or substantially all of Licensee's oncology business or assets, in each case (i) and (ii) whether by merger, acquisition or otherwise, provided that the acquiring party agrees in a writing delivered to the non-assigning Party to assume all of the rights and obligations of the assigning Party under this Agreement.

(c) A Party shall have the right to assign this Agreement to an Affiliate, with the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), provided that (i) the assigning Party guarantees the performance of this Agreement by such Affiliate, (ii) such Affiliate agrees in a writing delivered to the non-assigning Party to assume all of the rights and obligations of the assigning Party under this Agreement, and (iii) if the non-assigning Party reasonably believes such assignment could result in material adverse tax consequences to the non-assigning Party, the non-assigning Party shall have no obligation to consent to the proposed assignment.

(d) Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Article 17.8 shall be null and void.

(e) Notwithstanding anything contrary in this Agreement, Licensor shall not assign, pledge or otherwise transfer its rights to receive some or all of the Milestone Payments and Royalties payable hereunder without Licensee's prior written consent in its sole discretion.

17.9 Performance . Unless expressly otherwise provided hereunder, each Party or its Affiliates may perform its obligations hereunder through its Affiliates or Subcontractors, provided that such Party shall have entered into a written agreement (a " Subcontract ") with its Subcontractors which shall be consistent with the terms and conditions of this Agreement, shall contain confidentiality and non-use provisions no less restrictive than those set forth in Article 9 . Additionally, to the extent that such Subcontractor shall be responsible for performance of any Development activities undertaken in accordance with this Agreement, then the applicable Subcontract shall contain a certification that such Subcontractor has not been debarred, and is not subject to debarment, pursuant to Section 306 of the United States Federal Food, Drug and Cosmetics Act (or similar Laws of any other country), and is not the subject of a conviction described in such section. Notwithstanding the foregoing, the subcontracting Party (or Party whose Affiliate enters into a Subcontract) shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by its Subcontractors with the applicable provisions of this Agreement.

17.10 No Partnership or Joint Venture . Nothing in this Agreement is intended, or shall be deemed, to establish a joint venture or partnership between Licensee and Licensor. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

17.11 Interpretation . The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; and (b) the singular shall include the plural and vice versa. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under generally accepted cost accounting principles, but only to the extent consistent with its usage and the other definitions in this Agreement. This Agreement shall not confer any benefits on any Third Parties and no Third Party may enforce any term of this Agreement.

17.12 Compliance with Laws . Notwithstanding anything to the contrary contained herein, all obligations of Licensor and Licensee are subject to compliance with regulations of the European Union, or any other relevant country and such other Laws and regulations in effect in the European Union, or any other relevant country as may be applicable, such as but not limited to export, anti-corruption, Data Protection Law, anti-trust or competition laws, and to obtaining all necessary approvals required by the applicable agencies of the governments of the countries within the European Union, and any other relevant countries. Licensor and Licensee shall cooperate with each other and shall provide assistance to the other as reasonably necessary to obtain any required approvals.

17.13 Counterparts ; Other Matters . This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures to this Agreement delivered by facsimile or similar electronic transmission will be deemed to be binding as originals. This Agreement is established in the English language. Any translation in another language shall be deemed for convenience only and shall never prevail over the original English version.

[Page Signature Follows]

IN WITNESS WHEREOF , the Parties have executed this License Agreement as of the Effective Date.

PUMA BIOTECHNOLOGY, INC.

BY: _____
NAME: Alan Auerbach
TITLE: Chief Executive Officer and President

PIERRE FABRE MEDICAMENT SAS

BY: _____
NAME: Frédéric DUCHESNE
TITLE: Chief Executive Officer and President

SCHEDULE 2.2

[***]

SCHEDULE 14.2(c)

[***]

Schedule 14.2(d)

[***]

Schedule 14.2(p)

[***]

Schedule 14.4(a)

[***]

EXHIBIT 1

LICENSED PATENTS

[***]

EXHIBIT 2

TRANSITION PLAN

[***]

EXHIBIT 3

ONGOING CLINICAL TRIALS

[***]

EXHIBIT 4

POST-APPROVAL MARKETING STUDIES

[***]

EXHIBIT 5

PRODUCT TRADEMARKS AND DOMAIN NAMES

[***]

EXHIBIT 6

KEY SUPPLY TERMS

[***]

EXHIBIT 7

PRESS RELEASE

News Release

Puma Biotechnology and Pierre Fabre Enter into Exclusive License Agreement to Develop and Commercialize NERLYNX® (neratinib) in Europe

LOS ANGELES, Calif. and CASTRES, France, March XX, 2019 – Puma Biotechnology, Inc. (Nasdaq: PBYI) and Pierre Fabre have entered into an exclusive license agreement under which Pierre Fabre will develop and commercialize NERLYNX® (neratinib) within Europe and part of Africa. In September 2018 the European Commission granted marketing authorization for NERLYNX® (neratinib) 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.

