

**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, 2018

OR

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

For the transition period from _____ to _____

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024
(Address of principal executive offices) (Zip code)

(424) 248-6500
(Registrant's telephone number, including area code)

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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No .

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 37,811,611 shares of Common Stock, par value \$0.0001 per share, were outstanding as of May 7, 2018.

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 a securities class action lawsuit, derivative lawsuits and a defamation lawsuit;
- 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, 2017 that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

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

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 78,552	\$ 81,698
Accounts receivable, net	16,309	9,670
Inventory	2,742	2,029
Prepaid expenses and other, current	13,583	12,997
Total current assets	111,186	106,394
Property and equipment, net	4,320	4,470
Prepaid expenses and other, long-term	2,448	1,989
Intangible assets, net	47,368	48,355
Restricted cash	4,317	4,317
Total assets	\$ 169,639	\$ 165,525
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 23,560	\$ 27,692
Accrued expenses	34,558	30,648
Total current liabilities	58,118	58,340
Deferred rent	5,509	5,406
Long-term debt	48,556	48,477
Total liabilities	112,183	112,223
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock - \$.0001 par value per share; 100,000,000 shares authorized; 37,762,519 shares issued and outstanding at March 31, 2018 and 37,594,851 issued and outstanding at December 31, 2017	4	4
Additional paid-in capital	1,170,331	1,142,213
Receivable from exercise of stock options	(68)	(449)
Accumulated deficit	(1,112,811)	(1,088,466)
Total stockholders' equity	57,456	53,302
Total liabilities and stockholders' equity	\$ 169,639	\$ 165,525

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended March 31,	
	2018	2017
Revenue:		
Product revenue, net	\$ 36,016	\$ —
License revenue	30,500	—
Total revenue	66,516	—
Operating costs and expenses:		
Cost of sales	6,383	—
Selling, general and administrative	36,602	18,401
Research and development	46,925	54,801
Total operating costs and expenses	89,910	73,202
Loss from operations	(23,394)	(73,202)
Other (expenses) income:		
Interest income	174	350
Interest expense	(1,079)	—
Other expenses	(46)	(13)
Total other (expenses) income:	(951)	337
Net loss	\$ (24,345)	\$ (72,865)
Net loss applicable to common stockholders	\$ (24,345)	\$ (72,865)
Net loss per common share—basic and diluted	\$ (0.65)	\$ (1.97)
Weighted-average common shares outstanding—basic and diluted	37,699,024	36,931,167

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	<u>For the Three Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>
Net loss	\$ (24,345)	\$ (72,865)
Other comprehensive loss		
Unrealized loss on available-for-sale securities	—	(37)
Comprehensive loss	<u>\$ (24,345)</u>	<u>\$ (72,902)</u>

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	Common Stock		Additional Paid-in Capital	Receivables from the Exercises of Options	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount					
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	<u>37,762,519</u>	<u>\$ 4</u>	<u>\$ 1,170,331</u>	<u>\$ (68)</u>	<u>\$ —</u>	<u>\$ (1,112,811)</u>	<u>\$ 57,456</u>

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2018	2017
Operating activities:		
Net loss	\$ (24,345)	\$ (72,865)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,341	277
Stock-based compensation	25,352	29,764
Changes in operating assets and liabilities:		
Accounts receivable, net	(6,639)	—
Inventory	(713)	—
Prepaid expenses and other	(1,045)	516
Accounts payable	(4,217)	3,935
Accrued expenses	3,910	2,334
Accrual of deferred rent	103	(3)
Net cash used in operating activities	(6,253)	(36,042)
Investing activities:		
Purchase of property and equipment	(40)	(124)
Purchase of available-for-sale securities	—	(79,728)
Sale/maturity of available-for-sale securities	—	25,779
Net cash used in investing activities	(40)	(54,073)
Financing activities:		
Net proceeds from exercise of stock options	3,147	706
Net cash provided by financing activities	3,147	706
Net decrease in cash, cash equivalents and restricted cash	(3,146)	(89,409)
Cash, cash equivalents and restricted cash, beginning of period	86,015	198,811
Cash, cash equivalents and restricted cash, end of period	\$ 82,869	\$ 109,402
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment purchases in accounts payable	\$ 85	\$ —
Receivables related to stock option exercises	\$ 68	\$ —
Supplemental disclosure of cash flow information:		
Interest paid	\$ 989	\$ —

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
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 receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the development and commercialization of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. 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.

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 \$24.3 million and negative cash flows from operations of approximately \$6.3 million for the three months ended March 31, 2018. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process and early commercialization.

The Company has incurred significant operating losses and negative cash flows from operations since its inception, which raises substantial doubt about its ability to continue as a going concern. On July 17, 2017, the Company received U.S. Food and Drug Administration, or FDA, approval for its first product, NERLYNX® (neratinib), formerly known as PB272 (neratinib (oral)), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. Following FDA approval in July 2017, NERLYNX became available by prescription in the United States, and the Company commenced commercialization. The Company entered into exclusive license agreements with Specialised Therapeutics Asia Pte Ltd., or STA, Medison Pharma Ltd., or Medison, and CANbridgepharma Limited, or CANbridge, and, most recently, Pint Pharma International SA, or Pint, to pursue regulatory approval and commercialize NERLYNX, if approved, in South East Asia, Israel, greater China and South America, respectively. The Company plans to continue to pursue commercialization of NERLYNX in other countries outside the United States, if approved, and is evaluating various commercialization options in those countries, including developing a direct sales force, contracting with third parties to provide sales and marketing capabilities, or some combination of these two options. The Company is exploring methods by which to commercialize neratinib in the European Union should approval be granted by the European Medicines Agency, or EMA. In addition, the Company is required to make substantial payments to Pfizer upon the achievement of certain milestones and has contractual obligations for clinical trial contracts. Commercialization in the United States and, if approved, in the European Union may require funding in addition to the cash and cash equivalents totaling approximately \$78.6 million available at March 31, 2018. While the consolidated financial statements have been prepared on a going concern basis, the Company continues to remain dependent on its ability to obtain sufficient funding to sustain operations and successfully commercialize neratinib in the United States and, if approved, launch in the European Union. While the Company has been successful in raising financing in the past, there can be no assurance that it will be able to do so in the future. The Company's ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. The Company's continued operations will depend on its ability to successfully commercialize NERLYNX, the Company's only product approved by the FDA, and to obtain additional capital through various potential sources, such as equity and debt financing.

Since its inception through March 31, 2018, the Company's financing has primarily been through public offerings of Company common stock, private equity placements, borrowings under its loan and security agreement with Silicon Valley Bank, or SVB and licensing of its intellectual property.

The Company may need additional financing before it can achieve profitability, if ever. There can be no assurance that additional capital will be available on favorable terms or at all or that any additional capital that the Company is able to obtain will be

sufficient to meet its needs. If it is unable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

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 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 subsidiary. 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 expense or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale. The Company capitalizes technology licenses upon reaching technological feasibility.

The Company maintains definite-lived intangible assets related to the Company's license with Pfizer Inc., or the Licensor. 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 Licensor. 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, 2018. As of March 31, 2018, estimated future amortization expense related to the Company's intangible asset was approximately \$2.9 million for the remainder of 2018, approximately \$3.9 million for each year starting 2019 through 2029, and approximately \$1.0 million for 2030.

Royalties:

Royalties incurred in connection with the Company's license agreement with the Licensor are expensed to cost of sales as revenue from product sales is recognized.

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. Inventory acquired prior to receipt of marketing approval of a product candidate is recorded as research and development expense as 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, 2018, the Company's inventory balance consisted primarily of raw materials purchased subsequent to FDA approval of NERLYNX.

Revenue Recognition:

The Company adopted Accounting Standards Codification, or 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 the FDA approved NERLYNX on July 17, 2017. Subsequent to receiving FDA approval, the Company entered into a limited number of arrangements with specialty pharmacies and specialty distributors in the United States to distribute NERLYNX. These arrangements are the Company's initial contracts with customers. The Company has determined that these sales channels with customers are similar.

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 reserves for variable consideration, including discounts and allowances. The Company's payment terms range between 10 and 60 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, 2018.

Product revenue from customers who individually accounted for 10% or more of the Company's total revenue for the three months ended March 31, 2018 consisted of the following, shown as a percentage of total revenue:

	Three Months Ended March 31, 2018
Customer A	37%
Customer B	22%
Customer C	14%

License Revenue:

The Company also recognizes license revenue under certain of the Company's license agreements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. The Company evaluates these agreements under ASC 606 to determine the distinct performance obligations. Non-refundable, up-front 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. Variable consideration may include non-refundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from the collaboration.

If there are multiple distinct performance obligations, 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.

During the three months ended March 31, 2018, the Company entered into sub-licensing agreements with CANbridgepharma Limited, or CANbridge, and Medison Pharma Ltd., or Medison, to pursue regulatory approval and commercialize NERLYNX, if approved, in the People's Republic of China (including mainland China, Hong Kong, Macao, and Taiwan) and Israel, respectively. The license agreements granted intellectual property rights and set forth the parties' respective obligations with respect to development, commercialization and supply of the licensed product. For both license agreements, non-refundable, upfront license fees were received and recognized as license revenue in accordance with ASC 606. Each respective 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. The Company is obligated to supply both CANbridge and Medison with the licensed product in accordance with the respective supply agreements. These supply arrangements have been 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 no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in these agreements. These license agreements also include potential future milestone and royalty payments due to the Company upon successful completion of certain separate, distinct performance obligations.

Additionally, on March 30, 2018, the Company also entered into a sub-license agreement with Pint Pharma International SA (Pint), or Pint. The license agreement granted intellectual property rights and set forth the respective obligations with respect to development, commercialization and supply of NERYLNX in 22 countries and territories in Central and South America. 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. Under the terms of the license agreement, the Company is entitled to receive a \$10M non-deductible, non-creditable upfront payment. Prior to receipt of such payment, the Company must provide certain required documents on or before September 30, 2018 to the satisfaction of Pint. At March 31, 2018 the Company had not satisfied this performance obligation and no revenue has been recognized under the terms of the arrangement. The Company is obligated to supply Pint with the licensed product during development pursuant to a supply agreement. This supply arrangement has been identified as a separate performance obligation. 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 no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in these agreements. This license agreement also includes potential future milestone and royalty payments due to the Company upon successful completion of certain separate, distinct events, such as achieving regulatory approvals. The milestones consist of certain development and commercial performance obligations and could earn up to approximately \$24.5 million if achieved. At this time, the Company cannot estimate when these milestone related performance obligations are expected to be achieved. The period between when we transfer control of the promised goods to a customer and when we receive payment from such customer is expected to be one year or less.

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 a current liability. These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which 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, 2018 and, therefore, the transaction price was not reduced further during the quarter ended March 31, 2018. 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. However, 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, 2018.

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 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 that 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. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. 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 estimated 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, 2018 and December 31, 2017, 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, 2018	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 78,552	\$ —	\$ —	\$ 78,552
	<u>\$ 78,552</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 78,552</u>
December 31, 2017	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 81,698	\$ —	\$ —	\$ 81,698
	<u>\$ 81,698</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 81,698</u>

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

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

March 31, 2018	Maturity (in years)	Amortized cost	Unrealized		Estimated fair value
			Gains	Losses	
Cash equivalents		\$ 78,552	\$ —	\$ —	\$ 78,552
		<u>\$ 78,552</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 78,552</u>
December 31, 2017	Maturity (in years)	Amortized cost	Unrealized		Estimated fair value
Cash equivalents		\$ 81,698	\$ —	\$ —	\$ 81,698
		<u>\$ 81,698</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 81,698</u>

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, 2018, were approximately \$83.1 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, which was approved by the FDA for the extended adjuvant treatment of early stage, HER2-positive breast cancer in the United States on July 17, 2017, 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 expenses include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and clinical research organization, or CRO, costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company's accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. The objective of the Company's accrual policy is to match the recording of expenses in the unaudited condensed consolidated financial statements to the actual services received and efforts expended. 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 unaudited condensed 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 stock-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 6 years of publicly traded stock history. Prior to 2018, while the Company had a short period of publicly traded stock history, the Company calculated its estimate of average volatility based on a sampling of companies with similar attributes, 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 “trueed-up” upon the actual forfeiture of a stock option grant. Due to its limited history, 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:

In accordance with ASC 740, *Income Taxes*, or ASC 740, each interim reporting period is considered integral to the annual period, and tax expense is measured using an estimated annual effective tax rate. An entity is required to record income tax expense each quarter based on its annual effective tax rate estimated for the full fiscal year and use that rate to provide for income taxes on a current year-to-date basis, adjusted for discrete taxable events that occur during the interim period.

Our income tax returns are based on calculations and assumptions subject to audit by various tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws.

On December 22, 2017, H.R. 1/Public Law No. 115-97 known as the Tax Cuts and Jobs Act (the “Tax Act”), was signed into law. The effects of this new federal legislation are recognized upon enactment, which is the date a bill is signed into law. The Tax Act includes numerous changes in existing tax law, including a permanent reduction in the federal corporate income tax rate from 35% (as the top corporate tax rate) to 21%. As a result of the Tax Act, the Company has revalued its net deferred tax assets as of December 31, 2017 to reflect the rate reduction. Tax rates used for the ASC 740 interim reporting reflect the newly enacted corporate tax rate of 21% and adjustments used for the estimated annual effective tax rate calculation reflect changes from The Act

Pursuant to the SEC Staff Accounting Bulletin No. 118, “Income Tax Accounting Implications of the Tax Cuts and Jobs Act”, or SAB 118, a company may select between one of three scenarios to determine a reasonable estimate arising from the Tax Act. Those scenarios are (i) a final estimate which effectively closes the measurement window; (ii) a reasonable estimate leaving the measurement window open for future revisions; and (iii) no estimate as the law is still being analyzed. The Company was able to provide a reasonable estimate for the revaluation of deferred taxes by recording a net tax provision of \$141.1 million in the period ending December 31, 2017, which is offset by a full valuation allowance. Other impacts of the Act including, but not limited to, a limitation of the deduction for net operating losses, expensing of qualified property and additional limitations on the deductibility of executive compensation are not expected to have a material impact to the financial statement presentation or disclosures. The Company’s review of the final impact of the Tax Act may be different from certain provisional amounts reported due to changes in interpretations and assumptions of the current guidance available as well as the issuance of new regulatory guidance in the future. As of March 31, 2018, the Company has not made any measurement period adjustments related to SAB 118, which was elected during the fourth quarter of 2017. The other income tax accounting implications resulting from the act do not have a material impact to the Company. The Company anticipates the full financial impact will be determined at the time its 2017 U.S. corporate income tax return is filed in 2018.

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 common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the periods presented as required by ASC 260, *Earnings per Share*. For purposes of calculating diluted loss per common share, the denominator includes both the weighted average number of common shares 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 three months ended March 31, 2018 and the three months ended March 31, 2017, the

weighted average number of common stock equivalents not included in the computation of diluted loss per share were 9,891,878 and 9,549,076, respectively, as the effect would have been anti-dilutive.

Recently Issued Accounting Standards:

In January 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU No. 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the condensed consolidated financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU No. 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company has adopted ASU No. 2016-01 in the first quarter of 2018 with no impact to its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The amendments in ASU 2016-02 will 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 current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, ASU No. 2016-02 will require both types of leases to be recognized on the balance sheet. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently in the process of evaluating the impact of ASU 2016-02 on the Company's outstanding leases and expects that adoption will materially increase our assets and liabilities on the consolidated balance sheets related to recording right-of-use assets and corresponding lease liabilities.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force)*, which addresses the diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company has adopted ASU 2016-15 in the first quarter of 2018 with no impact to its consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This amendment is effective for the Company in the fiscal year beginning after December 15, 2017, but early adoption is permissible. The Company has adopted ASU 2016-18 in the first quarter of 2018. The Company noted a change in the beginning-of-period and end-of-period total amounts within the statement of cash flows due to the inclusion of restricted cash within cash and cash equivalents.

Note 3—Prepaid Expenses and Other:

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

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
Current:		
CRO services	\$ 6,279	\$ 7,188
Other clinical development	1,183	878
Insurance	963	1,306
Other	5,158	3,625
	<u>13,583</u>	<u>12,997</u>
Long-term:		
CRO services	876	860
Other clinical development	1,389	886
Insurance	36	26
Other	147	217
	<u>2,448</u>	<u>1,989</u>
Totals	<u>\$ 16,031</u>	<u>\$ 14,986</u>

Note 4—Property and Equipment:

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

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
Property and Equipment:		
Leasehold improvements	\$ 3,878	\$ 3,878
Computer equipment	2,269	2,147
Telephone equipment	302	302
Furniture and fixtures	2,206	2,206
	<u>8,655</u>	<u>8,533</u>
Less: accumulated depreciation and amortization	(4,335)	(4,063)
Totals	<u>\$ 4,320</u>	<u>\$ 4,470</u>

Note 5—Intangible assets, net:

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

	<u>March 31, 2018</u>	<u>Estimated useful life</u>
Acquired and in-licensed rights	\$ 50,000	13 Years
Less: accumulated amortization	(2,632)	
Total intangible asset, net	<u>\$ 47,368</u>	

Note 6—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
Accrued CRO services	\$ 7,493	\$ 8,335
Accrued other clinical development	4,513	3,438
Accrued legal fees	3,136	2,046
Accrued compensation	4,359	2,797
Accrued bonus	2,478	3,376
Accrued royalties	5,357	3,922
Accrued variable consideration	3,922	1,425
Other	3,300	5,309
Totals	<u>\$ 34,558</u>	<u>\$ 30,648</u>

Accrued CRO services and accrued other clinical development expenses represent the Company's estimate of such costs. Accrued compensation includes sales commissions and vacation. Additionally, vacation is accrued at the rate the employee earns vacation and reduced as vacation is used by the employee. Accrued royalties represent royalties incurred in connection with the Company's license agreement with the Licensor and accrued variable consideration represents estimates of variable consideration for which reserves are established. Accrued expenses are adjusted in the period the actual costs come known.

Note 7—Debt:

Long term debt consisted of the following at March 31, 2018 (dollars in thousands):

	March 31, 2018	Maturity Date
Long term debt	\$ 50,000	October 31, 2022
Less: deferred financing costs	(1,444)	
Total long term debt, net	<u>\$ 48,556</u>	

On October 31, 2017, the Company entered into a loan and security agreement with SVB, as administrative and collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC and SVB, pursuant to which the lenders agreed to make term loans available to the Company in an aggregate amount of \$100 million, consisting of (i) an aggregate amount of \$50 million available on October 31, 2017 and (ii) an aggregate amount of \$50 million available to be drawn at the Company's option between March 31, 2018 and June 30, 2018, provided the Company has achieved a specified minimum revenue milestone and no event of default is occurring. Proceeds from the term loans may be used for working capital and general business purposes. The term loans available under the credit facility are 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 credit facility limits the Company's ability to grant any interest in its intellectual property to certain permitted licenses and permitted encumbrances set forth in the agreement.

The term loans under the credit facility bear interest at an annual rate equal to the greater of (i) 7.75% 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 outstanding 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 December 1, 2019. Commencing on December 1, 2019, and continuing on the first calendar day of each calendar month thereafter, the Company is required to make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender, calculated pursuant to the credit facility. All unpaid principal and accrued and unpaid interest with respect to each term loan is due and payable in full on October 31, 2022. 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, it may prepay the outstanding principal balance of any term loan in whole but not in part, subject to a prepayment fee of 2.0% of any amount prepaid if the prepayment occurs through and including the first anniversary of the funding date of such term loan, or 1.0% of the 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.

The credit facility includes affirmative and negative covenants applicable to the Company, its current subsidiary and any subsidiaries it may create in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its corporate existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. The Company must also achieve product revenue, measured as of the last day of each fiscal quarter on a trailing three-month basis, that is (i) greater than or equal to 50% of its revenue target set forth in its board-approved projections for the 2018 fiscal year, and (ii) greater than or equal to 50% of its 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 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 credit facility, including foreclosure against the property securing the credit facilities, including its cash. These events of default include, among other things, any failure by the Company to pay principal or interest due under the credit facility, a breach of certain covenants under the credit facility, the Company's insolvency, a material adverse change,

the occurrence of any default under certain other indebtedness in an amount greater than \$500,000 and one or more judgments against the Company in an amount greater than \$500,000 individually or in the aggregate.

Note 8—Stockholders' Equity:

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, 2018, 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, 2018, 7,480,378 shares had been issued under the 2011 Plan.

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 RSUs, as well as other forms of equity-based compensation to employees, as an inducement to join the Company. The maximum term of stock options granted under the 2017 Plan is 10 years. 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, 2018, a total of 1,000,000 shares of the Company's common stock had been reserved for issuance under the 2017 Plan. As of March 31, 2018, 295,250 shares had been issued under the 2017 Plan.

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

	Three Months Ended March 31,	
	2018	2017
Stock-based compensation:		
Options -		
Research and development, or R&D	\$ 10,072	\$ 20,356
Selling, general and administrative, or SG&A	4,471	6,189
Restricted stock units -		
Selling, general and administrative, or SG&A	4,495	1,095
Research and development, or R&D	6,314	2,124
Total stock-based compensation expense	<u>\$ 25,352</u>	<u>\$ 29,764</u>

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, 2018 and 2017.

	2018	2017
Dividend yield	0.0%	0.0%
Expected volatility	95.5%	70.1%
Risk-free interest rate	2.5%	2.0%
Expected life in years	5.85	5.85

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, 2017	6,134,513	\$ 87.91	7.2	\$ 220,060
Granted	225,566	\$ 73.40	9.8	
Forfeited	(80,604)	\$ 54.33		
Exercised	(72,571)	\$ 38.11		\$ 2,256
Expired	(43,597)	\$ 145.51		
Outstanding at March 31, 2018	6,163,307	\$ 88.00	6.9	\$ 100,125
Nonvested at March 31, 2018	1,514,373	\$ 55.60	8.6	\$ 27,237

At March 31, 2018, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately \$46.3 million, which is expected to be recognized over a weighted-average period of 1.6 years. At March 31, 2018, the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately \$111.2 million, which is expected to be recognized over a weighted-average period of 2.4 years. The weighted-average grant date fair value of options granted during the three months ended March 31, 2018 and 2017 was \$56.46 and \$22.86 per share, respectively. The weighted average grant date fair value of RSUs awarded during the three months ended March 31, 2018 and 2017, were \$72.43 and \$0, per share, respectively.