Pierre Fabre will have exclusive commercialization rights for NERLYNX in European countries excluding Russia and Ukraine, along with countries in North Africa and francophone countries of West Africa. Pierre Fabre will also be responsible of conducting additional clinical studies and leading regulatory activities in connection with the European Medicines Agency (EMA).

Under the terms of the agreement, Puma will receive an upfront payment of $60 million, as well as additional regulatory and commercial milestone payments totaling up to $345 million. In addition, Puma will receive significant double-digit royalties on NERLYNX sales throughout the territory covered by the license agreement between Puma and Pierre Fabre.

“Puma is committed to providing access to NERLYNX to patients around the world and soon physicians and patients in Europe will have commercial availability of NERLYNX,” stated Alan H. Auerbach, Chief Executive Officer and President of Puma. “Pierre Fabre has a robust commercial and medical oncology infrastructure that we hope will lead to rapid commercial access to NERLYNX.”

“We are thrilled to provide this new therapy to patients with HER2-positive breast cancer throughout Europe,” said Frederic Duchesne, Chief Executive Officer, Pierre Fabre Pharmaceuticals. “Pierre Fabre has developed a strong expertise and presence in the breast cancer treatment and the addition of NERLYNX to our historical oncology portfolio will allow us to strengthen our commercial presence. We anticipate providing access to NERLYNX to patients throughout Europe in 2019 and 2020, starting with Germany.”

About HER2-Positive Breast Cancer

Approximately 20% to 25% of breast cancer tumors over-express the HER2 protein. HER2-positive breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Although research has shown that trastuzumab can reduce the risk of early stage HER2-positive breast cancer returning after surgery, up to 25% of patients treated with trastuzumab experience recurrence.

Important EU NERLYNX® (neratinib) Safety Information

All suspected adverse reactions should be reported in accordance with the national reporting system .

The adverse reactions described in this section were identified in the randomized Phase 3 clinical trial (n=2840). The most common adverse reactions of any grade were diarrhoea (93.6%), nausea (42.5%), fatigue (27.3%), vomiting (26.8%), abdominal pain (22.7%), rash (15.4%), decreased appetite (13.7%), abdominal pain upper (13.2%), stomatitis (11.2%), and muscle spasms (10.0%).

The most common Grade 3-4 adverse reactions were diarrhoea (Grade 3, 36.9% and Grade 4, 0.2%) and vomiting (Grade 3, 3.4% and Grade 4, 0.1%).

Adverse reactions reported as serious included diarrhoea (1.9%), vomiting (1.3%), dehydration (1.1%), nausea (0.5%), alanine aminotransferase increased (0.4%), aspartate aminotransferase increased (0.4%), abdominal pain (0.3%), fatigue (0.3%) and decreased appetite (0.2%).

For full European prescribing information, please refer to the NERLYNX (neratinib) Summary of Product Characteristics on the European Medicines Agency website (http://www.ema.europa.eu/ema/).

Important Safety Information Regarding NERLYNX® (neratinib) U.S. Indication

NERLYNX® (neratinib) tablets, for oral use

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

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- Diarrhea: Aggressively manage diarrhea occurring despite recommended prophylaxis with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade≥ 2 diarrhea that occurs after maximal dose reduction.

- Hepatotoxicity: Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue NERLYNX inpatients experiencing Grade 4 liver abnormalities.

- Embryo-Fetal Toxicity: NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS: The most common adverse reactions (≥ 5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.

To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) and www.NERLYNX.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch .

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors. When patients require gastric acid reducing agents, use an H2-receptor antagonist or antacid. Separate NERLYNX by at least 3 hours with antacids. Separate NERLYNX by at least 2 hours before or 10 hours after H2-receptor antagonists.

- Strong or moderate CYP3A4 inhibitors: Avoid concomitant use.