<u>Stock options</u>	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2017	1,788,436	\$ 33.37
Granted	225,566	\$ 56.46
Vested/Issued	(419,025)	\$ 38.79
Forfeited	(80,604)	\$ 32.66
Nonvested shares at March 31, 2018	1,514,373	\$ 35.34

<u>Restricted stock units</u>	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2017	1,637,662	\$ 85.58
Granted	168,050	\$ 72.43
Vested/Issued	(96,347)	\$ 54.35
Forfeited	(97,044)	\$ 84.02
Nonvested shares at March 31, 2018	1,612,321	\$ 86.17

Note 9—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately \$0.5 million and \$0.2 million for the three months ended March 31, 2018 and 2017, respectively.

Note 10—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 those 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.

Legal Proceedings

The Company and certain of its executive officers were named as defendants in the lawsuits detailed below. Due to the stage of these proceedings, the Company cannot reasonably predict the outcome, nor can it estimate the amount of loss or range of loss, if any, that may result. 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. An adverse outcome in these proceedings would likely not have a material adverse effect on the Company's results of operations, cash flows or financial condition.

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

On June 3, 2015, Hsingching Hsu individually and on behalf of all others similarly situated, filed a class action lawsuit against the Company and certain of the Company's 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. The consolidated complaint alleges that the Company and certain of its executive officers made false or misleading statements and failed to disclose material adverse facts about its business, operations, prospects and performance in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The plaintiff seeks damages, interest, costs, attorneys' fees, and other unspecified equitable relief. On September 30, 2016, the court denied the defendants' motion to dismiss the consolidated complaint. On June 6, 2017, the lead plaintiff filed a first amended complaint that included new claims about additional statements that plaintiff alleges are false or misleading. On June 19, 2017, the defendants moved to dismiss the new claims in the amended complaint. On July 25, 2017, the court denied the motion to dismiss. A trial date is currently set for November 6, 2018. The Company intends to vigorously defend against this matter.

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

On February 2, 2016, Fredric N. Eshelman filed a lawsuit against the Company's Chief Executive Officer and President, Alan H. Auerbach, and the Company in the United States District Court for the Eastern District of North Carolina (Case No. 7:16-cv-00018-D). The complaint generally alleges that Mr. Auerbach and the Company made defamatory statements regarding Dr. Eshelman in connection with a proxy contest. Dr. Eshelman seeks compensatory and punitive damages and expenses and costs, including attorneys' fees. On April 4, 2016, the Company filed a motion to dismiss the complaint. On May 2, 2016, Dr. Eshelman filed a notice of voluntary dismissal of the claims against Mr. Auerbach. On February 6, 2017, the court denied the Company's motion to dismiss. Discovery ended in September 2017. The Company intends to vigorously defend against Dr. Eshelman's claims.

Derivative Actions

On April 12 and April 14, 2016, purported stockholders of the Company filed two derivative lawsuits purportedly on behalf of the Company against certain of the Company's officers and directors in the Superior Court of the State of California, Los Angeles, captioned Xing Xie v. Alan H. Auerbach, No. BC616617, and Kevin McKenney v. Auerbach, No. BC617059. The complaints assert claims for breach of fiduciary duty, unjust enrichment, abuse of control, mismanagement and waste of corporate assets arising from substantially similar allegations as those contained in the securities class action described above. The complaints seek an unspecified sum of damages and equitable relief. The Company intends to vigorously defend against this matter.

Separately, on February 9, 2018, another purported 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 Arnaud Van Der Gracht De Ro mmerswael vs. Alan H. Auerbach, et al., No. 8:18-cv-00236. The complaint asserts claims for violation of securities law, breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from substantially similar allegations as those contained in the securities class action described above. The complaint seeks an unspecified sum of damages, corporate reforms, equitable relief, and restitution. The Company intends to vigorously defend against this matter.

Stockholder Demand

On September 13, 2017, a purported stockholder filed a complaint in the Court of Chancery of the State of Delaware seeking an equitable apportionment of attorneys' fees in an unspecified amount. The purported stockholder alleges that his actions caused the Company's board of directors to implement certain governance reforms and enhancements to its director compensation program, and that, as a result of his actions, the purported stockholder is entitled to attorneys' fees in an amount commensurate to those purported benefits. The Company filed an answer to the complaint on October 20, 2017. The Company intends to vigorously defend against this matter.

The pending proceedings described in this section involve complex questions of fact and law and will require the expenditure of significant funds and the diversion of other resources to defend. The results of legal proceedings are inherently uncertain, and material adverse outcomes are possible

Note 11—Subsequent Events:

The Company entered into a loan agreement with Silicon Valley Bank and Oxford Finance for a term loan of up to \$155.0 million, subject to funding in two tranches. The Company received gross proceeds of \$125.0 million from the first tranche of the credit facility upon closing on May 8, 2018 and intends to use the funds to pay down the existing term loan of \$50 million, for general corporate purposes and to further support NERLYNX commercial initiatives. The second tranche of \$30.0 million may be drawn at the Company's option between September 30, 2018 and December 31, 2018 provided the Company has achieved a specified minimum revenue milestone and no event of default is occurring. The loan will mature on May 1, 2023.

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, 2017.

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 subsidiary, Puma Biotechnology Ltd.

Overview

We are a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. We in-license 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. Before we can market neratinib in countries outside the United States, we must receive regulatory approval from the appropriate government entities in those countries. Developing drug products is a lengthy and very expensive process.

We completed a Phase III clinical trial of neratinib for the extended adjuvant treatment of patients with early stage HER2-positive breast cancer, which we refer to as the ExteNET trial. Based on the results from the ExteNET trial, we submitted a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in June 2016. We recently announced that the EMA's Committee for Medicinal Products for Human Use, or CHMP, adopted a negative opinion and recommended refusal of our MAA for neratinib for the extended adjuvant treatment of early stage HER2-positive breast cancer. We requested a re-examination and are awaiting the outcome of the same.

We have entered into exclusive license agreements with Specialised Therapeutics Asia Pte Ltd., Medison Pharma Ltd., CANbridgepharma Limited and, Pint Pharma International SA to pursue regulatory approval and commercialize NERLYNX, if approved, in South East Asia, Israel, greater China and Latin 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 sales force, 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 license agreement with Pfizer, Inc., or Pfizer, for PB272 established a limit for our expenses related to the Pfizer-initiated clinical trials for PB272 that were ongoing at the time of the agreement. This capped our "out-of-pocket" costs incurred in conducting these existing trials beginning January 1, 2012. We reached the cost cap during the fourth quarter of 2012, which resulted in a reduction of our research and development, or R&D, expenses for the fourth quarter of 2012 and for the year ended December 31, 2013. In July 2014, we signed an amendment to the license agreement with Pfizer whereby we would be responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013. Additionally, our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure. As we proceed with clinical development of PB272 (neratinib (oral)), and as we further develop PB272 (neratinib (intravenous)), and PB357, our second and third product candidates, respectively, we expect our R&D expenses and expenses related to our third-party contractors will begin to decline unless we decide to pursue additional clinical trials in alternate indications or acquire additional product candidates.

To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance R&D will increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance product development. Our major sources of working capital have been proceeds from public offerings of our common stock, proceeds from our credit facility, sales of our common stock in private placements and licensing of our own intellectual property.

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, 2018 from our accounting policies at December 31, 2017, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, with an exception of those listed below:

License Revenue:

We also 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 significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include nonrefundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from the collaboration.

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

During the three months ended March 31, 2018, we entered into sub-licensing agreements with CANBridgepharma Limited, or CANbridge, and Medison Pharma Ltd., or Medison, to pursue regulatory approval and commercialize NERLYNX, if approved, in the People's Republic of China (including mainland China, Hong Kong, Macao, and Taiwan) and Israel, respectively. The license agreements granted intellectual property rights and set forth the parties' respective obligations with respect to development, commercialization and supply of the licensed product. For both license agreements, non-refundable, upfront license fees were received and recognized as license revenue in accordance with ASC 606. Each respective 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. We are obligated to supply both CANbridge and Medison with the licensed product in accordance with the respective supply agreements. These supply arrangements have been 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 there was no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in these agreements. These license agreements also include potential future milestone and royalty payments due to us upon successful completion of certain separate, distinct performance obligations.

Additionally, on March 30, 2018, we also entered into a sub-license agreement with Pint Pharma International SA (Pint), or Pint. The license agreement granted intellectual property rights and set forth the respective obligations with respect to development, commercialization and supply of NERYLNx in 22 countries and territories in Central and South America. 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. Under the terms of the license agreement, we are entitled to receive a \$10M non-deductible, non-creditable upfront payment. Prior to receipt of such payment, we must provide certain required documents on or before September 30, 2018 to the satisfaction of Pint. At March 31, 2018 we had not satisfied this performance obligation and no revenue has been recognized under the terms of the arrangement.

We are obligated to supply Pint with the licensed product during development pursuant to a supply agreement. This supply arrangement has been identified as a separate performance obligation. 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 there was no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in these agreements. This license agreement also includes potential future milestone and royalty payments due to us upon successful completion of certain separate, distinct events, such as achieving regulatory approvals. The milestones consist of certain development and commercial performance obligations and could earn up to approximately \$24.5 million if achieved. At this time, we cannot

estimate when these milestone related performance obligations are expected to be achieved. The period between when we transfer control of the promised goods to a customer and when we receive payment from such customer is expected to be one year or less.

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 paid to us 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 the Licensor, the amortization of a milestone payment made to the Licensor 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.

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 manufacturing of clinical materials and clinical trials. During the three months ended March 31, 2018 and 2017, 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.

Results of Operations

Three Months Ended March 31, 2018 Compared to Three Months Ended March 31, 2017

Total revenue:

For the three months ended March 31, 2018, total revenue was approximately \$66.5 million, compared to \$0 for the three months ended March 31, 2017.

Product revenue, net:

Product revenue, net was approximately \$36.0 million for the three months ended March 31, 2018, compared to \$0 for the three months ended March 31, 2017. The increase in product revenue, net was entirely attributable to sales of NERLYNX, which had its commercial launch in July 2017.

License revenue:

License revenue was \$30.5 million for the three months ended March 31, 2018, compared to \$0 for the three months ended March 31, 2017. The increase in license revenue was entirely attributable to upfront payments associated with our licensing agreements with two license agreements that were entered into during the three months ended March 31, 2018.

Cost of sales:

For the three months ended March 31, 2018, cost of sales was approximately \$6.4 million compared to \$0 for the three months ended March 31, 2017. The increase in cost of sales was entirely attributable to the commercial launch of NERLYNX, our initial product, in July 2017.

Selling, general and administrative expenses:

For the three months ended March 31, 2018, SG&A expenses were approximately \$36.6 million, compared to approximately \$18.4 million for the three months ended March 31, 2017. SG&A expenses for the three months ended March 31, 2018 and 2017 were as follows:

Selling, general and administrative expenses (in thousands)	For the Three Months Ended March 31,		Annual Percentage Change
	2018	2017	2018/2017
External	\$ 13,258	\$ 6,662	99.0%
Internal	14,378	4,455	222.7%
Employee stock-based compensation expense	8,966	7,284	23.1%
	<u>\$ 36,602</u>	<u>\$ 18,401</u>	<u>98.9%</u>

For the three months ended March 31, 2018, SG&A expenses increased approximately \$18.2 million compared to the same period in 2017. Approximately \$7.8 million of the increase was due to increased internal payroll costs associated with an increase of headcount from 33 to 143, primarily in sales and marketing and associated with the commercialization of NERLYNX. The remaining approximately \$10.4 million of the increase in SG&A expense for the three months ended March 31, 2018, compared to the same period in 2017, was primarily attributable to:

- approximately \$6.6 million increase in external expenses, of which \$4.0 million reflects increased Marketing and Market Access expenses, an approximately \$2.1 million increase in other sales and marketing expenses from items such as website and data infrastructure set up, and an additional \$0.5 million increase in legal expenses
- an increase in internal expenses of approximately \$1.7 from travel expenses, primarily from the sales team, and an approximately \$0.4 million increase in other expenses such as software and rent; and
- an approximately \$1.7 million increase in employee stock-based compensation expense associated with additional headcount, primarily in support of the commercial launch of NERLYNX as well as additional grants to existing employees

We expect SG&A expenses in 2018 to remain higher than in 2017. While the majority of the salesforce and field based support personnel were hired in the late 3rd quarter of 2017, we expect a full years' worth of sales force expenses in 2018. This increase should be partially offset by an expected reduction in legal fees and system implementation fees.

Research and development expenses:

For the three months ended March 31, 2018, R&D expenses were approximately \$46.9 million, compared to approximately \$54.8 million for the three months ended March 31, 2017. R&D expenses for the three months ended March 31, 2018 and 2017 were as follows:

Research and development expenses (in thousands)	For the Three Months Ended March 31,		Annual Percentage Change
	2018	2017	2018/2017
External	\$ 18,658	\$ 22,615	(17.5%)
Internal	11,881	9,706	22.4%
Employee stock-based compensation	16,386	22,480	(27.1%)
	<u>\$ 46,925</u>	<u>\$ 54,801</u>	<u>(14.4%)</u>

For the three months ended March 31, 2018, R&D expenses decreased approximately \$7.9 million compared to the same period in 2017. Stock-based compensation expense decreased approximately \$6.1 million, reflecting forfeitures for employees who exited the company, the conclusion of vesting for certain stock options granted during 2014, partially offset by grants to new employees and additional awards to existing employees for the three months ended March 31, 2018. The remaining decrease of approximately \$1.8 million, was primarily attributable to:

- the reduction of external R&D costs by approximately \$4.0 million is primarily from an approximately \$4.2 million reduction in CRO costs, primarily associated with the ExteNET trial partially offset by an approximately \$0.2 million increase in other costs such as additional regulatory support; and
- the increase in internal R&D costs of approximately \$2.2 million is from an increase in payroll and payroll related costs of approximately \$2.1 million resulting from an increase in headcount from 141 as of March 31, 2017 to 163 as of March 31, 2018, and an increase of approximately \$0.1 million for additional software expenses. The increase in headcount is primarily due to the need to support medical affairs and commercial quality assurance.

We expect R&D expenses in 2018 to continue to decline slightly from R&D expenses in 2017 as clinical trial activities continue to wind down.

Interest income:

For the three months ended March 31, 2018, we recognized approximately \$0.2 million in interest income compared to approximately \$0.4 million of interest income for the three months ended March 31, 2017. The decrease in interest income reflects less cash in money market accounts and “high yield” savings accounts for 2018 compared to 2017.

Other expenses:

During both the three months ended March 31, 2018 and 2017, other expenses, consisting primarily of foreign exchange loss, were approximately \$0.1 million.

Interest expense:

For the three months ended March 31, 2018, we recognized approximately \$1.1 million in interest expense, compared to \$0 of interest expense for the three months ended March 31, 2017. This increase in interest expense is a result of the debt financing that closed in October 2017 (see Note 7 in the notes to the accompanying unaudited condensed consolidated financial statements).

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2018 and December 31, 2017, and for the three months ended March 31, 2018 and 2017, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	March 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 78,552	\$ 81,698
Working capital	53,068	48,054
Stockholders' equity	57,456	53,302

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Cash provided by (used in):		
Operating activities	\$ (6,253)	\$ (36,042)
Investing activities	(40)	(54,072)
Financing activities	3,147	706
Decrease in cash and cash equivalents	\$ (3,146)	\$ (89,408)

Operating Activities:

For the three months ended March 31, 2018, we reported a net loss of approximately \$24.3 million, compared to approximately \$72.9 million for the same period in 2017. Additionally, cash used in operating activities for the three months ended March 31, 2018 was approximately \$6.3 million, compared to approximately \$36.0 million for the same period in 2017.

Cash used in operating activities for the three months ended March 31, 2018 consisted of a net loss of approximately \$24.3 million, an increase in net accounts receivable of approximately \$6.6 million, an approximately \$1.0 million increase in pre-paid expenses and an approximately \$0.7 million increase in inventory, offset by approximately \$26.8 million of non-cash items such as stock-based compensation, depreciation and amortization and deferred rent expense.

Cash used in operating activities for the three months ended March 31, 2017 consisted of a net loss of \$72.9 million, offset by approximately \$30.0 million of non-cash items such as depreciation and amortization and stock-based compensation, an increase of approximately \$6.3 million in accrued expenses and accounts payable, and an increase of approximately \$0.5 million in prepaid expenses and other.

Investing Activities:

During the three months ended March 31, 2018, net cash used in investing activities was approximately \$0.1 million, compared to approximately \$54.1 million for the same period in 2017. The approximately \$0.1 million of net cash used in investing activities during the three months ended March 31, 2018 was made up entirely of cash used to purchase property and equipment. The approximately \$54.1 million of net cash used in investing activities during the three months ended March 31, 2017 was made up of approximately \$25.8 million of sales or maturities of available-for-sale securities, offset by \$79.7 million of cash invested in available-for-sale securities, and approximately \$0.1 million used to purchase property and equipment.

Financing Activities:

During the three months ended March 31, 2018, cash provided by financing activities consisted of approximately \$3.1 million of net proceeds from the exercise of stock options. During the same period in 2017, cash provided by financing activities was approximately \$0.7 million, also comprised of net proceeds from the exercise of stock options.

Loan and Security Agreement:

On October 31, 2017, we entered into a loan and security agreement with Silicon Valley Bank, or SVB, as administrative and collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC and SVB, pursuant to which the lenders agreed to make term loans available to us in an aggregate amount of \$100 million, consisting of (i) an aggregate amount of \$50 million available on October 31, 2017 and (ii) an aggregate amount of \$50 million available to be drawn at our option between March 31, 2018 and June 30, 2018, provided that we have achieved a specified minimum revenue milestone and no event of default is occurring. Proceeds from the term loans may be used for working capital and general business purposes. The term loans available under the credit facility are 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 credit facility limits our ability to grant any interest in our intellectual property to certain permitted licenses and permitted encumbrances set forth in the agreement.

The term loans under the credit facility bear interest at an annual rate equal to the greater of (i) 7.75% 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 outstanding 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 December 1, 2019. Commencing on December 1, 2019, and continuing on the first calendar day of each calendar month thereafter, we are required to make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender, calculated pursuant to the credit facility. All unpaid principal and accrued and unpaid interest with respect to each term loan is due and payable in full on October 31, 2022. 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 2.0% of any amount prepaid if the prepayment occurs through and including the first anniversary of the funding date of such term loan, or 1.0% of the 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.

The credit facility includes affirmative and negative covenants applicable to us, our current subsidiary and any subsidiaries we may create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our corporate 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 (i) greater than or equal to 50% of our revenue target set forth in our board-approved projections for the 2018 fiscal year, and (ii) 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 effecting a change in control, in each case subject to certain exceptions.

The 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 credit facility, including foreclosure against the property securing the credit facilities, including its cash. These events of default include, among other things, any failure by us to pay principal or interest due under the credit facility, a breach of certain covenants under the 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.

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 are currently exploring methods by which to commercialize our other product candidates if approved by the FDA or EMA. These methods may require funding in addition to the cash and cash equivalents totaling approximately \$78.6 million available at March 31, 2018. 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 impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. Although we may have access to an additional \$50 million from our loan and security agreement with SVB during 2018, provided we have achieved a specified minimum revenue milestone and no event of default is occurring, it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

Going Concern:

Our independent registered public accounting firm has issued a report on our audited consolidated financial statements for the year ended December 31, 2017 that included an explanatory paragraph referring to our significant operating losses and expressing substantial doubt in our ability to continue as a going concern. Our consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon our ability to generate profitable operations in the future and/ or to obtain the necessary financing to meet our obligations and repay our liabilities arising from normal business operations when they become due. The outcome of these matters cannot be predicted with any certainty at this time and raise substantial doubt that we will be able to continue as a going concern. Our consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

Contractual Obligations:

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Our 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 those 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.

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, 2018 and 2017, stock-based compensation represented approximately 28.3% and 40.7% of operating expenses, respectively. Although net loss is important to measure our financial performance, we currently place an emphasis on cash burn and, more specifically, cash used in operations. Because stock-based compensation appears in GAAP net loss but is removed from net loss to arrive at cash used in operations on the statement of cash flows, due to its non-cash nature, we believe these non-GAAP measures 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 (Loss) and GAAP Net Loss Per Share to Non-GAAP Adjusted Net Income (Loss) Per Share (in thousands except share and per share data)

	For the Three Months Ended March 31,	
	2018	2017
GAAP net loss	\$ (24,345)	\$ (72,865)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative	8,966	7,284 (1)
Research and development	16,386	22,480 (2)
Non-GAAP adjusted net income (loss)	\$ 1,007	\$ (43,101)
GAAP net loss per share—basic	\$ (0.65)	\$ (1.97)
Adjustment to net loss (as detailed above)	0.68	0.81
Non-GAAP adjusted basic net income (loss) per share	\$ 0.03	\$ (1.16) (3)
GAAP net loss per share—diluted	\$ (0.60)	\$ (1.97)
Adjustment to net loss (as detailed above)	0.62	0.81
Non-GAAP adjusted diluted net income per share	\$ 0.02 (4)	\$ (1.16) (5)

(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 loss per share was calculated based on 37,699,024 and 36,931,167 weighted average common shares outstanding for the three months ended March 31, 2018 and 2017, respectively.

(4) Non-GAAP adjusted diluted net income per share was calculated based on 40,642,311 weighted average common shares outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the three months ended March 31, 2018.

(5) Potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) were not included in this non-GAAP adjusted diluted net loss per share for the three months ended March 31, 2017 as these shares would be considered anti-dilutive.

Off-Balance Sheet Arrangements

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the cash equivalents to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. We invested our excess cash primarily in cash equivalents such as money market investments as of March 31, 2018. 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, 2018, the outstanding principal amount of the term loan was \$50.0 million. The term loan bears interest at an annual rate equal to the greater of (i) 7.75% 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 the term loan.

We do not believe that a 10% increase in the prime rate on March 31, 2018 would have had a material effect on our interest expense as of that date.

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 Senior Vice President, Finance and Administration and Treasurer, 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 Senior Vice President, Finance and Administration and Treasurer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of March 31, 2018. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer have concluded that these disclosure controls and procedures were effective as of March 31, 2018.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the first quarter ended March 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

On June 3, 2015, Hsingching Hsu or the “plaintiff,” 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. The consolidated complaint alleges that we and certain of our executive officers made false or misleading statements and failed to disclose material adverse facts about our business, operations, prospects and performance in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The plaintiff seeks damages, interest, costs, attorneys' fees, and other unspecified equitable relief. On September 30, 2016, the court denied our motion to dismiss the consolidated complaint. On June 6, 2017, the lead plaintiff filed a first amended complaint that included new claims about additional statements that plaintiff alleges are false or misleading. On June 19, 2017, we moved to dismiss the new claims in the amended complaint. On July 25, 2017, the court denied the motion to dismiss. On December 8, 2017, the court granted the plaintiff's motion for class certification. A trial date is currently set for November 6, 2018. We intend to vigorously defend against this matter.

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

On February 2, 2016, Fredric N. Eshelman filed a lawsuit against our Chief Executive Officer and President, Alan H. Auerbach, and us in the United States District Court for the Eastern District of North Carolina (Case No. 7:16-cv-00018-D). The complaint generally alleges that we and Mr. Auerbach made defamatory statements regarding Dr. Eshelman in connection with a proxy contest. Dr. Eshelman seeks compensatory and punitive damages and expenses and costs, including attorneys' fees. On April 4, 2016, we filed a motion to dismiss the complaint. On May 2, 2016, Dr. Eshelman filed a notice of voluntary dismissal of the claims against Mr. Auerbach. On February 6, 2017, the court denied our motion to dismiss. Discovery ended in September 2017. Summary judgment briefing was completed on November 17, 2017. It is unknown when the court will rule on the summary judgment motions. We intend to vigorously defend against Dr. Eshelman's claims.

Derivative Actions

On April 12 and April 14, 2016, purported 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 Xing Xie vs. Alan H. Auerbach, No. BC616617, and Kevin McKenney vs. Alan H. Auerbach, No. BC617059. The complaints assert claims for breach of fiduciary duty, unjust enrichment, abuse of control, mismanagement and waste of corporate assets arising from substantially similar allegations as those contained in the Hsu securities class action described above. The complaints seek an unspecified sum of damages and equitable relief. These two derivative claims are currently stayed, pending the outcome of the Hsu securities class action. We intend to vigorously defend against this matter.

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 Arnaud Van Der Gracht De Rommerswael vs. Alan H. Auerbach, et al., No. 8:18-cv-00236. The complaint asserts claims for violation of securities law, breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from substantially similar allegations as those contained in the Hsu securities class action described above. The complaint seeks an unspecified sum of damages, corporate reforms, equitable relief, and restitution. We intend to vigorously defend against this matter.

Stockholder Demand

On September 13, 2017, a purported stockholder filed a complaint in the Court of Chancery of the State of Delaware seeking an equitable apportionment of attorneys' fees in an unspecified amount. The purported stockholder alleges that his actions caused our board of directors to implement certain governance reforms and enhancements to our director compensation program, and that, as a result of his actions, the purported stockholder is entitled to attorneys' fees in an amount commensurate to those purported benefits. We filed an answer to the complaint on October 20, 2017. We intend to vigorously defend against this matter.

The pending proceedings described in this section involve complex questions of fact and law and will require the expenditure of significant funds and the diversion of other resources to defend. The results of legal proceedings are inherently uncertain, and material adverse outcomes are possible.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the SEC on March 9, 2018, 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, 2018.

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, 2018.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

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

Exhibit	Description
3.1	<u>Second Amended and Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 14, 2016 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016 and incorporated herein by reference)</u>
3.2	<u>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)</u>
10.1*	<u>Collaboration and License Agreement, dated January 30, 2018, between the Company and CANbridgepharma Limited</u>
10.2*	<u>License Agreement, dated March 30, 2018, between the Company and Pint Pharma International SA</u>
31.1	<u>Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018</u>
31.2	<u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018</u>
32.1	<u>Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2	<u>Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS	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

* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

SIGNATURES

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

PUMA BIOTECHNOLOGY, INC.

Date: May 10, 2018

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

Date: May 10, 2018

By: /s/ Charles R. Eyler
Charles R. Eyler
Senior Vice President, Finance and Administration and Treasurer
(Principal Financial and Accounting Officer)

Confidential Treatment Requested by Puma Biotechnology, Inc

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (this “Agreement”), entered into as of January 30th, 2018 (the “Effective Date”), is entered into by and between CANbridgepharma Limited, a corporation organized and existing under the laws of Hong Kong (“CANbridge”), and Puma Biotechnology, Inc., a corporation organized and existing under the laws of the State of Delaware (“PUMA”).

INTRODUCTION

WHEREAS, prior to the Effective Date, PUMA has entered into a License Agreement with Pfizer, Inc. (“Pfizer”) dated August 18, 2011, as amended (the “Pfizer License Agreement”), pursuant to which PUMA received an exclusive, worldwide license, with the right to grant sublicenses, to develop and commercialize neratinib;

WHEREAS, prior to the Effective Date, PUMA has obtained regulatory approval of neratinib in the United States; and

WHEREAS, CANbridge wishes to obtain from PUMA and PUMA wishes to grant to CANbridge certain rights and licenses under intellectual property owned or controlled by PUMA to Develop and Commercialize Licensed Products in the Territory (each as defined below) subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

**ARTICLE 1
DEFINITIONS**

As used in this Agreement, the following terms will have the meanings set forth below:

1.1 “Accounting Standards” means, with respect to a Person, generally accepted accounting principles as practiced in the United States (“GAAP”) or applicable international standards followed by such Person.

1.2 “Acquirer” has the meaning set forth in Section 14.2 (Acquisition Transactions).

1.3 “Acquired Party” has the meaning set forth in Section 14.2 (Acquisition Transactions).

1.4 “Acquisition Transaction” has the meaning set forth in Section 14.2 (Acquisition Transactions).

1.5 “Action” means any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.6 “Adverse Event” or “AE” has the meaning set forth in 21 C.F.R. § 312.32 and generally means any untoward medical occurrence associated with the use of a product in human subjects, whether or not considered related to such product. An AE does not necessarily have a causal relationship with a product, that is, an AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of such product.

1.7 “Adverse Ruling” has the meaning set forth in Section 12.3.1 (Termination for Material Breach).

1.8 “Affiliate” means, with respect to any Person, any Person controlling, controlled by or under common control with such first Person, for as long as such control exists. For purposes of this Section 1.8 (Affiliate), “control” means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such Laws; provided, however, that such ownership interest provides actual control over such Person), (b) status as a general partner in any partnership, or (c) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

1.9 “Alliance Manager” has the meaning set forth in Section 5.6.1 (Appointment).

1.10 “Anti-Corruption Laws” means (a) the U.S. Foreign Corrupt Practices Act of 1977 (the “FCPA”), the U.K. Bribery Act 2010, (b) the criminal code of each Region in the Territory, and (c) the domestic laws of the Territory.

1.11 “Bankruptcy Code” has the meaning set forth in Section 2.6 (Bankruptcy Code §365(n) Election).

1.12 “Blocking Third Party Patents Rights” means, with respect to a Licensed Product in any Region in the Territory, any patent Controlled by a Third Party that, absent a license thereunder, would be infringed by the Exploitation of such Licensed Product in such Region.

1.13 “Blocking Third Party Intellectual Property Costs” means any [***] CANbridge, its Affiliates or its Sublicensees to a Third Party who Controls Blocking Third Party Patent Rights for the right to Exploit Licensed Products under such Blocking Third Party Patent Rights.

1.14 “Breaching Party” has the meaning set forth in Section 12.3.1 (Termination for Material Breach).

1.15 “Business Day” means any day other than a Saturday or a Sunday on which the banks in New York, New York and Beijing, China are open for business.

1.16 “Calendar Quarter” means each of the three month periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year; provided, however: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the Calendar Quarter in which the Effective Date occurs; and (b) the last Calendar Quarter shall extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.

1.17 “Calendar Year” means, for the first Calendar Year, the period beginning on the Effective Date and ending on December 31, 2018, and for each Calendar Year thereafter each twelve (12)-month period commencing on January 1, and ending on December 31, except that the last Calendar Year shall commence on January 1 of the year in which this Agreement expires or terminates and end on the effective date of such expiration or termination.

1.18 “CANbridge Indemnified Parties” has the meaning set forth in Section 10.1 (Indemnification by PUMA).

1.19 “CANbridge Invention” has the meaning set forth in Section 7.1.2 (Ownership).

1.20 “Clinical Trial Application” or “CTA” has the meaning set forth in Section 1.56 (“IND”).

1.21 “CMC” means the Chemistry, Manufacturing and Controls portion of any Regulatory Filing.

1.22 “CMC Data” means any data included in the CMC portion of a Regulatory Filing or in any supporting development reports thereto, in each case, with respect to any Licensed Product in any country in the world.

1.23 “Clinical Study” means a study in which human subjects or patients are dosed with a drug, whether approved or investigational, including any Phase II Clinical Study, Phase IIa Clinical Study, Phase III Clinical Study, or Phase IIIb Clinical Study.

1.24 “Clinical Trial Waiver” means the receipt of written confirmation from the applicable Regulatory Authority that the data generated by PUMA and submitted to such Regulatory Authority is sufficient for approval of an application for Regulatory Approval for the First Indication without additional comparative Clinical Study requirements

1.25 “Commercialization”, “Commercializing” or “Commercialize” means any and all activities related to the pre-marketing, launching, marketing, promotion (including advertising and detailing), labeling, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, having sold, importing and exporting for sale, having imported and exported for sale, distribution, having distributed, customer service and support, and post-marketing safety surveillance and reporting of a product (including a Licensed Product), but not including Manufacturing.

1.26 “Commercially Reasonable Efforts” means, in respect of a Party, the level of efforts and resources (measured as of the time that such efforts and resources are required to be used under this Agreement) that are commonly used by a company in the industry of a similar size and profile

as such Party to Develop, Manufacture or Commercialize, as the case may be, a product owned by such company or to which it has rights, which product is at a similar stage in its development or product life and is of a similar market and profitability potential to the Licensed Product and taking into account all relevant factors including, without limitation, the intellectual property protection of the product, product labeling or anticipated labeling, market potential, financial return, medical and clinical considerations, regulatory environments and competitive market conditions, market exclusivity, and other technical legal, scientific, medical or commercial factors that such a company would reasonably deem to be relevant.

1.27 “Confidential Information” means (a) all trade secrets or confidential or proprietary information (including any tangible materials embodying any of the foregoing) of the disclosing Party or its Affiliates provided or disclosed to the other Party or any of its Affiliates pursuant to this Agreement, (b) “Confidential Information” (as defined in the Prior CDA) that was disclosed by a Party or any of its Affiliates to the other Party or any of its Affiliates under the Prior CDA, and (c) the terms and conditions of this Agreement; provided, however, that Confidential Information will not include information that:

(i) has been published by a Third Party or otherwise is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party or its Affiliates;

(ii) has been in the receiving Party’s or its Affiliates possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information (as evidenced by the receiving Party’s or such Affiliate’s written records or other competent evidence);

(iii) is subsequently received by the receiving Party or its Affiliate from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party; or

(iv) has been independently developed by or for the receiving Party or its Affiliates without reference to, or use or disclosure of, the disclosing Party’s Confidential Information (as evidenced by the receiving Party’s or such Affiliate’s written records or other competent evidence);

provided, further, that clauses (ii) through (iv) above will not apply to the terms and conditions of this Agreement.

All Regulatory Filings owned by a Party will be deemed to be the Confidential Information of such Party and such Party will be deemed to be the disclosing Party and the other Party will be deemed to be the receiving Party with respect thereto.

1.28 “Compound” means the compound designated under the Pfizer License Agreement as PF-05208767, also known as “neratinib,” “WAY 179272” or “HKI-272,” and [***].

1.29 “Contract Manufacturing Organization” or “CMO” means any Third Party contract manufacturing organization.

1.30 “Control” or “Controlled” means, with respect to any Know-How, Patent Right, Regulatory Filing, Regulatory Approval or other property right, the legal authority or right (whether by ownership, license (other than a license granted pursuant to this Agreement) or otherwise) of a Person or its Affiliate, to grant access, a license or a sublicense of or under such Know-How, Patent Right, Regulatory Filing, Regulatory Approval or other property right, without breaching the terms of any agreement with a Third Party.

1.31 “Cover,” “Covering” or “Covered” means, when referring to a Licensed Product: (a) with respect to a Patent Right, that, in the absence of a license granted to a Person under an issued claim included in such Patent Right, the practice by such Person of a specified activity with respect to such Licensed Product would infringe such claim, or (b) with respect to an application for Patent Rights, that, in the absence of a license granted to a Person under a claim included in such application, the practice by such Person of a specified activity with respect to such Licensed Product would infringe such claim if such patent application were to issue as a patent.

1.32 “Development” or “Develop” means non-clinical and clinical drug research and development activities, whether before or after Regulatory Approval, including drug metabolism and pharmacokinetics, translational research, toxicology, pharmacology, test method development and stability testing, process and packaging development and improvement, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, conduct of Clinical Studies, regulatory affairs, the preparation and submission of Regulatory Filings, Clinical Study regulatory activities, and any other activities directed towards obtaining Regulatory Approval of any Licensed Product. Development includes use and importation of the relevant compound or Licensed Product to conduct such Development activities. Development will not include Commercialization activities.

1.33 “Development Milestone Event” has the meaning set forth in Section 6.1.2(a) (Development Milestone Payments).

1.34 “Development Milestone Payment” has the meaning set forth in Section 6.1.2(a) (Development Milestone Payments).

1.35 “Development Plan” has the meaning set forth in Section 3.2 (Development Plan).

1.36 “Dollars” or “\$” means United States dollars.

1.37 “Effective Date” has the meaning set forth in the preamble.

1.38 “Executive Officers” means (a) with respect to PUMA, the Chief Executive Officer of PUMA, and (b) with respect to CANbridge, the Chief Executive Officer of CANbridge. If the position of any of the Executive Officers identified in this Section 1.38 (Executive Officers) no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable title of the Executive Officer set forth herein will be replaced with the title of another executive officer with responsibilities and seniority

comparable to the eliminated Executive Officer, and the relevant Party will promptly provide notice of such replacement title to the other Party.

1.39 “Existing Third Party License Agreements” means the license agreements by and between PUMA and Third Parties listed on Schedule 1.39 attached hereto.

1.40 “Exploit” or “Exploitation” means to import, have imported, export, have exported, use, have used, sell, have sold, offer for sale or otherwise exploit, including to Develop, Commercialize, register, modify, enhance, improve, hold, or keep (whether for disposal or otherwise), or otherwise dispose of.

1.41 “FDA” means the United States Food and Drug Administration or any successor agency thereto.

1.42 “FFDCA” means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq.

1.43 “Field” means the diagnosis, treatment or prevention of disease in humans.

1.44 “First Commercial Sale” means with respect to a Licensed Product in any Region in the Territory, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such Region after the receipt of the Marketing Authorization for such Licensed Product has been obtained in such Region.

1.45 “First Indication” means extended adjuvant HER2 overexpressing breast cancer.

1.46 “Force Majeure Event” has the meaning set forth in Section [14.10](#) (Force Majeure).

1.47 “GAAP” has the meaning set forth in Section 1.1 (Accounting Standards).

1.48 “GCP” or “Good Clinical Practice” means all applicable then-current standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Studies, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products, (b) the Declaration of Helsinki (2013) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (d) the equivalent applicable Laws in any relevant Region, in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.49 “Generic Competition” means, with respect to any Region in the Territory, that any one or more Third Parties sell one or more Generic Products in such Region that have, in the aggregate, achieved [***] or more of the aggregate market share of Licensed Products and Generic Products (based on data provided by IMS Health Incorporated, Fairfield, Connecticut) in any Calendar Quarter as measured on an aggregate sales basis (in unit sales), or if

such data is not available, a methodology to be mutually agreed upon by the Parties for estimating the percentage of aggregate sales (in unit sales) based on market share of Generic Products in such Region.

1.50 “Generic Product” means, with respect to a Licensed Product, a [***].

1.51 “GLP” or “Good Laboratory Practice” means all applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA’s Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58 or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (OECD), and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which a Licensed Product is intended to be sold by the Party that is subject to such standards, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.52 “GMP” or “Good Manufacturing Practice” means all applicable then-current standards for Manufacturing, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. §§ 201, 211, 600 and 610 and all applicable FDA guidelines and requirements, (b) European Directive 2003/94/EC for medicines and investigational medicines for human use and the applicable guidelines stated in the Eudralex guidelines, (c) the principles detailed in the applicable ICH guidelines, (d) the conduct of an inspection by a Qualified Person and the execution by such Qualified Person of an appropriate certification of inspection; and (e) the equivalent applicable Laws in any relevant Region, each as may be amended and applicable from time to time.

1.53 “Governmental Authority” means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

1.54 “Government Order” means any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority.

1.55 “ICH” means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.56 “IND” means an application filed with a Regulatory Authority for authorization to commence Clinical Studies, including (a) an Investigational New Drug Application as defined in the FDCA or any successor application or procedure filed with the FDA, (b) any equivalent of a United States IND in other countries or regulatory jurisdictions, including a Clinical Trial Application (“CTA”) and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.57 “Indemnified Party” means a Person entitled to indemnification under ARTICLE 10 (Indemnification; Damages).

1.58 “Indemnifying Party” means a Party from whom indemnification is sought under ARTICLE 10 (Indemnification; Damages).

1.59 “Indications” means, collectively, the First Indication and the Second Indication.

1.60 “Infringement Action” has the meaning set forth in Section 7.3.2 (Enforcement of Licensed Patents in the Territory).

1.61 “Infringement Claim” has the meaning set forth in Section 7.4 (Claimed Infringement).

1.62 “Insolvent Party” has the meaning set forth in Section 2.6 (Bankruptcy Code § 365(n) Election).

1.63 “International Chamber of Commerce” or “ICC” has the meaning set forth in Section 13.2 (Arbitration).

1.64 “Invention” has the meaning set forth in Section 7.1.1 (Inventorship).

1.65 “Joint Know-How” means any Know-How that is first conceived or reduced to practice jointly by the Parties or their Affiliates or others acting on behalf of the Parties or their Affiliates in the conduct of Development, Manufacturing or Commercialization of the Licensed Product under this Agreement during the Term.

1.66 “Joint Inventions” has the meaning set forth in Section 7.1.2 (Ownership).

1.67 “Joint Patent Rights” means any Patent Rights that contain one or more claims that claim any Joint Know-How or Joint Invention.

1.68 “JSC” has the meaning set forth in Section 5.1 (Formation; Purposes and Principles).

1.69 “Know-How” means all chemical and biological materials and other tangible materials, inventions, practices, methods, protocols, formulae, knowledge, know-how, trade secrets, processes, procedures, assays, skills, experience, techniques, data and results of experimentation and testing, including pharmacological, toxicological and pre-clinical and clinical test data and analytical and quality control data, patentable or otherwise.

1.70 “Knowledge” means [***].

1.71 “Law” or “Laws” means all laws, statutes, rules, codes, regulations, orders, decrees, judgments or ordinances of any Governmental Authority, or any license, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

1.72 “Letter” means that letter agreement by and between CANbridge and PUMA dated as of the Effective Date.

1.73 “Licensed Know-How” means any and all Know-How Controlled by PUMA or its Affiliates as of the Effective Date or during the Term (including any and all information contained in Regulatory Filings, CMC Data, PUMA Inventions and PUMA’s interest in the Joint Know-How and Joint Inventions) that is necessary or useful to Exploit any Licensed Product in the Field and in the Territory.

1.74 “Licensed Patents” means any and all Patent Rights Controlled by PUMA or its Affiliates as of the Effective Date or during the Term (including (a) the Patent Rights identified on Schedule 9.2.1 (Licensed Patents) and (b) PUMA’s interest in the Joint Patent Rights), in each case, that are necessary or useful to Exploit any Licensed Product in the Field and in the Territory.

1.75 “Licensed Product” means any pharmaceutical product containing the Compound.

1.76 “Licensed Trademark” means the NERLYNX® mark that is registered with the U.S. Patent and Trademark Office under registration number 5311871, and all other filings for the analogous trademark in jurisdictions outside the U.S.

1.77 “Losses” means damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, taxes, expenses, or amounts paid in settlement (in each case, including reasonable attorneys’ and experts’ fees and expenses), in each case resulting from an Action by a Third Party.

1.78 “Manufacture” or “Manufacturing” means all activities related to the production of a Licensed Product, including the production of any of the following to the extent used in a Licensed Product: any drug substance produced in bulk form for use as an active pharmaceutical ingredient, drug product, compounded or finished final packaged and labeled form, and in intermediate states, including but not limited to the following activities: reference standard preparation, cell bank preparation, mammalian cell production, purification, formulation, scale- up, packaging, quality assurance oversight, quality control testing (including in-process release and stability testing), validation activities directly related to all of the foregoing, and data management and recordkeeping related to all of the foregoing. References to a Person engaging in Manufacturing activities will include having any or all of the foregoing activities performed by a Third Party.

1.79 “Marketing Authorization” means the grant of all necessary permits, registrations, authorizations, licenses and approvals (or waivers) required for the Manufacture and Commercialization of a Licensed Product for use in the Field and in the Territory, including any Regulatory Approval for sale or marketing, and, where required, Pricing and Reimbursement Approvals.