- Strong or moderate CYP3A4 inducers: Avoid concomitant use.

- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

·Lactation: Advise women not to breastfeed.

Please see Full Prescribing Information< https://nerlynx.com/pdf/full-prescribing-information.pdf > for additional safety information.

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. NERLYNX was granted marketing authorization by the European Commission in September 2018 for the extended adjuvant treatment of adult patients with early stage hormone receptor-positive HER2-overexpressed/amplified breast cancer and who are less than one year from completion of prior adjuvant trastuzumab-based therapy. NERLYNX is a registered trademark of Puma Biotechnology, Inc .

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

About Oncology at Pierre Fabre

Pierre Fabre's expertise in oncology is based on almost four decades of experience in the discovery, development and global marketing of innovative cancer drugs, including monoclonal antibodies and ADCs. Navelbine® has been one of the company's major successes and is valuable in the treatment of breast cancer patients. The company conducts its R&D in two oncology centers, based in Saint-Julien-en-Genevois (near Geneva) and at the Oncopole campus in Toulouse. The Oncopole is officially recognized by the French government as a National Center of Excellence for cancer research. In 2015, Pierre Fabre entered into an agreement with the American biotech company, Array BioPharma, to codevelop two small molecules (kinase inhibitors), Braftovi® & Mektovi®. The primary indication (melanoma) was approved in September 2018 by EMA and marketing is already underway in Germany, the UK, the Netherlands, Austria, Norway and Denmark.

About Pierre Fabre

With a portfolio representing a continuum of activities spanning from prescription drugs and consumer healthcare products to dermo-cosmetics, Pierre Fabre is the 2 nd largest dermo-cosmetics laboratory in the world, the 2 nd largest private French pharmaceutical group and the market leader in France for products sold over the counter in pharmacies. Its portfolio includes several global brands and franchises among which Eau Thermale Avène, Klorane, Ducray, René Furterer, A-Derma, Galénic, Elancyl, Naturactive, Pierre Fabre Health Care, Pierre Fabre Oral Care, Pierre Fabre Dermatologie and Pierre Fabre Oncologie.

In 2018, Pierre Fabre generated 2,3 billion euros in revenues, of which 63% came from its international business and 61% from its dermo-cosmetics division. Pierre Fabre, which has always been headquartered in the South-West of France, counts about 11,000 employees worldwide, owns subsidiaries and offices in 47 countries and enjoys distribution agreements in over 130 countries. In 2018, Pierre Fabre dedicated 187 million euros to R&D efforts, split between oncology, consumer healthcare, dermatology and dermo-cosmetics.

Pierre Fabre is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan.

The independent French certification group AFNOR audited in 2015 Pierre Fabre for its corporate social responsibility policy at the "exemplary" level, according to the ISO 26000 standard for CSR.

To find out more about Pierre Fabre, please go to www.pierre-fabre.com .

Forward-Looking Statements

This p r ess release cont a i n s forwar d -l o oking stat e m ents, including statements regarding the commercialization and commercial availability of NERLYNX ® in European countries excluding Russia and Ukraine, along with countries in North Africa and francophone countries of West Africa; the registration and regulatory approval of NERLYNX in the region; and potential payments and royalties payable under the license agreement.. All forward-looking statements involve risks and uncertainties that could cause Puma's actual results to differ materially from the anticipated results and

expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the risk factors disclosed in the periodic and current reports filed by Puma with t he Securities and Exchange Commission from time to time, including Puma 's Annual Report on Form 10-K for the year ended December 31, 2018 . Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Puma assumes no obligation to update these forward-looking statements, except as required by law.

Contact:

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com

David Schull or Alex Fudukidis, Russo Partners, +1-212-845-4271
david.schull@russopartnersllc.com
alex.fudukidis@russopartnersllc.com

Valérie Roucoules, Pierre Fabre + 33 1 49 10 83 84 / + 33 6 20 88 61 65
valerie.roucoules@pierre-fabre.com

# # # # #

EXHIBIT 8

TEMPLATE OF ROYALTY REPORTS

[***]

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 March 31, 2019;

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: May 10, 2019

/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 March 31, 2019;

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: May 10, 2019

/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 March 31, 2019, 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 March 31, 2019, 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: May 10, 2019

/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 March 31, 2019, 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 March 31, 2019, 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: May 10, 2019

/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.