1.80 “New Drug Application” or “NDA” means a new drug application or product license application or its equivalent filed with and accepted by the FDA after completion of human clinical trials to obtain marketing approval for a Licensed Product, or any comparable application filed with and accepted by the regulatory authorities of a country or Region other than the U.S.

1.81 “Net Sales” means the gross amount invoiced by or on behalf of CANbridge, its Affiliates and their respective Sublicensees for sales of any Licensed Product in the Territory (other than sales among CANbridge, its Affiliates or its 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 (a) included in the gross invoiced sales price of the Licensed Product or otherwise directly incurred by CANbridge, its Affiliates and their respective Sublicensees with respect to the sale of the Licensed Product, (b) normal and customary, and (c) not otherwise deducted in computing other amounts hereunder: (i) rebates, quantity and cash discounts, and other discounts to customers, (ii) taxes (except income taxes) and tariffs or duties paid, absorbed or allowed which are directly related to the sale of the Licensed Product, (iii) credits, allowances, discounts and rebates to, and chargebacks for, spoiled, damaged, out-dated, rejected or returned Licensed Product (including in connection with Licensed Product withdrawals, expired Licensed Product and Licensed Product recalls), (iv) actual freight and insurance costs, including without limitation the costs of export licenses, shipping, postage and handling charges, incurred in transporting the Licensed Product to customers, (v) discounts or rebates or other payments required by applicable Law, including any governmental special medical assistance programs, (vi) customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of the Licensed Product, and (vii) bad debts actually written off in connection with such Licensed Products.

Subsections (i) through (vii) shall be collectively referred to as “Deductions”. The following principles shall apply in the calculation of Net Sales:

In the case of any sale of Licensed Product which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the Licensed Product is paid for, if paid for before shipment or invoice.

In the case of any sale or other disposal of Licensed Product for non-cash consideration, Net Sales shall be calculated as the fair market price of the Licensed Product in the Region of sale or disposal. Notwithstanding the foregoing, provision of the Licensed Product for the purpose of conducting pre-clinical or clinical research shall not be deemed to be a sale. For clarity, any Licensed Product provided as free samples or as charitable donations shall not give rise to any Net Sales.

Net Sales shall be determined in accordance with the Accounting Standards.

1.82 “Non-Breaching Party” has the meaning set forth in Section 12.3.1 (Termination for Material Breach).

1.83 “Party” means either PUMA or CANbridge; “Parties” means PUMA and CANbridge, collectively.

1.84 “Party Vote” has the meaning set forth in Section [5.5](#) (Decision-Making; Escalation to Executive Officers).

1.85 “Patent Rights” means the rights and interests in and to (a) all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, (b) any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing, (c) any and all patents that have issued or in the future issue from the foregoing patent applications, including author certificates, utility models, petty patents, innovation patents and design patents and certificates of invention.

1.86 “Person” means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

1.87 “Pfizer” has the meaning set forth in the Recitals hereto.

1.88 “Pfizer License Agreement” has the meaning set forth in the Recitals hereto.

1.89 “Phase II Clinical Study” means a clinical study in humans of the safety, dose ranging and efficacy of a pharmaceutical product, as described in federal regulation 21 C.F.R. § 312.21(b) or its foreign equivalents.

1.90 “Phase IIa Clinical Study” means a Phase II Clinical Study specifically designed to assess dosing range and requirements.

1.91 “Phase III Clinical Study” means a controlled clinical study, or a portion of a controlled study, in humans of the efficacy and safety of a Licensed Product, which study (in its entirety or portion, as applicable), is prospectively designed to demonstrate statistically whether such Licensed Product is effective and safe for use in a particular indication in a manner sufficient to file a Regulatory Approval Application to obtain Regulatory Approval, as further defined in federal regulation 21 C.F.R. § 312.21(c) or its foreign equivalents. For clarity, with respect to what is commonly called a phase 2/3 study, the Phase III Clinical Study definition is met upon the first patient, first visit in the portion of such study that is prospectively designed to demonstrate statistically whether such Licensed Product is effective and safe for use in a particular indication in a manner sufficient to file a Regulatory Approval Application to obtain Regulatory Approval, as further defined in federal regulation 21 C.F.R. § 312.21(c) or its foreign equivalents.

1.92 “Pricing and Reimbursement Approval” means, with respect to a Licensed Product, the governmental approval, agreement, determination or decision establishing the price or level of reimbursement for such Licensed Product, in a given jurisdiction in the Territory prior to the sale of such Licensed Product in such jurisdiction in the Territory.

1.93 “Prior CDA” means the Confidential Disclosure Agreement between PUMA and CANbridge, dated October 31, 2017 (the “Prior CDA Effective Date”).

1.94 “Prior CDA Effective Date” has the meaning set forth in Section [1.93](#) (Prior CDA).

1.95 “Public Official or Entity” means (a) an individual or entity operating in an official or public capacity on behalf of a Governmental Authority (including physicians, hospital administrators, and other healthcare professionals working for or on behalf of state-controlled healthcare organization), (b) any official or employee of a quasi-public or non-governmental international organization, (c) any employee or other person acting for or on behalf of any entity that is wholly or partially government owned or controlled by a Governmental Authority, (d) any person exercising legislative, administrative, judicial, executive, or regulatory functions for or pertaining to a Governmental Authority (including any independent regulator), (e) any political party official, officer, employee, or other person acting for or on behalf of a political party and (f) any candidate for public office.

1.96 “PUMA Indemnified Parties” has the meaning set forth in Section 10.2 (Indemnification by CANbridge).

1.97 “PUMA Inventions” has the meaning set forth in Section 7.1.2 (Ownership).

1.98 “Qualified Person” or “QP” means a qualified person as defined in the Clinical Trial Directive 2001/20/EC and Annex 13 to the European GMP Guide.

1.99 “Redacted Pfizer License Agreement” means the terms and conditions of the Pfizer License Agreement to the extent that the same appear in the redacted version of the Pfizer License Agreement attached to the Letter.

1.100 “Region” means each of mainland China, Hong Kong, Macao, and Taiwan.

1.101 “Regulatory Approval Application” means an NDA or other equivalent application to seek Regulatory Approval of a Licensed Product for sale or marketing in any country(ies) or Region(s) outside the United States, as defined in the applicable Laws and filed with the Regulatory Authority of such country(ies) or Region(s).

1.102 “Regulatory Approval” means the approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in the Field in a country(ies) or Region(s), excluding separate Pricing and Reimbursement Approval that may be required.

1.103 “Regulatory Authority” means any multinational, federal, national, state, provincial or local regulatory agency, department, bureau or other Governmental Authority with authority over the clinical development, manufacture, marketing or sale of a Licensed Product in a Region, including FDA in the United States and EMA in the EU.

1.104 “Regulatory Filing” means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to a Licensed Product, including any documents submitted to any Regulatory Authority, including INDs, Regulatory Approval Applications, and all correspondence with any Regulatory Authority with respect to any Licensed Product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

1.105 “Royalty Term” has the meaning set forth in Section 6.2.2 (Royalty Term).

1.106 “Rules” has the meaning set forth in Section 13.2 (Arbitration).

1.107 “Safety Data” means any Adverse Event information from human trials and all results from non-clinical safety studies, including, but not limited to, toxicology and carcinogenicity data (if any), with respect to a Licensed Product required by one or more Regulatory Authorities to be collected or to be reported to such Regulatory Authorities under applicable Laws, but excluding any information related to the efficacy of the Licensed Product.

1.108 “Sales Milestone Event” has the meaning set forth in Section 6.1.2(b) (Sales Milestone Payments).

1.109 “Sales Milestone Payment” has the meaning set forth in Section 6.1.2(b) (Sales Milestone Payments).

1.110 “Second Indication” means metastatic HER2 overexpressing breast cancer for patients that have failed two or more lines of therapy.

1.111 “Serious Adverse Event” or “SAE” has the meaning set forth in 21 C.F.R. § 312.32, and generally means any Adverse Event that (a) results in death, (b) is life-threatening, (c) requires inpatient hospitalization or prolongation of existing hospitalization, (d) results in persistent or significant disability or incapacity or (e) is a congenital anomaly or birth defect.

1.112 “Severed Clause” has the meaning set forth in Section 14.5 (Severability).

1.113 “Sublicense” means a grant of rights from CANbridge to a Sublicensee under any of the rights licensed to CANbridge by PUMA under Section 2.1 (License Grant; Right of Reference) with respect to the Development or Commercialization of any Licensed Product.

1.114 “Sublicensee” means, with respect to a Party, a Third Party sublicensee of rights granted to such Party under this Agreement or a Third Party licensee of rights with respect to a Licensed Product which rights are retained by such Party under this Agreement with respect to such Licensed Product.

1.115 “Supply Agreement” has the meaning set forth in Section 4.1 (Supply Terms).

1.116 “Term” has the meaning set forth in Section 12.1 (Term).

1.117 “Territory” means the People’s Republic of China, including, for the avoidance of doubt, each of the Regions.

1.118 “Third Party” means any Person other than a Party or any of its Affiliates.

1.119 “Third Party Claim” has the meaning set forth in Section 10.3.1 (Notice).

1.120 “Trademark” means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

1.121 “Tyrosine Kinase Inhibitor” means [***]. For the avoidance of doubt, “Tyrosine Kinase Inhibitor” shall not include [***].

1.122 “United States,” “U.S.” “US” or “US Territory” means the United States of America and its territories and possessions.

1.123 “Valid Claim” means either: (a) 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 (b) 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 [***] from its priority date, and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

ARTICLE 2 LICENSE GRANTS

2.1 License Grant; Right of Reference.

2.1.1 Exclusive License Grant. Subject to the terms and conditions of this Agreement, PUMA hereby grants to CANbridge an exclusive (even with respect to PUMA and its Affiliates), sublicensable (subject to Section 2.2.1 (CANbridge Right to Sublicense)), royalty-bearing right and license under the Licensed Patents, Licensed Know-How and, pursuant to Section 4.2.4(c) (Trademarks), the Licensed Trademark, to (a) Develop, Commercialize and otherwise Exploit Licensed Products in the Field in the Territory, including the right to co-administer (but not co-formulate) Licensed Products with other pharmaceutical products in the Territory, and (b) Develop Licensed Products outside of the Territory solely for the purpose of Exploiting such Licensed Products in the Territory. For clarity, this Section 2.1.1 does not grant any license to CANbridge under any intellectual property rights Controlled by PUMA to Develop, Commercialize, and otherwise Exploit, including the right to co-administer (but not co-formulate) any product being developed or commercialized by or on behalf of PUMA, its Affiliates or sublicensees other than Licensed Product.

2.1.2 CANbridge Right of Access and Reference. Subject to the terms of this Agreement, PUMA hereby grants CANbridge access to, and a right of reference with respect to, (a) its and its Affiliates’ Regulatory Filings, Regulatory Approvals and all corresponding documentation Controlled by PUMA or its Affiliates at any time during the Term, and (b) all Safety Data and CMC Data contained or referenced in any Regulatory Filings and all corresponding documentation Controlled by PUMA or its Affiliates at any time during the Term, in each case ((a) and (b)), for the sole purpose of Developing, seeking and securing Regulatory Approval for, Commercializing, and otherwise Exploiting Licensed Products in the Territory. The foregoing rights include without limitation the right for CANbridge and, to the extent permitted under this Agreement, its Affiliates and Sublicensees, to make copies of and reproduce such

documentation and information for the purposes set forth in this Section 2.1.2 (CANbridge Right of Access and Reference).

2.1.3 PUMA Right of Reference. Subject to the terms of this Agreement, CANbridge hereby grants PUMA, its Affiliates and sublicensees access to, and a right of reference with respect to, (a) its and its Affiliates' Regulatory Filings, Regulatory Approvals and all corresponding documentation Controlled by CANbridge or its Affiliates at any time during the Term, and (b) all Safety Data and CMC Data contained or referenced in any Regulatory Filings and all corresponding documentation Controlled by CANbridge or its Affiliates at any time during the Term, in each case ((a) and (b)), for the sole purpose of Developing, seeking and securing Regulatory Approval for, Commercializing, and otherwise Exploiting Licensed Products outside the Territory. The foregoing rights include without limitation the right for PUMA, its Affiliates and sublicensees, to make copies of and reproduce such documentation and information for the purposes set forth in this Section 2.1.3 (PUMA Right of Reference). Upon termination (but not expiration) of this Agreement, and subject to Section [12.2](#) (Paid-Up License Upon End of Royalty Term) of this Agreement, PUMA's rights under this Section 2.1.3 shall apply on a worldwide basis.

2.1.4 Delivery of Documentation. From time-to-time during the Term, upon CANbridge's reasonable request, Puma shall provide CANbridge with copies of all data and information (including existing Regulatory Filings) relating to Licensed Products that are (a) Controlled by PUMA, its Affiliates or its sublicensees and (b) reasonably necessary to support Development of, or Regulatory Approval for, Licensed Products in the Territory.

2.2 Sublicensing and Subcontracting.

2.2.1 CANbridge Right to Sublicense. CANbridge will have the right to grant Sublicenses (through multiple tiers) in the Territory of any and all rights granted to CANbridge by PUMA pursuant to Section 2.1 (License Grant; Right of Reference) to (a) its Affiliates and (b) solely to the extent required by applicable Law or any relevant Governmental Authority, Third Parties with the identity of such Third Parties being subject to PUMA's advance written consent, not to be unreasonably withheld. [In](#) the event that CANbridge grants a Sublicense pursuant to this Section 2.2.1 (CANbridge Right to Sublicense), CANbridge will remain responsible for its obligations under this Agreement and will ensure that each of its Sublicensees complies with all relevant provisions of this Agreement.

2.2.2 Sublicense Requirements. Each Sublicense granted by CANbridge to an Affiliate or a Third Party pursuant to Section 2.2.1 (CANbridge Right to Sublicense) will be in writing and will be consistent with the relevant restrictions and limitations set forth in this Agreement. No Sublicense will diminish, reduce or eliminate any obligation of either Party under this Agreement.

2.2.3 Performance by CANbridge Sublicensees. CANbridge will promptly provide PUMA with a copy of any fully executed Sublicense agreement covering any Sublicense granted hereunder. Any such Sublicense agreement entered into by CANbridge will contain the following provisions: (a) a requirement that such Sublicensee submit applicable sales or other reports to PUMA consistent with the reporting requirements set forth in Section 6.3 (Royalty Payments and Reports); (b) an audit requirement consistent with that set forth in Section 6.5

(Financial Audits); (c) a requirement that such Sublicensee comply with the confidentiality provisions and restrictions on use of Confidential Information contained in [Section 8.1 \(Confidential Information\)](#) with respect to PUMA's Confidential Information; and (d) those provisions required by the Existing Third Party License Agreements.

2.3 Performance by Independent Contractors. CANbridge may contract or delegate any portion of its obligations hereunder to a contractor subject to the terms and condition of [Section 14.9](#) (Affiliates, Sublicensees, and Contractors).

2.4 Exclusivity Covenant. During the Term, neither Party nor its Affiliates will directly or indirectly conduct, have conducted, engage in or fund any activity that involves the Development, Manufacture or Commercialization of any Tyrosine Kinase Inhibitor that [***] other than the Licensed Product pursuant to the terms and conditions set forth in this Agreement.

2.5 Reservation of Rights. No rights, other than those expressly set forth in this Agreement, are granted to either Party under this Agreement, and no additional rights will be deemed granted to either Party by implication, estoppel or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party or its Affiliates to the other under this Agreement are reserved.

2.6 Bankruptcy Code § 365(n) Election. All rights and licenses now or hereafter granted under or pursuant to this Agreement, are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the "Bankruptcy Code")). Each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. In the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code (the "Insolvent Party"), the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to it under this Agreement and all embodiments of such intellectual property (including all information related to such intellectual property and rights of reference with respect to Regulatory Approvals), and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless the Insolvent Party continues to perform all of its obligations under this Agreement, or (b) if not delivered or granted under (a) above, following the rejection of this Agreement by or on behalf of the Insolvent Party upon written request therefor by the other Party. The Parties hereto acknowledge and agree that all payments by CANbridge to PUMA under this Agreement, other than royalty payments pursuant to Section 6.2 (Royalties), do not constitute royalties within the meaning of Bankruptcy Code

§365(n) or relate to licenses of intellectual property under this Agreement.

2.7 Not Inconsistent Third Party Agreements. During the Term, neither PUMA nor any of its Affiliates will enter into any license of intellectual property pursuant to which PUMA or any of its Affiliates grants to a Third Party rights under or to any Know-How, Patent Rights or Licensed Trademarks, or otherwise enters into any agreement, that would contravene or be inconsistent or in conflict with the rights of CANbridge or the obligations of PUMA under this Agreement. During the Term, neither PUMA nor any of its Affiliates will amend, modify or terminate any in-license of Third Party intellectual property (including, without limitation, any such in-license that is in effect as of the Effective Date) without the prior written consent of

CANbridge if such amendment, modification or termination would materially adversely affect any of the rights that CANbridge or any of its Affiliates has under this Agreement.

2.8 The Pfizer License Agreement. CANbridge acknowledges that the rights granted to CANbridge under this Agreement that constitute a sublicense under the Pfizer License Agreement, in addition to being limited by and subject to the terms and conditions of this Agreement, are further limited by the terms and conditions of the Redacted Pfizer License Agreement. Notwithstanding ARTICLE 8 (Confidentiality and Publicity), pursuant to the Pfizer License Agreement, CANbridge acknowledges that PUMA will furnish to Pfizer a true and complete copy of this Agreement and any current and future amendments thereto, which Agreement shall be redacted to omit any and all information not directly relevant to the performance of PUMA's obligations under the Pfizer License Agreement, within [***] after the Effective Date of this Agreement or any amendments hereto have been executed. To the extent requested by PUMA from time to time, CANbridge will take reasonable steps (without requiring CANbridge to bear additional costs) to support PUMA's compliance with the Pfizer License Agreement.

ARTICLE 3 DEVELOPMENT

3.1 Development Diligence; Development Responsibilities; Manner of Performance.

3.1.1 Development Diligence. CANbridge (directly, or through its Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for a Licensed Product for the Indications in the Territory. For the avoidance of doubt, CANbridge's Development diligence obligations set forth in this Section 3.1.1 (Development Diligence) shall not be deemed to require CANbridge to conduct a full comparative Phase III Clinical Study, which, for clarity, does not include pharmacokinetic, safety or bridging studies (i.e., any study that does not include a clinical comparative study for efficacy), for any Licensed Product for the First Indication in the Territory.

3.1.2 Development Responsibilities. Subject to the terms and conditions of this Agreement, including this [ARTICLE 3](#) (Development) and Section [5.2](#) (Specific Responsibilities), CANbridge will have sole authority to, at its own expense, Develop Licensed Product for the purpose of obtaining Regulatory Approval in the Field and in the Territory, subject to PUMA's written approval (such approval not to be unreasonably withheld) of all protocols, study designs, and any amendments thereto, for any Clinical Studies to be conducted by or on behalf of CANbridge for the Licensed Product in the Field in the Territory. CANbridge will be responsible for the day-to-day implementation of any Development activities for which it (or any of its Affiliates) is assigned responsibility under this Agreement and the Development Plan, and will keep PUMA reasonably informed as to the progress of such activities.

3.1.3 Manner of Performance. CANbridge will perform its Development obligations under this Agreement in good scientific manner and in compliance with all applicable Laws (including with respect to each such activity that will or would reasonably be expected to be submitted to a Regulatory Authority in support of a regulatory filing or Regulatory Approval Application in the Territory, and then-current Good Laboratory Practice standards and Good Clinical Practices in the Territory).

3.2 Development Plan. Any Development of Licensed Products in the Territory for the Indications shall be conducted by CANbridge pursuant to a written plan describing the Development activities to be performed by CANbridge with respect to Clinical Studies for the Indications in the Territory (the “Development Plan”). The Development Plan shall be mutually agreed to by the Parties through the JSC pursuant to Section 5.2 (Specific Responsibilities). Any material changes to the Development Plan, including the addition of any clinical trial protocols (or any material changes to such protocols), shall be drafted by the proposing Party and agreed upon by the JSC pursuant to Section 5.2 (Specific Responsibilities), subject to the decision-making and escalation procedures set forth in Section 5.5 (Decision-Making; Escalation to Executive Officers). In the event of any proposed change to the Development Plan as a result of any interaction with any Regulatory Authority, the JSC shall meet as promptly as practicable to review and discuss any such proposed changes and determine an appropriate revision (if any) to the Development Plan. For clarity, this Section 3.2 (Development Plan) shall not (a) supersede PUMA’s right to approve the protocols, study designs, or any amendments thereto, for proposed Clinical Studies for Licensed Product in the Field in the Territory pursuant to Section 3.1.2 (Development Responsibilities), or (b) prevent or limit CANbridge’s right to pursue the Development of indications other than the Indications (including the conduct of Clinical Trials), subject to the foregoing subsection (a).

3.3 Development Records and Reporting.

3.3.1 Records. CANbridge shall maintain complete and accurate records of all work conducted by or on behalf of CANbridge in furtherance of the Development of the Licensed Product and all material results, data and developments made in conducting such activities. Such records shall be maintained in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in accordance with applicable Law.

3.3.2 Reporting. CANbridge will provide to PUMA a written report at least [***], in English, describing in reasonable detail CANbridge’s activities and progress related to the Development of the Licensed Product in the Territory. CANbridge shall promptly respond to PUMA’s reasonable questions or requests for additional information relating to such Development activities.

3.4 Regulatory Submissions and Approvals; Communications; Meetings.

3.4.1 Regulatory Filings and Approvals. CANbridge, or its relevant Affiliates or Sublicensees, will have the sole right to file and hold all Regulatory Filings, and to apply for, own, and maintain all Regulatory Approvals, in each case for all Licensed Products in the Territory at CANbridge’s cost and expense.

3.4.2 Regulatory Communications. Subject to applicable Law and this Section 3.4 (Regulatory Submissions and Approvals; Communications; Meetings), CANbridge will oversee, monitor and manage all interactions and communications with Regulatory Authorities with respect to Licensed Products in the Territory. CANbridge will have final decision-making authority regarding all regulatory activities, including the labeling strategy and the content of Regulatory Filings within the Territory, subject to the terms and conditions of this Agreement. CANbridge will promptly notify PUMA of all material communications or correspondence with Regulatory Authorities with respect to Licensed Products in the Territory that are received by

CANbridge from any Regulatory Authority or submitted by CANbridge to any Regulatory Authority.

3.4.3 Regulatory Meetings. Until such time as CANbridge obtains Regulatory Approval for a Licensed Product in the Territory, to the extent legally permissible and practicable, CANbridge shall provide PUMA with prior written notice of all material meetings with Regulatory Authorities (including advisory committee meetings and any other meeting of experts convened by a Regulatory Authority) regarding the Licensed Product, such notice to be provided within [***] after CANbridge receives notice of the scheduling of such meeting. PUMA shall have the right to request to be present at (but not to participate in, unless requested by CANbridge or the Regulatory Authority) all such meetings with Regulatory Authorities to the extent permitted under applicable Laws, at PUMA's sole cost and expense, and CANbridge shall consider any such request in good faith.

3.4.4 Termination or Suspension of Clinical Studies. Notwithstanding anything to the contrary in this Agreement or the Pharmacovigilance Agreement, CANbridge may terminate or suspend any Clinical Study relating to the Licensed Product of which it or its Affiliate or Sublicensee is the sponsor, without the approval or consent of the JSC or PUMA, if (a) a Regulatory Authority, institutional review board or safety data review board for such Clinical Study has required or recommended such termination or suspension or (b) CANbridge believes in good faith that such termination or suspension is warranted because of observed safety risks to the study subjects or patients. In either case, CANbridge will promptly notify PUMA in writing of such termination or suspension.

3.4.5 Regulatory Investigation or Inquiry. If any Regulatory Authority (a) contacts CANbridge or its Affiliate with respect to the alleged improper Development, or Commercialization of any Licensed Product, (b) conducts, or gives notice of its intent to conduct, an inspection at CANbridge's or its Affiliate's facilities used in the Development of the Licensed Product, or (c) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of CANbridge or its Affiliate that could reasonably be expected to adversely affect any Development or Commercialization activities with respect to a Licensed Product in the Territory or outside of the Territory, then CANbridge will promptly notify PUMA in writing of such contact, inspection or notice.

3.5 Pharmacovigilance. Within [***], the Parties shall define and finalize the actions that the Parties shall employ with respect to Licensed Products to protect patients and promote their well-being in a written pharmacovigilance agreement (the "Pharmacovigilance Agreement"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of Adverse Event reports and any other information concerning the safety of any Licensed Product, including recall and withdrawal responsibilities, processes and procedures. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable Laws. Furthermore, such agreed procedure shall be consistent with relevant ICH guidelines, except where said guidelines may conflict with existing local regulatory reporting safety reporting requirements, in which case local reporting requirement shall prevail. CANbridge shall be responsible for reporting quality complaints, Adverse Events and safety data related to the Licensed Product to applicable Regulatory Authorities in the Territory, as well as responding to safety issues and to all requests

of Regulatory Authorities relating to Licensed Products in the Territory. PUMA shall be responsible for reporting quality complaints, Adverse Events and safety data related to Licensed Product to applicable Regulatory Authorities outside the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Licensed Product outside the Territory. The Pharmacovigilance Agreement shall also provide for a worldwide safety database to be maintained by PUMA [***], which worldwide safety database will be accessible by CANbridge, its Affiliates, Sublicensees and contractors to the full extent necessary for CANbridge to exercise its rights under this Agreement, comply with its obligations under this Agreement, and comply with all applicable Laws. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and permitted sublicensees and contractors to comply with such obligations.

ARTICLE 4 MANUFACTURE AND COMMERCIALIZATION

4.1 **Manufacture Supply Terms.** Except as otherwise expressly set forth in the Supply Agreement, CANbridge hereby agrees to purchase any and all of its requirements of clinical and commercial supply of the Licensed Product during the Term from PUMA. The per unit supply price for each [***] of the Licensed Product in [***] form shall be (a) \$[***] for Licensed Product supplied for clinical use, and (b) \$[***] for Licensed Product supplied for commercial use. Such prices shall be revised every [***] to account for any increase in the relevant Producer Price Index applicable to the prior [***]. The Parties will execute a supply agreement containing supply and quality terms and conditions consistent with the principles set forth on Schedule [4.1](#) hereto (Supply Agreement Key Terms) and typical for such agreements (the "Supply Agreement").

4.2 Commercialization.

4.2.1 **Commercialization Diligence.** Upon receipt of Marketing Authorization for a given Licensed Product in a given Region in the Territory for a given Indication, CANbridge (directly, or through its Affiliates, Sublicensees or contractors) shall use Commercially Reasonable Efforts to Commercialize such Licensed Products in such Region for such Indication.

4.2.2 **Commercialization Responsibilities.** CANbridge will be solely responsible for at its expense, and subject to Section [4.2.4](#) (Coordination of Commercial Activities), will have sole discretion with respect to, Commercializing Licensed Product in the Territory.

4.2.3 **Manner of Performance.** CANbridge will perform its Commercialization obligations under this Agreement in good scientific manner and in compliance with all applicable Laws.

4.2.4 Coordination of Commercial Activities

(a) **General.** The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of Licensed Products in the Territory. As such, the Parties will coordinate such activities, where appropriate, through the JSC. Following Regulatory Approval in a Region in the Territory, CANbridge shall update PUMA in

writing on a quarterly basis through the JSC of the expected timing of the commercial launch of Licensed Product in such Region.

(b) Global Brand Elements. The Parties may, through their respective Alliance Managers and the JSC, endeavor to develop and adopt the key distinctive colors, logos, images, symbols, and trademarks to be used both in and outside of the Territory in connection with the Commercialization of the Licensed Product. Each Party shall own the rights in such global brand elements in its respective territory and shall Commercialize the Licensed Product in its respective territory in a manner consistent with the applicable global brand elements.

(c) Trademarks. Subject to Section 4.2.4(b) (Global Brand Elements), CANbridge shall have the right to brand the Licensed Products in the Territory using CANbridge related trademarks and any other trademarks and trade names it determines appropriate for the Licensed Products, including, for the avoidance of doubt, the Licensed Trademark, which branding may vary by Region or within a Region. Except with respect to the Licensed Trademark, CANbridge shall own all rights in such trademarks and register and maintain such trademarks in the countries and regions within the Territory, where and how it determines appropriate.

(d) Market Research and Materials. At each regularly scheduled JSC meeting, each Party shall update the other Party regarding the material market research that it is performing with respect to the Licensed Products, and shall provide the other Party with a copy of such research upon request if such material market research is necessary for the other Party to Commercialize the Licensed Products in its respective territory or is otherwise requested by any Regulatory Authority.

4.2.5 Diversion. Each Party hereby covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its licensees, sublicensees and contractors not to, directly or indirectly, actively promote, market, distribute, import, sell or have sold any Licensed Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory. Neither Party shall engage, nor permit its Affiliates, sublicensees or contractors to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of such product located in any country, Region or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country, Region or jurisdiction in the other Party's territory.

4.2.6 No Violation. Notwithstanding anything to the contrary contained herein, CANbridge (including its Affiliates, Sublicensees and contractors) will not be obligated to undertake or continue any Commercialization activities with respect to Licensed Products if CANbridge (or its Affiliates, Sublicensees or contractors, as applicable) reasonably determines that performance of such Commercialization activity would violate applicable Law or infringe any Third Party Patent Rights.

ARTICLE 5 GOVERNANCE; JOINT STEERING COMMITTEE

5.1 Formation; Purposes and Principles. Promptly following the Effective Date, but in no event later than [***] thereafter, PUMA and CANbridge will form a joint steering

committee (the “**JSC**”) to provide oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement .

5.2 Specific Responsibilities. In addition to its overall responsibility to provide oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement, the JSC will:

(a) discuss and agree upon the initial Development Plan;

(b) review and approve changes to the Development Plan on an as- needed basis;

(c) coordinate and share information with respect to the Development and Commercialization of Licensed Products, including as set forth in Section [4.2.4](#) (Coordination of Commercial Activities);

(d) keep each Party reasonably informed of the other Party’s Development and Commercialization activities and interactions with Regulatory Authorities, by receiving updates from the Party conducting such activities;

(e) coordinate and share information with respect to PUMA’s Manufacture and supply of Licensed Products and activities associated therewith to the extent relevant for Development and Commercialization of Licensed Products in the Territory in accordance with this Agreement;

(f) attempt to resolve in the first instance all matters between the Parties that are in dispute; and

(g) perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement to the extent agreed to in writing by the Parties.

5.3 Membership. The JSC will be composed of a total of [***] representatives, [***] of which will be appointed by each of PUMA and CANbridge. Each individual appointed by a Party as a representative to the JSC will be an employee or contractor of such Party, or an employee or contractor of such Party’s Affiliate. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party’s co-chairperson. The JSC will be co-chaired by one designated representative of each Party. The co-chairperson of the JSC will cast its Party’s vote on the JSC and such designee will have the authority to make decisions on behalf of such Party. Each co- chairperson will alternate being responsible for each meeting for (a) calling meetings, (b) preparing and circulating an agenda in advance of each meeting; provided, however, that the applicable co- chairperson will include any agenda items proposed by either Party on such agenda, and (c) preparing and issuing minutes of each meeting promptly thereafter. Each JSC representative will be subject to confidentiality obligations no less stringent than those in [ARTICLE 8](#) (Confidentiality and Publicity).

5.4 Meetings; Reports. The JSC will hold meetings [***] during the Term for so long as the JSC exists. The JSC may meet in person or by audio or video conference as its

representatives may mutually agree. Other representatives of the Parties, their Affiliates and Third Parties involved in the Development, Manufacture, or Commercialization of Licensed Products may be invited by the members of the JSC to attend meetings as non-voting observers; provided, however, that such representatives are subject to confidentiality obligations no less stringent than those set forth in ARTICLE 8 (Confidentiality and Publicity); and, provided further, that each representative appointed by a Party to take action at a meeting will have sufficient authority to execute such action on behalf of such Party. No action taken at a meeting will be effective unless at least one representative of each Party is present or participating. Neither Party will unreasonably withhold attendance of at least one representative of such Party at any meeting of the JSC for which reasonable advance notice was provided.

5.5 Decision-Making; Escalation to Executive Officers. The Parties will endeavor in good faith to reach unanimous agreement with respect to all matters within the JSC's authority. Each Party's representatives on the JSC shall collectively have one vote, (the "Party Vote") and no action or decision shall be taken by the JSC without unanimous Party Vote (*i.e.* , the affirmative Party Vote of each Party), which will be documented by a written consent signed by each Party's co-chairperson. Should the JSC not be able to reach agreement with respect to a matter at a duly called meeting of the JSC, either Party may refer such matter to the Executive Officers for resolution, and the Executive Officers will attempt to resolve the matter in good faith. If the Executive Officers fail to resolve such matter within [***] after the date on which the matter is referred to the Executive Officers (unless a longer period is agreed to by the Parties), then, (a) [***] shall have final decision-making authority with respect to the [***], including any [***], subject to [***] right to [***], and (b) with respect to all other such matters, [***]. Notwithstanding any provision of this Section 5 (Governance; Joint Steering Committee) to the contrary, the JSC shall not have the authority to amend the terms or conditions of this Agreement.

5.6 Alliance Managers.

5.6.1 Appointment. Each Party shall appoint a person to oversee interactions between the Parties for all matters related to the Development and Commercialization of Licensed Products between meetings of the JSC (each, an "Alliance Manager"). The Alliance Managers will have the right to attend all meetings of the committees as non-voting participants and may bring to the attention of the JSC any matters or issues either Alliance Manager reasonably believes should be discussed and will have such other responsibilities as the Parties may mutually agree in writing. Each Party may replace its Alliance Manager at any time or may designate different Alliance Managers with respect to Development and Commercialization matters, respectively, by notice in writing to the other Party.

5.6.2 Responsibility. The Alliance Managers, if appointed, will have the responsibility of creating and maintaining a constructive work environment within the JSC and between the Parties for all matters related to this Agreement. Without limiting the generality of the foregoing, each Alliance Manager will:

(a) provide a single point of communication within the Parties' respective organizations and between the Parties with respect to this Agreement; coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and

(b) take such other steps as may be required to ensure that meetings of the JSC occur as set forth in this Agreement, that procedures are followed with respect to such meetings (including the giving of proper notice and the preparation and approval of minutes) and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

ARTICLE 6 FINANCIAL PROVISIONS

6.1 Upfront Payment; Milestone Payments.

6.1.1 Upfront Payment. Subject to the terms and conditions of this Agreement, CANbridge will pay PUMA a non-refundable, non-creditable payment in the amount of thirty million Dollars (\$30,000,000), which upfront payment will be due and payable to PUMA within [***] following the Effective Date, or such longer period of time as is required to effectuate the transfer of such upfront payment in accordance with applicable Laws.

6.1.2 Milestone Payments.

(a) Development Milestone Payments. Subject to the terms and conditions of this Agreement, CANbridge will pay to PUMA the following non-refundable, non-creditable one-time milestone payments (each, a "Development Milestone Payment") within [***] of achieving each of the following milestones in [***] (each a "Development Milestone Event"):

Development Milestone Event	Development Milestone Payment
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]

Each Development Milestone Payment will be payable only one-time and only upon the first achievement of the applicable Development Milestone Event in [***], and no amounts would be due for subsequent or repeated achievements.

(b) Sales Milestone Payments. Subject to the terms and conditions of this Agreement, CANbridge will pay to PUMA the following non-refundable, non-creditable one-time sales milestone payments (each, a “Sales Milestone Payment”) within [***] during the Royalty Term in which the aggregate Net Sales of Licensed Products by CANbridge and its Affiliates and Sublicensees in the Territory achieves each of the following sales thresholds (each a “Sales Milestone Event”):

Sales Milestone Event	Sales Milestone Payment
Aggregate Single Calendar Year Net Sales Greater than or Equal to \$[***]	\$[***]
Aggregate Single Calendar Year Net Sales Greater than or Equal to \$[***]	\$[***]
Aggregate Single Calendar Year Net Sales Greater than or Equal to \$[***]	\$[***]
Aggregate Single Calendar Year Net Sales Greater than or Equal to \$[***]	\$[***]

Each Sales Milestone Payment will be payable only one-time and only upon the first achievement of the applicable Sales Milestone Event in the Territory, and no amounts would be due for subsequent or repeated achievements. If a Sales Milestone Event is achieved prior to the achievement of the preceding Sales Milestone Event set forth in the relevant chart (i.e., if a lower-listed Sales Milestone Event is achieved before a Sales Milestone Event that is listed higher up in the relevant chart), then upon achievement of the relevant Sales Milestone Event, [***].

6.1.3 Milestone Event Notice. Within [***] after a Party becomes aware that a Milestone Event was achieved, it will notify the other Party thereof in writing.

6.2 Royalties.

6.2.1 Royalty Rates. Subject to the terms and conditions in this Agreement, on a Region-by-Region and Licensed Product-by-Licensed Product basis during the applicable Royalty Term, CANbridge will pay to PUMA royalties on Net Sales of Licensed Products in the Territory, as calculated by multiplying the applicable royalty rates below by the corresponding amount of incremental Net Sales in the Territory of all Licensed Products in each Calendar Year:

Annual Net Sales of Products	Royalty Rate
For that portion of aggregate annual Net Sales less than \$[***]	[***]%
For that portion of aggregate annual Net Sales greater than or equal to \$[***] and less than \$[***]	[***]%
For that portion of aggregate annual Net Sales greater than or equal to \$[***]	[***]%

For example, if the Net Sales of Licensed Products in the Territory in a given Calendar Year totaled \$[***], CANbridge would pay to PUMA a [***] percent ([***]%) royalty on the first \$[***] and a [***] percent ([***]%) royalty on the next \$[***], for a total royalty payment ([***]) equal to \$[***].

6.2.2 Royalty Term. Royalties will be due under this Section 6.2.2 (Royalty Term) with respect to a given Licensed Product and given Region in the Territory during the period commencing upon the earlier of (a) the first sale of such Licensed Product for use in a named patient access program in such Region or (b) the First Commercial Sale of such Licensed Product in such Region (the earlier of (a) and (b) referred to herein as the “Royalty Commencement Date”), and ending upon the later of (x) the expiration or abandonment of the last Valid Claim within the Licensed Patents Covering such Licensed Product in such Region, or (y) the earlier of (i) the time when Generic Competition first exists with respect to such Licensed Product in such Region, or

(ii) the 10th anniversary of the First Commercial Sale for such Licensed Product in such Region (such period, the “Royalty Term”).

6.3 Royalty Payments and Reports. CANbridge will pay to PUMA any amounts due pursuant to Section 6.2.1 (Royalty Rates) within [***] after the end of each Calendar Quarter, and will provide to PUMA concurrently with such payment a statement setting forth (a) the monthly sales calculation of Net Sales on a Licensed Products-by-Licensed Product and Region-by-Region basis in the Territory during such Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars); (b) the type and amount of permitted Deductions from gross sales to determine Net Sales and the total amount of such Deductions; (c) the applicable royalty rates for each Licensed Product in each Region in the Territory after applying any permitted Deductions set forth above; and (d) a calculation of the royalties due to PUMA for such Calendar Quarter.

6.4 Payment Reduction for Blocking Third Party Intellectual Property. With respect to a particular Region in the Territory, CANbridge will be entitled to credit from royalty payments under Section 6.2 (Royalties) otherwise payable to PUMA in such Region [***] of any Blocking Third Party Intellectual Property Costs applicable to such Region. Notwithstanding the foregoing, in no event shall such deductions reduce the royalties otherwise payable to PUMA by more than [***] pursuant to this Section [6.4](#).

6.5 Financial Audits.

6.5.1 Record Keeping. CANbridge and its Affiliates will keep complete and accurate records in accordance with its Accounting Standards of the items underlying (a) the Sales Milestone Payments, (b) the Development Milestone Payments, (c) Net Sales, (d) royalty payments, (e) any other payments under this Agreement, and (f) CANbridge’s prosecution, maintenance and enforcement of Patent Rights pursuant to this Agreement (collectively, “Relevant Records”). CANbridge, and its Affiliates and Sublicensees, shall maintain the Relevant Records for the longer of: (i) the period of time required by applicable Law or (ii) [***] following expiration or termination of this Agreement. CANbridge shall require its Sublicensees to provide to CANbridge (so that PUMA may provide the same to Pfizer) copies of all Relevant Records relating to such Sublicensees’ sale of Licensed Products as necessary to allow PUMA or, if applicable, Pfizer (under the Pfizer License Agreement) to review such Relevant Records when conducting an audit of CANbridge or PUMA, as applicable, pursuant to this Section 6.5.1 (Record

Keeping). Notwithstanding [ARTICLE 8](#) (Confidentiality and Publicity), pursuant to the Pfizer License Agreement, Pfizer will be allowed to review such Relevant Records. PUMA will have the right [***], at its own expense, to have an independent, certified public accountant, selected by PUMA and reasonably acceptable to CANbridge, review any such records of CANbridge in the location(s) where such records are maintained by CANbridge upon reasonable prior written notice, during regular business hours and under obligations of confidentiality, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement and to verify compliance with the terms of this Agreement, within the prior [***] Calendar Year period. The records for any Calendar Year may be audited no more than [***].

6.5.2 Audit Report. The report prepared by the independent certified public accounting firm pursuant to Section 6.5.1 (Record Keeping), a copy of which will be sent or otherwise provided to each Party by such independent public accountant at the same time, will contain the conclusions of such accounting firm regarding the audit and will specify that the amounts paid pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment, and the specific details regarding any discrepancies. No other information will be provided to PUMA without the prior consent of CANbridge unless disclosure is required by Law, regulation or judicial order, and if so determined by PUMA, it will, if permitted, give CANbridge prior notice thereof reasonably sufficient for CANbridge to seek a protective order against or limiting such disclosure. If such report shows any underpayment, then CANbridge will remit to PUMA, within [***] after receipt of such report, (a) the amount of such underpayment and (b) if such underpayment exceeds [***] of the total amount owed for the period then being audited, the [***] costs incurred by PUMA in conducting such review. For the avoidance of doubt, payment of the underpayment will be considered a late payment, subject to Section 6.9. If such report shows any overpayment, then the overpaid amount will be deducted from future payments owed to PUMA. The Parties mutually agree that all information subject to review under this Section 6.5.2 is Confidential Information of CANbridge and that PUMA will retain and cause the accountant to retain all such information in confidence in accordance with ARTICLE 8 (Confidentiality and Publicity).

6.5.3 Audit Period. Upon the expiration of [***] following the end of any Calendar Year, the audit rights set forth in this Section 6.5 shall no longer apply to such Calendar Year and the calculation of amounts payable with respect to such Calendar Year will be binding and conclusive.

6.6 Tax Matters.

6.6.1 Tax Responsibility. Any taxes imposed on CANbridge or with respect to CANbridge's business operations or activities hereunder, and any value added, consumption, transfer, sales, use and other such taxes relating to the transactions contemplated herein, including any imposed with respect to the rights and obligations under Article III, shall be borne by CANbridge (and, for the avoidance of doubt, all amounts stated in this Agreement exclusive of such taxes), and CANbridge shall timely pay, and indemnify and hold harmless, PUMA from and against all such taxes, including any penalties or interest associated therewith. PUMA shall bear and be responsible for all taxes based on income to PUMA.

6.6.2 Tax Withholding; Gross Up. In the event any tax (other than any tax based on income to PUMA) is required to be withheld and deducted from payments by CANbridge

pursuant to this Agreement under applicable Law, notwithstanding anything to the contrary herein, CANbridge will make such deduction and withholding and shall pay such additional amounts as may be necessary to ensure that PUMA receives the amount it would have received had no such withholding applied (including any withholding imposed in respect of such additional amounts), and any amounts so withheld and deducted will be remitted by CANbridge on a timely basis to the appropriate Governmental Authority for the account of PUMA and CANbridge will provide PUMA reasonable evidence of the remittance within [***] thereof.

6.7 Currency of Payments. All amounts payable and calculations under this Agreement shall be in Dollars. As applicable, Net Sales and any royalty reductions shall be translated into Dollars using the average of the applicable daily foreign exchange rates published in the Wall Street Journal (or any other qualified source that is acceptable to both Parties) for the last day of each month of the Calendar Quarter in which such Net Sales occurred. All payments under this Agreement will be paid in Dollars by wire transfer to an account designated by the receiving Party (which account the receiving Party may update from time to time in writing).

6.8 Blocked Currency. Notwithstanding the provisions of Section 6.7 (Currency of Payments), if by applicable Law or fiscal policy of a Region in the Territory, conversion into Dollars or transfer of funds of a convertible currency to the United States is restricted, forbidden or substantially delayed, then amounts accrued in such Region under this ARTICLE 6 shall be paid to PUMA in Region in local currency by deposit in a local bank designated by PUMA, unless the Parties otherwise agree.

6.9 Late Payments. Any late payment shall bear interest, to the extent permitted by Law, at [***] above the Prime Rate of interest as reported in the Wall Street Journal on the date payment is due.

ARTICLE 7 INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

7.1 Ownership of Inventions.

7.1.1 Inventorship. Ownership of inventions, improvements, developments or discoveries, whether patentable or non-patentable, invented or otherwise developed or generated by either Party or its Affiliates, or any of its or their employees, sublicensees (where permitted), independent contractors or agents during the Term, in the course of Developing, Manufacturing or Commercializing any Licensed Product under this Agreement (“Inventions”), and any and all intellectual property rights therein, will be determined based on the principles of inventorship in accordance with United States patent Laws.

7.1.2 Ownership. Subject to the remainder of this Section 7.1.2, any Invention made, conceived, reduced to practice, or otherwise discovered solely by the employees, independent contractors, or agents of PUMA (“PUMA Inventions”), and all intellectual property rights therein, will, subject to the licenses granted to CANbridge under this Agreement, be solely owned by PUMA. Subject to the remainder of this Section 7.1.2, any Invention made, conceived, reduced to practice or otherwise discovered by the employees, independent contractors or agents of CANbridge (“CANbridge Inventions”), and all intellectual property rights therein, will be solely

owned by CANbridge. Subject to the remainder of this [Section 7.1.2](#), any Invention made, conceived, reduced to practice or otherwise discovered jointly by the employees, independent contractors or agents of CANbridge and PUMA (“[Joint Inventions](#)”), and all intellectual property rights therein, will be owned jointly by PUMA and CANbridge. Notwithstanding anything to the contrary in this [Section 7.1.2](#), [***], including their [***] (“[Licensed Product Inventions](#)”), and all intellectual property rights therein. Such Licensed Product Inventions [***]. CANbridge hereby grants to PUMA a non-exclusive, worldwide, transferable, royalty-free, fully paid-up, perpetual and irrevocable license, with the right to sublicense through multiple tiers, under CANbridge Inventions [***], to Develop, Commercialize and otherwise Exploit Licensed Products in the Field outside the Territory. Upon termination (but not expiration) of this Agreement, and subject to [Section 12.2 \(Paid-Up License Upon End of Royalty Term\) of this Agreement](#), [PUMA’s rights under the foregoing sentence shall apply on a worldwide basis. Each Party shall, and shall cause its sublicensees and Affiliates, and all contractors, employees, and agents](#), 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 joint right, title and interest in and to all Joint Inventions and intellectual property rights therein. Subject to: (a) the licenses granted to CANbridge and to PUMA in this Agreement; and (b) the other terms and conditions of this Agreement, CANbridge and PUMA as joint owners will each have the right to exploit and grant licenses under all Joint Inventions, and to assign or otherwise dispose of their respective joint interest in the Joint Inventions, without an accounting or obligation to, or consent required from, the other Party. Each Party grants to the other Party a nonexclusive, fully-paid, royalty-free, irrevocable, perpetual and sublicensable (through multiple tiers) license under its interest in the Joint Inventions, and intellectual property rights therein, to make, use, sell, offer for sale and import all Joint Inventions, provided that: (i) PUMA’s rights in all Joint Inventions shall remain subject to the licenses granted to CANbridge pursuant to this Agreement; and (ii) CANbridge’s rights in all Joint Inventions shall remain subject to the licenses granted to PUMA pursuant to this Agreement.

7.1.3 Assignment Obligation. Each Party will cause all employees of such Party who perform activities for such Party under this Agreement to be under an obligation to assign their rights in any Patent Rights and Know-How, whether or not patentable, resulting therefrom to such Party. With respect to any activities of a Party under this Agreement that are contracted to a Person that is not an employee, the Party retaining such contractor will use Commercially Reasonable Efforts to include in the applicable contract an assignment to such Party of all rights in Patent Rights and Know-How made by such contractor resulting from such activities, and in any event will include in the applicable contract a license to such Party that is sublicensable to the other Party under this Agreement, of any Patent Rights and Know-How made by such contractor resulting from such activities.

7.1.4 Right to Practice Joint Patent Rights and Joint Know-How. The Parties will jointly own any Joint Know-How and Joint Patent Rights. Subject to the licenses granted to CANbridge under this Agreement, each Party is entitled to practice the Joint Patent Rights and

Joint Know-How for all purposes on a worldwide basis and license the Joint Patent Rights and Joint Know-How without the consent of and without a duty of accounting to the other Party. Each Party will: (a) grant and hereby does grant all permissions, consents and waivers with respect to, and all licenses under, the Joint Patent Rights and Joint Know-How, throughout the world, necessary to provide the other Party with such rights of use and Exploitation of the Joint Patent Rights and Joint Know-How, (b) execute documents as reasonably necessary to accomplish the foregoing, and (c) reasonably cooperate with the other Party to transfer to such other Party physical embodiments (or copies thereof) of any Joint Know-How, at such other Party's request and expense.

7.2 Prosecution and Maintenance.

7.2.1 Licensed Patents and Joint Patents. PUMA will have the first right, [***], to prepare, file, prosecute and maintain the Licensed Patents and the Joint Patent Rights [***] in all Regions in the Territory. PUMA will keep CANbridge reasonably informed of all steps with regard to and the status of such preparation, filing, prosecution, and maintenance of such Patent Rights, including by providing CANbridge with (a) copies of all correspondence and material communications it sends to or receives from any patent office or agency in the Territory relating to the Licensed Patents or Joint Patent Rights, (b) a draft copy of all applications sufficiently in advance of filing to permit reasonable review and comment by CANbridge, and (c) a copy of applications as filed, together with notice of its filing date and serial number. Before PUMA submits any material filing, including a new patent application, or response to such patent authorities with respect to the Licensed Patents or Joint Patent Rights, PUMA will provide CANbridge with a reasonable opportunity to review and comment on such filing or response and will take into account and consider in good faith CANbridge's reasonable and timely requests and suggestions regarding the filing, prosecution and maintenance of the Licensed Patents and Joint Patent Rights under this Section 7.2.1 (Licensed Patents and Joint Patents). The Parties' rights and obligations with respect to rights licensed to PUMA pursuant to the Pfizer License Agreement that are sublicensed to CANbridge under this Agreement are expressly subject to the terms of Section 7.4 of the Redacted Pfizer License Agreement. The Parties agree to cooperate reasonably with Pfizer with respect to matters described under this Agreement to the extent required by the Redacted Pfizer License Agreement.

7.2.2 Step-In Right. If PUMA elects not to continue to prosecute or maintain a given Patent Right within the Licensed Patents or Joint Patent Rights [***] in the Territory pursuant to Section 7.2.1 (Licensed Patents and Joint Patents), then PUMA will give CANbridge notice thereof within a reasonable period (but not less than [***]) prior to allowing such Patent Rights to lapse or become abandoned or unenforceable, and only to the extent permitted under Section 7.4 of the Redacted Pfizer License Agreement and in accordance with Section 7.4 of the Redacted Pfizer License Agreement, as applicable, CANbridge will have the right to prosecute or maintain such Patent Right in the name of PUMA. CANbridge will have the right, but not the obligation, to assume responsibility for continuing the prosecution of such Patent Rights in such Region and paying any required fees to maintain such Patent Rights in such Region or defending such Patent Rights, [***], through patent counsel or agents of its choice. CANbridge will not become an assignee of any such Patent

Right as a result of its assumption of any such responsibility. Upon transfer of PUMA's responsibility for filing, prosecuting and maintaining any of the Patent Rights to CANbridge under this [Section 7.2.2 \(Step-In Right\)](#), PUMA will promptly deliver to CANbridge copies of all necessary files related to the Patent Rights with respect to which responsibility has been transferred and will take all actions and execute all documents reasonably necessary for CANbridge to assume such prosecution, maintenance and defense.

7.2.3 Solely-Owned CANbridge Inventions. CANbridge shall have the sole right to prepare, file, prosecute and maintain patents claiming the CANbridge Inventions [***] on a worldwide basis.

7.2.4 Cooperation. Each Party will, and will cause its Affiliates to, reasonably cooperate, with the other Party with respect to the preparation, filing, prosecution and maintenance of Licensed Patents pursuant to this Section 7.2 (Prosecution and Maintenance).

7.3 Third Party Infringement.

7.3.1 Notice. Each Party will promptly notify the other in writing of any (a) apparent, threatened or actual infringement by a Third Party of any Licensed Patent, or (b) unauthorized use or misappropriation of any Licensed Know-How by a Third Party of which it becomes aware, and, in each case, will provide the other Party with all evidence in such Party's possession or control supporting such infringement or unauthorized use or misappropriation (each, an "Infringement").

7.3.2 Enforcement of Licensed Patents in the Territory. CANbridge will have the first right, but not the obligation, using counsel of its choosing and [***], to institute any Action alleging Infringement of the Licensed Patents (including the Joint Patent Rights) in the Territory (any such Action, an "Infringement Action"). CANbridge will notify and keep PUMA apprised in writing of any such Infringement Action and will consider PUMA's reasonable interests and requests regarding such Infringement Action; provided, that, if CANbridge does not intend to prosecute an Infringement Action, or ceases to diligently pursue an Infringement Action, (a) it will promptly inform PUMA in writing and (b) PUMA shall have the right, but not the obligation, [***] to institute an Infringement Action against the applicable Third Party infringer(s).

7.3.3 Cooperation. In any Infringement Action brought under the Licensed Patents pursuant to Sections 7.3.2 (Enforcement of Licensed Patents in the Territory) each Party will, and will cause its Affiliates to, reasonably cooperate with each other, in good faith, relative to the other Party's efforts to protect the Licensed Patents and will join such suit as a party, if requested by the other Party. Furthermore, the Party initiating any Infringement Action pursuant to Sections [7.3.2 \(Enforcement of Licensed Patents in the Territory\)](#) will consider in good faith all reasonable and timely comments from the other Party on any proposed arguments asserted or to be asserted in litigation related to the enforcement or defense of any such Patent Rights.

7.3.4 Allocation of Recoveries. Any settlements, damages or monetary awards recovered by either Party pursuant to any Infringement Action with respect to the Licensed Patents will, after reimbursing the Parties for their reasonable out-of-pocket expenses in making such

recovery (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses), be allocated as follows: (a) if PUMA is the enforcing Party, first to pay any amounts payable to Pfizer with respect to such Infringement Action, and then [***] to PUMA and [***] to CANbridge or (b) if CANbridge is the enforcing Party, first to pay any amounts payable to Pfizer with respect to such Infringement Action, and then the remaining amount will be [***].

7.4 Claimed Infringement.

7.4.1 Claimed Infringement. Each Party will promptly notify the other Party if a Third Party brings any Action alleging patent infringement by CANbridge or PUMA or any of their respective Affiliates or sublicensees with respect to the Development, Manufacture or Commercialization of any Licensed Product (any such Action, an "Infringement Claim"). In the case of any Infringement Claim, CANbridge will have the right, but not the obligation, to control the defense and response to any such Infringement Claim in the Territory, and PUMA will have the right, but not the obligation, to control the defense and response to any such Infringement Claim outside of the Territory. Upon the request of the Party controlling the response to the Infringement Claim, the other Party will reasonably cooperate with the controlling Party in the reasonable defense of such Infringement Claim. The other Party will have the right to consult with the controlling Party concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation. If the Infringement Claim is brought against both Parties, then each Party will have the right to defend against the Infringement Claim. The Party defending an Infringement Claim under this Section 7.4 (Claimed Infringement) will (a) consult with the other Party as to the strategy for the prosecution of such defense, (b) consider in good faith any comments from the other Party with respect thereto and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense. The Party controlling the defense against an Infringement Claim will have the right to settle such Infringement Claim on terms deemed reasonably appropriate by such Party, provided, that, unless any such settlement includes a full and unconditional release from all liability of the other Party and does not adversely affect the rights of the other Party, any such settlement will be subject to the other Party's prior written consent.

ARTICLE 8 CONFIDENTIALITY AND PUBLICITY

8.1 Confidential Information.

8.1.1 Confidentiality Obligation. During the Term and for a period of [***] after any termination or expiration of this Agreement, each Party agrees to, and will cause its Affiliates, sublicensees and contractors to, keep in confidence and not to disclose to any Third Party, or use for any purpose, except to exercise its rights or perform its obligations under this Agreement, any Confidential Information of the other Party.

8.1.2 Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to the other Party's Confidential Information only to the receiving Party's employees, consultants, advisors and sublicensees, and to the employees, consultants and advisors of the receiving Party's Affiliates, in each case on a need to know basis who are subject to obligations of confidentiality and non-use with respect to such Confidential Information no less

stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this [Section 8.1](#) (Confidential Information); provided, however, that each Party will remain responsible for any failure by its Affiliates and sublicensees, and its and its Affiliates' respective employees, consultants and advisors, to treat such Confidential Information as required under this [Section 8.1](#) (Confidential Information) as if such Affiliates, employees, consultants, advisors and sublicensees were parties directly bound to the requirements of this [Section 8.1](#) (Confidential Information).

8.1.3 Confidentiality Limitation. Notwithstanding anything to the contrary herein, each Party may use and disclose the other Party's Confidential Information as follows: (a) under appropriate written confidentiality obligations substantially equivalent to those in this Agreement, to its Affiliates, potential and actual permitted sublicensees, contractors and any other Third Parties, to the extent such use or disclosure is reasonably necessary to perform its obligations or to exercise its rights under this Agreement, (b) to the extent such use or disclosure is consistent with this Agreement, is not prohibited by the Existing Third Party License Agreements and is reasonably necessary for filing or prosecuting the Licensed Patents, (c) to its advisors (including financial advisors, attorneys and accountants), actual or potential acquisition partners, financing sources or investors and underwriters on a need to know basis, in each case under appropriate confidentiality obligations (which may include professional ethical obligations) substantially equivalent to those in this Agreement; provided, however, that each Party will remain responsible for any failure by any of the foregoing individuals to treat such Confidential Information as required under Section 8.1 (Confidential Information) as if such individuals were parties directly bound to the requirements of this [Section 8.1](#), or (d) as required by any court or other governmental body or as otherwise required by applicable Law (including any such disclosures as are required by a Regulatory Authority in connection with seeking Regulatory Approval for any Licensed Product in the Territory); provided, that, notice is promptly given to the other Party and the disclosing Party cooperates with reasonable requests from the other Party to seek a protective order or other appropriate remedy to protect the Confidential Information.

8.1.4 Secrecy of Licensed Know-How. PUMA will protect, and will cause its Affiliates and its sublicensees and its and their respective officers, directors, employees, and agents to protect, the secrecy and confidentiality of the Licensed Know-How and PUMA's interest in the Joint Know-How using at least the same degree of care as it uses to prevent the disclosure of its own other confidential information of like importance.

8.2 Publicity.

8.2.1 Initial Press Releases. Promptly following the Effective Date, the Parties will issue a mutually agreed upon press release regarding the subject matter of this Agreement, including a description of the financial terms, a high-level description of the overall scope of the transaction and the scope of planned Development and value of the Agreement in the form attached hereto as [Schedule 8.2.1](#).

8.2.2 Further Publicity; Publications. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Product in the Field, and each Party may make such disclosures from time to time, subject to this [Section 8.2.2](#) (Further Publicity; Publications). Such disclosures may include achievement of milestones, significant events in the Development process with respect to Licensed

Products, Commercialization activities with respect to Licensed Products and the like. Except for the initial press releases described in [Section 8.2.1 \(Initial Press Releases\)](#)):

(a) Whenever either Party elects to make any such public disclosure, it will first notify the other Party of such planned press release or public announcement and provide a draft for review no less than [***] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Law, with as much advance notice as possible under the circumstances if it is not possible to provide notice no less than [***] in advance). Each Party will have the right to review and approve any such planned press release or public announcement proposed by the other Party, including any oral presentation or abstract, that contains clinical data or pertains to results of Clinical Studies or other studies with respect to Licensed Products, or that includes Confidential Information of the other Party; provided, however, that (i) the reviewing Party will attempt to provide such approval as soon as reasonably possible and will not unreasonably withhold such approval; (ii) the reviewing Party will provide explanations of its disapproval of such press release; and (iii) a Party desiring to make such public disclosure may issue such press release or public announcement without such prior review by the other Party if (A) the entire contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by such Party, and (B) such press release or public announcement does not materially differ from a previously issued press release or other publicly available information; and provided, further, that the other Party will have the right to review, but not approve, any press release or public announcement that the proposing Party determines is required by applicable Law based on the advice of counsel, which public disclosures are subject to Section 8.2 (Publicity; Publications). The Party reviewing a press release provided under this Section 8.2.2(a) (Further Publicity) will review and approve or disapprove such press release within [***] after its receipt thereof.

(b) The principles to be observed in such disclosures will include accuracy, compliance with applicable Law and regulatory guidance documents, reasonable sensitivity to potential negative reactions of Regulatory Authorities and the need to keep investors informed regarding the business of the Party making such public disclosure. Nothing in this Section [8.2](#) (Publicity) will restrict a Party from making a disclosure required by Law as reasonably determined by such Party's counsel, including disclosures required by any laws or regulations relating to the public sale of securities; provided, however, that such disclosure will include the minimum amount of Confidential Information required by such applicable laws and regulations, and the Parties will use reasonable efforts to seek confidential treatment of Confidential Information to be included in such disclosures.

(c) In the event that either Party proposes to publish or present the results of Development or Commercialization carried out on a Licensed Product, such publication or presentation will be subject to the prior review by the other Party for patentability and protection of such other Party's Confidential Information. Each Party will provide to the other Party the opportunity to review any proposed abstracts, manuscripts or summaries of presentations that cover the results of Development or Commercialization of Licensed Products during the Term. The other Party will respond in writing promptly and in no event later than [***] after receipt of the proposed material with either approval of the proposed material or a specific statement of concern, based upon either the need to seek patent protection or concern regarding

competitive disadvantage arising from the proposal. In the event of any such concern, the submitting Party agrees not to submit such publication or to make such presentation that contains such information until the other Party is given a reasonable period of time to seek patent protection for any material in such publication or presentation that it believes is patentable or to resolve any other issues, and the submitting Party will remove from such proposed publication any Confidential Information of the other Party as requested by such other Party. The Parties acknowledge that Pfizer has certain review and approval rights with respect to publications relating to the Development of Licensed Products under Section 14.2 of the Pfizer License Agreement, and the Parties agree that such rights shall apply to any such publications under this Agreement, provided that, PUMA shall be required to obtain any such approvals from Pfizer within the [***] period required by this Section 8.2.2 (c) (Further Publicity: Publications).

**ARTICLE 9
REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS**

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

9.1.1 Organization. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

9.1.2 Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement, and this Agreement and the performance by such Party of this Agreement do not violate such Party's charter documents, bylaws or other organizational documents.

9.1.3 Consents. Except for any Marketing Authorizations, Regulatory Filings, manufacturing approvals or similar approvals necessary for the Development, Manufacture or Commercialization of Licensed Products, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained.

9.1.4 No Conflict. It is not under any obligation, contractual or otherwise, to any Person that would adversely affect the diligent and complete fulfillment of obligations under this Agreement and the execution and delivery of this Agreement by such Party, and the performance of such Party's obligations under this Agreement (as contemplated as of the Effective Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (a) do not conflict with or violate any requirement of Laws applicable to such Party, (b) do not conflict with or violate any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party, and (c) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates.

9.1.5 Enforceability. This Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to the general principles of equity and subject to bankruptcy, insolvency, moratorium, judicial principles affecting the

availability of specific performance and other similar Laws affecting the enforcement of creditors' rights generally.

9.2 Additional Representations and Warranties of PUMA. PUMA represents and warrants to CANbridge that, as of the Effective Date:

9.2.1 Licensed Patents. All Licensed Patents existing in the Territory as of the Effective Date are listed in Schedule 9.2.1. Except as otherwise noted in Schedule 9.2.1, PUMA is the sole and exclusive owner of the Licensed Patents, all of which are free and clear of any claims, liens, charges or encumbrances. With respect to Licensed Patents not solely owned by PUMA, PUMA licenses such Licensed Patents pursuant to the Redacted Pfizer License Agreement. All Licensed Patents owned by PUMA and, to PUMA's Knowledge, all other Licensed Patents, are (a) subsisting and in good standing and (b) being diligently prosecuted in the applicable patent offices in accordance with Law, and have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment. To PUMA's Knowledge, all issued Licensed Patents are valid and enforceable.

9.2.2 Licensed Know-How. To PUMA's Knowledge, the Development and Manufacture of the Product by or on behalf of PUMA prior to the Effective Date did not misappropriate the Know-How of any Third Party. PUMA owns or Controls the Licensed Know-How, and to PUMA's Knowledge, the Licensed Know-How is free and clear of any claims, liens, charges or encumbrances. Except as otherwise set forth in Schedule 9.2.2, PUMA has independently developed all Licensed Know-How.

9.2.3 Delivery of Documentation. True, complete, and correct copies of all material adverse information with respect to the safety and efficacy of the Licensed Products in PUMA's possession and control have been provided or made available to CANbridge.

9.2.4 Third Party Challenges. There are no claims, judgments, or settlements against, or amounts with respect thereto, made against PUMA or any of its Affiliates relating to the Licensed Patents or the Licensed Know-How. Except as otherwise disclosed in writing to CANbridge, no claim or litigation has been brought or, to PUMA's Knowledge, threatened by any Person (a) alleging that the Licensed Patents are invalid or unenforceable, (b) asserting the misuse, or non-infringement of any of the Licensed Patents, (c) challenging PUMA's Control of the Licensed Patents or (d) alleging misappropriation of the Know-How used in the Development and Manufacture of Licensed Products by or on behalf of PUMA prior to the Effective Date.

9.2.5 Non-Infringement of Third Party IP. To PUMA's Knowledge, the Development and Manufacture of Licensed Products, as conducted by PUMA, its Affiliates or its sublicensees prior to the Effective Date, did not infringe any Patent Right or misappropriate or otherwise violate any Know-How of any Person. To PUMA's Knowledge the Development, supply, or Commercialization of Licensed Products in the Field and in the Territory as contemplated by this Agreement will not infringe any Patent Right or misappropriate or otherwise violate any Know-How of any Third Party. No claim of infringement of the Patent Rights or misappropriation of the Know-How of any Third Party has been made, or to PUMA's Knowledge, threatened, against PUMA or any of its Affiliates with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field and in the Territory.

9.2.6 Absence of Litigation. There are no judgments or settlements against or owed by PUMA, its Affiliates or its sublicensees, or, to PUMA's Knowledge, pending litigation against PUMA, its Affiliates, or its sublicensees, or litigation threatened against PUMA, its Affiliates, or its sublicensees, in each case related to Licensed Products, including any such litigation any relating to any Regulatory Filings Controlled by PUMA, its Affiliates or its sublicensees as of the Effective Date.

9.2.7 Maintenance of Regulatory Filings, Good Laboratory and Clinical Practices. PUMA, its Affiliates, and its sublicensees have generated, prepared, maintained, and retained all Regulatory Filings that are required to be maintained or retained pursuant to and in material compliance with applicable Law, and have conducted in material compliance with applicable Law, including GLP and GCP all Development of Licensed Products in the Field conducted prior to the Effective Date.

9.2.8 Confidentiality of Know-How. To the Knowledge of PUMA, no material breach of confidentiality has been committed by any Person with respect to the Licensed Know-How that is maintained as a trade secret and PUMA has used reasonable measures to protect the confidentiality thereof.

9.2.9 Assignment of Third Party Rights; Third Party Consents.

(a) PUMA has obtained from each of its employees and agents, and from the employees and agents of its Affiliates, who are participating in the Exploitation of Licensed Products, rights to any and all Know-How created by such employees and agents in the course of his or her employment by or engagement with PUMA that relates to Licensed Products, such that CANbridge will, by virtue of this Agreement, receive from PUMA, without payments beyond those required by [ARTICLE 6](#) (Financial Provisions), the licenses and other rights granted to CANbridge under this Agreement.

(b) Each Person who has or has had any ownership rights in or to any Licensed Patents purported to be owned solely by PUMA, has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Licensed Patents to PUMA; to PUMA's Knowledge, no current officer, employee, agent, or consultant of PUMA or any of its Affiliates is in violation of any term of any assignment or other agreement, in each case, regarding the protection of the Licensed Patents.

(c) Prior to the Effective Date, PUMA has obtained all consents from Third Parties necessary to grant CANbridge the licenses and rights PUMA purports to grant to CANbridge under this Agreement.

9.2.10 Statements to FDA and Other Regulatory Authorities. Neither PUMA nor any of its Affiliates or sublicensees, nor, to PUMA's knowledge, any of its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development of Licensed Products, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of Licensed Products, or committed an act, made a statement, or failed to make a statement with respect to the Development of Licensed Products that could reasonably be expected to provide a basis for the FDA to invoke its

policy respecting “ Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities ”, set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the applicable Territory.

9.2.11 Compliance with Law. To PUMA’s Knowledge, all of the studies, tests and pre-clinical and clinical trials of Licensed Products conducted prior to, or being conducted as of, the Effective Date by or on behalf of PUMA have been and are being conducted in all material respects in accordance with applicable Laws.

9.2.12 In-licenses. Except as set forth in Schedule 1.39, there are no agreements between PUMA or any of its Affiliates, on the one hand, and any Third Party, on the other hand, pursuant to which PUMA has (a) in-licensed any Patent Rights or Know-how owned or Controlled by such Third Party that are included as part of the Licensed Patents or Licensed Know-How or (b) agreed to provisions that would require CANbridge to make any payments (including royalties) to any Third Party or to undertake or observe any restrictions or obligations with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory.

9.3 No Debarment. Each Party represents and warrants that neither it nor any of its or its Affiliates’ employees or agents performing under this Agreement has ever been, or is currently: (a) debarred under 21 U.S.C. § 335a; (b) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (c) listed on the FDA’s Disqualified and Restricted Lists for clinical investigators; or (d) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates’ employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, such Party will promptly notify the other Party. This provision will survive termination or expiration of this Agreement.

9.4 Additional Representations and Warranties of CANbridge. CANbridge represents and warrants to PUMA that, as of the Effective Date:

9.4.1 There is no pending or, to CANbridge’s Knowledge, threatened claim, litigation or any other proceeding brought by a Third Party against CANbridge claiming that CANbridge’s or its Affiliates’ commercialization of any pharmaceutical product constitutes or would constitute infringement of such Third Party’s intellectual property right(s);

9.4.2 To CANbridge’s Knowledge, neither CANbridge, nor any of its directors, officers, employees, Affiliates, or any Person authorized to act on behalf of CANbridge or its Affiliates, have violated any Anti-Corruption Law;

9.4.3 Neither CANbridge nor its Affiliates, nor, to CANbridge’s Knowledge any Person acting on behalf of CANbridge or its Affiliates, has offered, given, authorized, or promised anything of value (as defined by applicable Anti-Corruption Laws), either directly or indirectly, to any Person, including to any Public Official or Entity, for the purpose of (a) improperly influencing any official act or decision; (b) inducing performance or non-performance of any act in violation

of a lawful duty; or (c) securing an improper benefit or business advantage, in each case ((a) – (c)) in any manner that violates the applicable Anti-Corruption Laws;

9.4.4 Neither CANbridge nor any of its Affiliates have received any written notice, request, or citation from any Governmental Authority with respect to any alleged or suspected violation of Anti-Corruption Laws;

9.4.5 To CANbridge’s Knowledge, neither CANbridge nor any of its Affiliates are under investigation or are being prosecuted by a Governmental Authority with respect to any alleged or suspected violation of Anti-Corruption Laws;

9.4.6 All due diligence materials that CANbridge has provided to PUMA are accurate, truthful and complete; and

9.4.7 To CANbridge’s Knowledge, no officer, director, or employee of CANbridge or its Affiliates (an “Interested Person”), is a Public Official or Entity or Governmental Authority.

9.5 Covenants of CANbridge. CANbridge hereby covenants to PUMA that, during the Term:

9.5.1 CANbridge and its Affiliates shall, and shall ensure that its Sublicensees and contractors, comply in all material respects with all applicable Laws with respect to the performance of its and their activities pursuant to this Agreement;

9.5.2 Without limiting the generality of Section 9.5.1, CANbridge shall comply with the Anti-Corruption Laws (as modified or amended), and CANbridge will not directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value (as defined by applicable Anti-Corruption Laws), for purposes of improperly seeking to influence any Public Official or Entity or Governmental Authority in any manner that violates applicable Anti-Corruption Laws in connection with this Agreement;

9.5.3 All employees and officers of CANbridge and its Affiliates working under this Agreement shall execute agreements requiring assignment to CANbridge 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 their association with CANbridge, whether or not patentable, to CANbridge, or its applicable Affiliates, as the sole owner thereof;

9.5.4 CANbridge shall, and shall cause its Affiliates, Sublicensees and contractors to, reasonably cooperate with PUMA and PUMA’s Affiliates in ensuring compliance with the Anti-Corruption Laws, Export Control Laws and all other applicable Laws. CANbridge shall provide PUMA with any information reasonably requested by PUMA in connection with its efforts to ensure compliance with applicable Laws;

9.5.5 CANbridge shall promptly notify PUMA if CANbridge becomes aware of any material information that would reasonably suggest that there may be a violation of the Anti- Corruption Laws, Export Control Laws or any other applicable Law in connection with the performance of this Agreement or the sale of the Licensed Product in the Territory;

9.5.6 CANbridge shall, promptly following discovery, notify PUMA if (a) any Interested Person becomes a Public Official or Entity or Governmental Authority or (b) any Public Official or Entity or Governmental Authority acquires a legal or beneficial interest in CANbridge or any of its Affiliates or Sublicensees; and

9.5.7 On or prior to the date on which CANbridge first communicates with a Regulatory Authority in connection with the Licensed Product, CANbridge shall implement [***]. Within [***]. As part of its [***].

9.6 No Other Warranties. EXCEPT AS EXPRESSLY STATED IN SECTION 9.1 (MUTUAL REPRESENTATIONS AND WARRANTIES), SECTION 9.2 (ADDITIONAL REPRESENTATIONS AND WARRANTIES OF PUMA), SECTION 9.3 (NO DEBARMENT) OR SECTION 9.4 (ADDITIONAL REPRESENTATIONS AND WARRANTIES OF CANBRIDGE), NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON- INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 10 INDEMNIFICATION; DAMAGES

10.1 Indemnification by PUMA. PUMA will indemnify and hold harmless CANbridge, its Affiliates and their respective directors, officers, employees and agents (collectively, the “CANbridge Indemnified Parties”), from, against and in respect of any and all Losses incurred or suffered by any CANbridge Indemnified Party to the extent resulting from: (a) any breach of any representation or warranty made by PUMA in this Agreement, or any breach by PUMA of any obligation, covenant or agreement in this Agreement; (b) the negligence or intentional misconduct of PUMA or any of its Affiliates, sublicensees, or contractors, or any of their respective directors, officers, employees and agents, in performing PUMA’s obligations or exercising PUMA’s rights under this Agreement; (c) activities conducted by or on behalf of PUMA, its Affiliates or its sublicensees or contractors related to the Development, Manufacture, Commercialization or other Exploitation of Licensed Products anywhere in the world prior to the Effective Date; and (d) activities conducted by or on behalf of PUMA or its Affiliates, sublicensees or contractors related to the Development, Manufacture, Commercialization or other Exploitation of Licensed Products outside the Territory during the Term.

10.2 Indemnification by CANbridge. CANbridge will indemnify and hold harmless PUMA, its Affiliates and their respective directors, officers, employees and agents (collectively,

the “ PUMA Indemnified Parties ”), from, against and in respect of any and all Losses incurred or suffered by any PUMA Indemnified Party to the extent resulting from: (a) any breach of any representation or warranty made by CANbridge in this Agreement, or any breach by CANbridge of any covenant or agreement in this Agreement, (b) the negligence or intentional misconduct of, or violation of Law by, CANbridge, any of its Affiliates, Sublicensees or contractors, or any of their respective directors, officers, employees and agents, in performing CANbridge’s obligations or exercising CANbridge’s rights under this Agreement, or (c) the Development, Commercialization, Manufacture or other Exploitation of any Licensed Product by or on behalf of CANbridge, its Affiliates, Sublicensees or contractors in the Territory during the Term.

10.3 Claims for Indemnification.

10.3.1 Notice. An Indemnified Party entitled to indemnification under Sections 10.1 (Indemnification by PUMA) or 10.2 (Indemnification by CANbridge) will give prompt written notification to the Indemnifying Party from whom indemnification is sought of the commencement of any Action by a Third Party for which indemnification may be sought (a “ Third Party Claim ”) or, if earlier, upon the assertion of such Third Party Claim by a Third Party; provided, however, that failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 10.3.1 (Notice) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement, except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice.

10.3.2 Defense. Within [***] after delivery of a notice of any Third Party Claim in accordance with Section 10.3.1 (Notice), the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party may control such defense. The Party not controlling such defense may participate therein at its own expense.

10.3.3 Cooperation. The Party controlling the defense of any Third Party Claim will keep the other Party advised of the status of such Third Party Claim and the defense thereof and will reasonably consider recommendations made by the other Party with respect thereto. The other Party will reasonably cooperate with the Party controlling such defense and its Affiliates and agents in defense of the Third Party Claim, with all out-of-pocket costs of such cooperation to be borne by the Party controlling such defense.

10.3.4 Settlement. The Indemnified Party will not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. The Indemnifying Party will not, without the prior written consent of the Indemnified Party, which will not be unreasonably withheld, agree to any settlement of such Third Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party.

10.4 Insurance. Each Party, at its own expense, will maintain liability insurance (or self-insure) with respect to its activities under this Agreement in an amount consistent with industry standards. Each Party will provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. Without limiting the foregoing, during

the Term and thereafter for the period of time required below, each Party will maintain on an ongoing basis comprehensive general liability insurance in the minimum amount of [***] for [***]; provided, however, that (a) [***], and (b) commencing not later than [***] prior to [***], and thereafter [***]. All of such insurance coverage may be maintained through a self-insurance plan that substantially complies with the foregoing limits and requirements and may be satisfied through one or more policies, including an umbrella policy; provided, however, that such self-insurance is determined to be investment quality by a recognized rating agency such as Moody's or Standard & Poor's. Not later than [***] following receipt of written request from a Party, the other Party will provide to the requesting Party a letter(s) affirming appropriate self-insurance or a certificate of insurance evidencing such coverage in accordance with this Agreement. Each Party will maintain such insurance or self-insurance coverage without interruption during the Term and for a period of [***] thereafter, and, if applicable, will provide certificates or letters evidencing such insurance coverage without interruption as reasonably requested during the period of time for which such coverage must be maintained. Each Party will be provided at least [***] prior written notice of any cancellation or material decrease in the other Party's insurance coverage limits described above. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance will not relieve that Party of its obligations set forth in this Agreement.

ARTICLE 11 LIMITATION OF LIABILITY

11.1 No Consequential or Punitive Damages. EXCEPT AS SET FORTH IN SECTION

11.2 (Exclusion from Liability Limitation), NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES OR FOR ANY LOST PROFITS ARISING OUT OF THIS AGREEMENT, IN EACH CASE HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

11.2 Exclusion from Liability Limitation. THE LIMITATIONS AND DISCLAIMER SET FORTH IN SECTION 11.1 (No Consequential or Punitive Damages) WILL NOT APPLY TO A CLAIM (A) FOR WILLFUL MISCONDUCT; (B) FOR A BREACH OF ARTICLE 8 (Confidentiality and Publicity); OR (C) FOR INDEMNIFIABLE LOSSES PURSUANT TO SECTION 10.1 (Indemnification by PUMA), OR SECTION 10.2 (Indemnification by CANbridge).

ARTICLE 12
TERM AND TERMINATION

12.1 Term. Unless terminated earlier in accordance with this ARTICLE 12 (Term and Termination), this Agreement will become effective as of the Effective Date and will continue in full force until the last to expire Royalty Term in the Territory (the “Term”).

12.2 Paid-Up License Upon End of Royalty Term. Upon the expiration of the Royalty Term for a given Licensed Product in a given Region in the Territory, the licenses and rights of reference granted to CANbridge pursuant to Section 2.1 (PUMA License Grant; Right of Reference) will become perpetual, irrevocable, fully paid-up, and royalty free with respect to such Licensed Product in such Region.

12.3 Early Termination.

12.3.1 Termination for Material Breach. Upon (a) any material breach of this Agreement by PUMA or (b) any material breach of this Agreement by CANbridge (the Party so allegedly breaching being the “Breaching Party”), the other Party (the “Non-Breaching Party”) will have the right, but not the obligation, to terminate this Agreement in its entirety (1) immediately upon written notice for any material breach of Sections 9.4.2, 9.4.3, 9.4.4, 9.4.5, 9.4.6, 9.5.2, or 9.5.5 that results in a material violation of the Anti-Corruption Laws by CANbridge or (2) by providing thirty (30) days’ written notice to the Breaching Party in the case of any other material breach, which notice will, in each case (i) expressly reference this Section 12.3.1 (Termination for Material Breach), (ii) reasonably describe the alleged breach which is the basis of such termination, and (iii) clearly state the Non-Breaching Party’s intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. Notwithstanding the foregoing, (A) if the alleged material breach by CANbridge is that it has materially failed to satisfy its Development Diligence obligations under Section 3.1.1 (Development Diligence) in a particular Region in the Territory or has materially failed to satisfy its Commercialization Diligence obligations under Section 4.2.1 (Commercialization Diligence) in a particular Region in the Territory, then PUMA may only seek to terminate this Agreement solely with respect to such Region (and not in its entirety); (B) if such material breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period will be extended if the Breaching Party provides a written plan for curing such breach to the Non-Breaching Party and uses Commercially Reasonable Efforts to cure such breach in accordance with such written plan; provided, however, that no such extension will exceed sixty (60) days without the written consent of the Non-Breaching Party; and (C) if the Breaching Party disputes that it has materially breached this Agreement, the dispute will be resolved pursuant to ARTICLE 13 (Dispute Resolution), and this Agreement may not be terminated during the pendency of such dispute resolution procedure. The termination will become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period; provided, however, that the Non-Breaching Party may, by notice to the Breaching Party, designate a later date for such termination in order to facilitate an orderly transition of activities relating to Licensed Products. If, as a result of the application of such dispute resolution procedures, the

Breaching Party is determined to be in material breach of this Agreement (an “ Adverse Ruling ”), then if the Breaching Party fails to cure such material breach within sixty (60) days after such ruling (whether or not such actions are specified by the Adverse Ruling) (or ten (10) days after such ruling in the case of a payment breach), then the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party as provided in this Section 12.3.1 (Termination for Material Breach).

12.3.2 Termination by CANbridge for Convenience. CANbridge may, upon [***] prior written notice to PUMA, terminate this Agreement for convenience, without cause, and for any or no reason.

12.3.3 Termination for Bankruptcy. This Agreement may be terminated, to the extent permitted by applicable Law, by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy, reorganization, liquidation or receivership proceeding such right to terminate shall only become effective if the Party subject to such proceeding consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

12.3.4 Effect of Termination of the Pfizer License Agreement. In the event of termination of the Pfizer License Agreement, PUMA will request that Pfizer grant CANbridge a direct license in the Territory pursuant to the terms and conditions of Section 13.6.4 of the Redacted Pfizer License Agreement.

12.4 Effects of Termination.

12.4.1 Effects of Termination Generally. Upon termination of this Agreement in its entirety pursuant to Section 12.3 (Early Termination), the Parties’ rights and obligations under this Agreement will terminate and neither Party will have any further rights or obligations under this Agreement from and after the effective date of termination, except as set forth in this Section 12.4 (Effects of Termination); provided, however, that, if this Agreement is terminated with respect to a particular Region only, then such rights and obligations will terminate only to the extent they relate solely to the terminated Region.

12.4.2 Accrued Obligations. Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability which, on the effective date 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.

12.4.3 Survival. This Section 12.4.3 (Survival), the provisions set forth in the following Sections, as well as, to the extent applicable, any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect, will survive any expiration or termination of this Agreement in its entirety: Sections 2.1.3, 3.3.1 (until the earlier of (a) one (1) year following any termination hereof, or (b) completion of the technology transfer activities set forth in Section 12.4.8), 3.4.5 (for so long as CANbridge remains the holder of the Marketing Authorizations for any Licensed Products in the Territory), 6.5 (for the time period provided therein), 6.6 (to the extent applicable to payments becoming due during the Term), 6.7, 6.8, 6.9 (to

the extent applicable to payments becoming due during the Term), 7.1, 7.2 (solely with respect to Joint Patent Rights), [8.1](#) (during the [***] period set forth therein), [12.2](#) (if applicable), and 12.4 and ARTICLE 10 (as to Sections 10.1 - 10.3, solely to the extent applicable to activities conducted during the Term pursuant to this Agreement, and as to Section 10.4, for the time period provided therein), ARTICLE 11, ARTICLE 13, and ARTICLE 14. Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement, including applicable definitions in ARTICLE 1 (Definitions), will survive to the extent required. Except as otherwise expressly provided in this Agreement, all rights and obligations of the Parties under this Agreement, including any licenses granted under this Agreement, will terminate upon expiration or termination of this Agreement in its entirety or solely with respect to the terminated Region, as the case may be, for any reason.

12.4.4 Inventory. Upon termination of this Agreement, CANbridge shall have the right to sell its remaining inventory of Licensed Products following the termination of this Agreement so long as CANbridge has fully paid, and continues to fully pay when due, any and all royalties and milestone payments owed to PUMA under [ARTICLE 6](#), and CANbridge is otherwise not in material breach of this Agreement.

12.4.5 Transfer of Regulatory Filings and Regulatory Approvals. Following the effectiveness of any termination of this Agreement pursuant to Section 12.3 (Early Termination), as promptly as practicable after PUMA's written request and unless prohibited by applicable Law, CANbridge will, to the extent permitted by applicable Law and relevant Regulatory Authorities and at PUMA's sole cost and expense (unless the applicable termination giving rise to PUMA's rights under this Section 12.4.5 was for CANbridge's material breach pursuant to Section 12.3.1, in which case such transfer shall be at CANbridge's sole cost and expense), assign and transfer to PUMA all Regulatory Filings, filings for Pricing and Reimbursement Approval and Marketing Authorizations for Licensed Products that are held by or under authority of CANbridge or its Affiliates or Sublicensees as of the effective date of termination, with respect to the terminated Region in the Territory, as the case may be, and will take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under such Regulatory Filings, filings for Pricing and Reimbursement Approval and Marketing Authorizations to PUMA. If applicable Law or relevant Regulatory Authorities prevent or delay the transfer of ownership of any such Regulatory Filing, filing for Pricing and Reimbursement Approval and Marketing Authorizations to PUMA, then CANbridge will grant, and hereby does grant, to PUMA an exclusive and irrevocable right of access and right of reference to such Regulatory Filing, filing for Pricing and Reimbursement Approval and Marketing Authorizations for Licensed Products in the Territory or the terminated Region, as the case may be, and will reasonably cooperate with PUMA, at PUMA's expense (unless the applicable termination giving rise to PUMA's rights under this Section 12.4.5 was for CANbridge's material breach pursuant to Section 12.3.1, in which case such transfer shall be at CANbridge's sole cost and expense), to make the benefits of such Regulatory Filings, filings for Pricing and Reimbursement Approval and Marketing Authorizations available to PUMA or its designee(s).

12.4.6 Licenses Upon Termination. Upon any termination of this Agreement pursuant to Section 12.3 (Early Termination), CANbridge will grant, and hereby does grant to PUMA: (a) a non-exclusive, fully paid-up, royalty-free, worldwide, transferable, perpetual and irrevocable license, with the right to sublicense, under all intellectual property rights Controlled

by CANbridge claiming Inventions that are necessary or reasonably useful to make, use, sell, offer for sale, or import the Licensed Products as they exist at the time of such termination of this Agreement to make, use, sell, offer for sale, or import the Licensed Products and (b) a fully paid-up, royalty-free, worldwide, transferable, sublicensable, perpetual and irrevocable license to use Trademarks specifically identifying the Licensed Products, excluding for clarity all Trademarks also used in connection with CANbridge's business other than with respect to Licensed Product, for the purpose of manufacturing, marketing, distributing, selling, and otherwise Developing and Commercializing, such Licensed Product.

12.4.7 Return of Confidential Information. Within [***] after the effective date of termination (but not expiration) of this Agreement in its entirety, and subject to Section 12.2 (Paid-Up License Upon End of Royalty Term), each Party will, and cause its Affiliates to (a) destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or Control, and provide written certification of such destruction, or (b) prepare such tangible items of the other Party's Confidential Information for shipment to such other Party, as such other Party may direct, at the first Party's expense; provided, however, that, in any event, (i) each Party may retain one (1) copy of the Confidential Information of the other Party to the extent necessary to perform its obligations that survive expiration or termination of this Agreement; and (ii) such first Party may retain one copy of such Confidential Information of the other Party for its legal archives.

12.4.8 Third-Party Agreements; Transfer of Know-How. Within [***] following the termination (but not expiration) of this Agreement, and subject to Section 12.2 (Paid-Up License Upon End of Royalty Term) of this Agreement, at PUMA's written request, CANbridge shall and shall cause its Affiliates to assign all of its right, title and interest in and to any Third Party agreements that solely relate to the Licensed Product and not to another product ("Third Party Agreement") to PUMA [***]. Promptly following the termination (but not expiration) of this Agreement, and subject to Section 12.2 (Paid-Up License Upon End of Royalty Term) of this Agreement, CANbridge shall provide copies to PUMA or its designee of any Know-How in CANbridge's possession or control that is (a) reasonably useful or necessary to make, use, sell, offer for sale, or import the Licensed Products and (b) developed by CANbridge in the course of performing its obligations and exercising its rights under this Agreement. Such Know-How shall include without limitation customer lists, but only to the extent such customer lists relate solely to the Licensed Product and not another product.

12.4.9 Cooperation. Each Party will cause its Affiliates, sublicensees and contractors to comply with the obligations in this Section 12.4 (Effects of Termination).

ARTICLE 13
DISPUTE RESOLUTION

13.1 Dispute Resolution; Escalation. The Parties recognize that disputes as to certain matters arising out of or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedited manner by mutual cooperation. To accomplish this objective, any and all disputes between the Parties arising out of or in connection with this Agreement will first be referred to the JSC for resolution. Should the JSC not be able to reach agreement at a duly called meeting of the JSC within [***] after the date on which the matter is referred to the JSC, then either Party may refer such matter to the Executive Officers for resolution and the Executive Officers will attempt to resolve the matter in good faith. If the Executive Officers fail to resolve such matter within [***] after the date on which the matter is referred to the Executive Officers (unless a longer period is agreed to by the Parties), then either Party may submit the dispute to the [***] for final resolution by binding arbitration in accordance with Section 13.2 (Arbitration).

13.2 Arbitration. Except as set forth in this Section 13.2 (Arbitration), each dispute, difference, controversy or claim arising in connection with or related or incidental to, or question occurring under, this Agreement or the subject matter hereof will be referred to and finally resolved by arbitration in accordance with the Rules of Arbitration (the "Rules") of the [***], by an arbitral tribunal composed of three arbitrators, all of whom will have previous judicial experience, with each Party appointing one arbitrator and the third arbitrator to be selected by mutual agreement of the two arbitrators appointed by the Parties. The foregoing arbitration proceedings may be commenced by either Party by notice to the other Party. Unless otherwise agreed by the Parties hereto, all such arbitration proceedings will be held in [***] ; provided, however, that proceedings may be conducted by telephone conference call with the consent of the Parties and the arbitrator(s). All arbitration proceedings will be conducted in the English language. The arbitrator(s) will consider grants of equitable relief and orders for specific performance as co-equal remedies along with awards of monetary damages. The arbitrator(s) will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney's fees, will be [***]. The Parties hereby agree that the arbitrator(s) has authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. All rulings by the arbitrator(s) will be final. Notwithstanding any contrary provision of this Agreement, any Party may seek equitable measures of protection in the form of attachment of assets or injunctive relief (including, without limitation, specific performance and injunctive relief) in any matter relating to the proprietary rights and interests of either Party from any court of competent jurisdiction, pending a decision by the arbitral tribunal in accordance with this Section 13.2 (Arbitration). The Parties hereby exclude any right of appeal to any court on the merits of such matter. The provisions of this Section 13.2 (Arbitration) may be enforced and judgment on the award (including without limitation equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Except to the extent necessary to confirm an award or as may be required by Law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written

consent of both Parties. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. Nothing in this [Section 13.2 will preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief](#), concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, scope, validity, enforceability or infringement of, Patent Rights shall not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.

13.3 Jury Waiver. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES TO ARBITRATE AS SET FORTH IN SECTION 13.2 (Arbitration). THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

ARTICLE 14 MISCELLANEOUS

14.1 Assignment; Successors.

14.1.1 Assignment. This Agreement and the rights and obligations of each Party under this Agreement will not be assignable, delegable, transferable, pledged or otherwise disposed of by either Party without the prior written consent of the other Party; provided, however, that either Party may assign or transfer this Agreement together with all of its rights and obligations hereunder, without such consent (but with written notice to the other Party), (a) to an Affiliate or (b) to a successor in interest in connection with the transfer or sale of all or substantially all of its business or assets to which this Agreement relates, or in the event of its merger or consolidation, reorganization or similar transaction, subject to the assignee agreeing in writing to be bound by the terms and conditions of this Agreement. Any assignment in violation of this Section 14.1.1 (Assignment) shall be null and void.

14.1.2 Successors. Any permitted assignment of the rights and obligations of a Party under this Agreement will be binding on, and inure to the benefit of and be enforceable by and against, the successors and permitted assigns of the assigning Party. The permitted assignee or transferee will assume all obligations of its assignor or transferor under this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section [14.1.2](#) (Successors) will be null, void and of no legal effect.

14.2 Acquisition Transactions. Notwithstanding anything to the contrary in this Agreement, in the event of an acquisition of a Party or its business (an "Acquired Party") by a

Third Party (an “Acquirer”) after the Effective Date, directly or indirectly, whether by merger, asset purchase or otherwise (each, an “Acquisition Transaction”), then, as to any such Acquirer, (a) any Patent Rights, Know-How, or Regulatory Approvals that are held at the time of such acquisition by the Acquirer, or any Affiliate of the Acquirer that becomes an Affiliate of the Acquired Party as a result of such acquisition, will be deemed not to be Controlled by the Acquired Party, and (b) such Acquirer (including its Affiliates, but excluding the acquired Party) will not be obligated to comply with the covenants in Section 2.4 (Exclusivity Covenant).

14.3 Choice of Law. This Agreement will be governed by and interpreted under the laws of the State of New York, without referring to conflicts of law principles; provided, however, that all questions concerning (a) inventorship of Patent Rights under this Agreement will be determined in accordance with Section 7.1 (Ownership of Inventions) and (b) the construction or effect of Patent Rights will be determined in accordance with the laws of the country, Region or other jurisdiction in which the particular patent within such Patent Rights has been filed or granted, as the case may be. Any communication or proceedings resulting of disputes under this Agreement shall be in English language. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods.

14.4 Notices. Any notice or report required or permitted to be given or made under this Agreement by one Party to the other will be in writing and will be deemed to have been delivered (a) upon personal delivery, (b) on the second Business Day (at the place of delivery) next following deposit with a reputable, internationally recognized overnight courier that maintains records of delivery and (c) in the case of notices provided by telecopy (which notice will be followed immediately by an additional notice pursuant to clause (a) or (b) above if the notice is of a default under this Agreement), upon completion of transmission, with transmission confirmed, to the addressee’s facsimile machine, as follows (or at such other addresses or facsimile numbers as may have been furnished in writing by a Party to the other as provided in this Section 14.4 (Notices)). This Section 14.4 (Notices) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to PUMA:

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

With copies to:

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

Latham & Watkins 140 Scott Drive
Menlo Park, CA 94025-1008, USA
Attention: [***]
Fax: [***]

If to CANbridge:

CANbridgepharma Limited
Sterling Centre No.11
Cheung Yue Street, Kowloon
Hong Kong
Attn : [***]
Fax: [***]

With copies to:

CANbridge Life Sciences Ltd.
303A, Building E
Wangjing Pioneer Park
No. 2 LizeZhongEr Road
Chaoyang District, Beijing, China
Attn : [***]
Fax: [***]

Ropes & Gray LLP 800
Boylston Street
Prudential Tower
Boston, Massachusetts 02199-3600
Attn : [***]
Fax: [***]

14.5 Severability. In the event that one or more provisions of this Agreement is held invalid, illegal or unenforceable in any respect, then such provision shall not render any other provision of this Agreement invalid or unenforceable, and all other provisions shall remain in full force and effect and shall be enforceable, unless the provisions that have been found to be invalid or unenforceable shall substantially affect the remaining rights or obligations granted or undertaken by either Party. The Parties agree to attempt to substitute for any invalid or unenforceable provision a provision which achieves to the greatest extent possible the economic objectives of the invalid or unenforceable provision.

14.6 Integration. This Agreement, together with all schedules and exhibits attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral, including the Prior CDA. In the event of a conflict between the Development Plan or any schedules or attachments to this Agreement, on the one hand, and this Agreement, on the other hand, the terms of this Agreement will govern. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement.

14.7 Waivers and Amendments. The failure of any Party to assert a right under this Agreement or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or

condition by the other Party. The exercise by any Party of any right or election under the terms or covenants herein shall not preclude or prejudice any Party from exercising the same or any other right it may have under this Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. Notwithstanding the authority granted to the JSC under this Agreement,

(a) no waiver will be effective unless it has been given in writing and signed by the Party giving such waiver, and (b) no provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

14.8 Independent Contractors; No Agency. Neither Party will have any responsibility for the hiring, firing or compensation of the other Party's or such other Party's Affiliates' employees or for any employee benefits with respect thereto. No employee or representative of a Party or its Affiliates will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on such other Party, without such other Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party will be that of independent contractor, and the relationship between the two Parties will not constitute a partnership, joint venture, or agency, including for all tax purposes.

14.9 Affiliates, Sublicensees, and Contractors. To the extent that this Agreement imposes obligations on Affiliates, sublicensees or contractors of a Party, such Party will cause its Affiliates and its sublicensees and contractors to perform such obligations. Either Party may use one or more of its Affiliates, sublicensees or contractors to perform its obligations and duties or exercise its rights under this Agreement; provided, however, that (a) each such Affiliate, sublicensee or contractor will perform any such obligations delegated to it in compliance with the applicable terms and conditions of this Agreement, (b) the performance of any obligations of a Party's by its Affiliates, sublicensees or contractors will not diminish, reduce or eliminate any obligation of such Party under this Agreement, and (c) subject to such Party's assignment to an Affiliate pursuant to Section 14.1 (Assignment; Successors), such Party will remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement.

14.10 Force Majeure. Neither Party will be responsible to the other for, or be deemed to have defaulted under or breached this Agreement for, any failure or delay in performing any of its obligations under this Agreement or for other nonperformance under this Agreement (excluding, in each case, the obligation to make payments when due) if such delay or nonperformance is caused by or results from events beyond the reasonable control of the non-performing Party, including strike, fire, flood, earthquake, hurricanes, accident, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), act of terrorism, act of God or acts, omissions or delays in acting of the government of any country or Region or of any local government, or by cause unavoidable or beyond the reasonable control of such Party (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement) (a "Force Majeure Event"). In such event, the Party affected will promptly (and, in any event, within [***]) notify the other Party in writing of such Force Majeure Event, stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no

greater scope and no longer duration than is necessary and the non-performing Party and will use Commercially Reasonable Efforts to resume performance of its obligations.

14.11 No Third Party Beneficiary Rights. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Person. This Agreement is not intended to and will not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than, to the extent provided in ARTICLE 10 (Indemnification; Damages), the Indemnified Parties.

14.12 Non-exclusive Remedy. Except as expressly provided herein, the rights and remedies provided herein are cumulative and each Party retains all remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief, with respect to any breach of this Agreement. Neither Party will be required to terminate this Agreement due to a breach of this Agreement by the other Party.

14.13 Interpretation. The Article and Section headings used herein are for reference and convenience only, and will not enter into the interpretation of this Agreement. Except as otherwise explicitly specified to the contrary, (a) references to an Article, Section, Exhibit or Schedule means an Article or Section of, or a Schedule or Exhibit to this Agreement and all subsections thereof, unless another agreement is specified; (b) references in any Section to any clause are references to such clause of such Section; (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto; (d) references to a particular Law mean such Law as in effect as of the relevant time, including all rules and regulations thereunder and any successor Law in effect as of the relevant time, and including the then-current amendments thereto; (e) words in the singular or plural form include the plural and singular form, respectively; (f) unless the context requires a different interpretation, the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (g) the terms "including," "include(s)," "such as," "e.g." and "for example" mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; (h) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (i) "monthly" means on a calendar month basis, (j) "quarter" or "quarterly" means on a Calendar Quarter basis; (k) "annual" or "annually" means on a Calendar Year basis; (l) "year" means a 365 day period unless Calendar Year is specified; (m) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (n) all words used in this Agreement will be construed to be of such gender or number as the circumstances require; (o) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative manner; (p) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (q) the words "hereof," "herein," "hereby" and

derivative or similar words refer to this Agreement (including any Exhibits or Schedules); (r) neither Party or its Affiliates will be deemed to be acting “on behalf of” the other Party under this Agreement, except to the extent expressly otherwise provided; (s) there will be no double-counting in calculating Development costs or any components thereof; (t) provisions that require that a Party, or the JSC hereunder “agree”, “consent” or “approve” or the like will be deemed to require that such agreement, consent or approval be specific and in writing in a written agreement, letter or approved minutes, but, except as expressly provided herein, excluding e-mail and instant messaging; and (u) the word “will” shall be construed to have the same meaning and effect as the word “shall”.

14.14 Further Assurances. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

14.15 Ambiguities; No Presumption. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption will apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

14.16 Execution in Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

14.17 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to the Parties from time to time (“Export Control Laws”). Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other Governmental Authority.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this Agreement to **be** duly executed by its authorized representative under seal, in duplicate on the Effective Date.

PUMA BIOTECHNOLOGY, INC.

/s/ Alan Auerbach

Name: Alan Auerbach

Title: CEO/President

CANBRIDGEPHARMA LIMITED

/s/ Xue James Qun

Name: Xue James Qun

Title: Director

Jan. 30, 2018

[Signature Page to Collaboration and License Agreement]

*** Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Confidential Treatment Requested by Puma Biotechnology, Inc.

Schedule 1.39

Existing Third Party License Agreements

The Pfizer License Agreement

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Schedule 4.1
Supply Agreement Key Terms

The Supply Agreement shall incorporate the following key terms and conditions:

- **Supply Price**
 - The per unit supply price for each [***] of the Licensed Product in [***] form shall be (a) \$[***] for Licensed Product supplied for clinical use, and (b) \$[***] for Licensed Product supplied for commercial use. Such prices shall be revised every [***] to account for any increase in the relevant [***] applicable to the prior [***]. [***].
- **Forecasting / Delivery Against Forecasts**
 - CANbridge shall provide to PUMA a rolling [***] forecast setting forth its estimated requirements for Licensed Product (the “*Rolling Forecast*”), and shall update such forecast [***]. The first [***] of each Rolling Forecast shall be binding on both Parties (the “*Binding Forecast*”). The last [***] of each Rolling Forecast shall be used for planning purposes only. PUMA shall supply CANbridge with its requirements for Licensed Product as set forth in each Binding Forecast, and CANbridge shall be obligated to purchase the amount of Licensed Product set forth in each Binding Forecast.
 - If at any time during the Term, PUMA believes that it will not be able to meet CANbridge’s requirements for Licensed Product, as set forth in any Rolling Forecast, then PUMA shall provide notice to CANbridge within [***] of becoming aware of such anticipated supply shortfall. Promptly following any such notice, the Parties will discuss strategies for addressing any potential shortfall.
- **Initial Supply and Back-Up Supply**
 - The Parties shall agree to forecasting and delivery mechanics with the intent to [***].
- **Remedies for Supply Failures and Shortfalls**
 - PUMA shall maintain [***] qualified third party contract manufacturing organization for the supply of Licensed Product (“*Third Party CMO*”). In the event of a Supply Failure (to be defined in the Supply Agreement), CANbridge shall have the right to source Licensed Product for the CANbridge Territory directly from any such Third Party CMO for the duration of such Supply Failure and PUMA shall use commercially reasonable efforts to enable such direct sourcing relationship.
 - In the event of any supply shortfall, PUMA may supply the US market first, but shall distribute available Licensed Product to all other countries (or regions, as applicable) in the world on a proportionate basis, to be determined by [***], and [***].
 - The Parties shall discuss and agree upon additional remedies in the event of any Supply Failure.

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Confidential Treatment Requested by Puma Biotechnology, Inc.

Schedule 8.2.1

Form of Initial Press Release

*** Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CANbridge Press Release

Puma Biotechnology and CANbridge Life Sciences Enter into Exclusive Licensing Agreement to Commercialize NERLYNX® (neratinib) in Greater China

CANbridge Life Sciences, a biopharmaceutical company focused on developing Western drug candidates in China and North Asia, announced today that it has exclusively licensed the rights to develop and commercialize NERLYNX® (neratinib) in China, Taiwan, Hong Kong and Macao (collectively, greater China) from Puma Biotechnology, Inc (Nasdaq: PBYI).

Neratinib was approved by the U.S. Food and Drug Administration (FDA) in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets.

“We are very proud to be partnering with Puma. By addressing a significant unmet medical for the extended adjuvant treatment of patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, we believe that NERLYNX will transform the lives of patients. We are honored to have been selected by Puma to develop and commercialize this important therapy which we believe has significant commercial potential in greater China in HER2-positive cancers including gastric cancer where CANbridge will be leading the development in greater China.” said James Xue, Chief Executive Officer of CANbridge Life Sciences. “This transformative collaboration is an important demonstration of our capabilities as a leading biopharmaceutical company and partner of choice in the greater China region. We will work closely with Puma and regulatory authorities toward earliest market approval of NERLYNX.”

“CANbridge was selected to be our partner in greater China because of the strength and depth of the team and we are confident in CANbridge’s capabilities to make NERLYNX® a commercial success in greater China.” stated Alan H. Auerbach, Chief Executive Officer and President of Puma.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.



News Release

Puma Biotechnology and CANbridge Life Sciences Enter into Exclusive Licensing Agreement to Commercialize NERLYNX® (neratinib) in Greater China

LOS ANGELES, Calif., Jan. XX, 2018 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, and CANbridge Life Sciences, a biopharmaceutical company focused on developing Western drug candidates in China and North Asia, have entered into an exclusive agreement under which CANbridge will commercialize NERLYNX® (neratinib) in China, Taiwan, Hong Kong, and Macau (greater China).

NERLYNX is not approved currently for commercialization outside of the United States. CANbridge will be responsible for seeking the requisite regulatory approval and, once approved, for commercializing NERLYNX in greater China. Puma will receive an upfront payment of \$30 million and other potentially near term regulatory milestone payments totaling an additional \$40 million. In addition, Puma will receive significant double digit royalties on NERLYNX sales in greater China and sales-based milestones may be realized in later years.

“Puma is committed to providing access to NERLYNX to patients around the world and greater China represents a very large market opportunity,” stated Alan H. Auerbach, Chief Executive Officer and President of Puma. “While we continue to focus our commercial resources on the U.S. market, we are confident this new partnership with CANbridge will help patients in greater China access NERLYNX at the earliest opportunity.”

“We are excited about the opportunity to provide this therapy to women in our region. We plan to engage our local regulatory authorities in greater China to expedite commercial access to NERLYNX in parts of greater China by mid-2019.” said James Xue, Chief Executive Officer of CANbridge Life Sciences. “We are honored to have been selected by Puma to develop and commercialize this important therapy which we believe has significant commercial potential in greater China in HER2-positive cancers, including gastric cancer, where CANbridge will be leading the clinical development in greater China.”

Neratinib was approved by the U.S. Food and Drug Administration (FDA) in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets.

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.

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IMPORTANT SAFETY INFORMATION

NERLYNX® (neratinib) tablets, for oral use

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

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea occurring despite recommended prophylaxis with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade ≥ 2 diarrhea that occurs after maximal dose reduction.
- **Hepatotoxicity:** Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue NERLYNX in patients experiencing Grade 4 liver abnormalities.
- **Embryo-Fetal Toxicity:** NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

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

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

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors (PPI) and H₂-receptor antagonists. Separate NERLYNX by 3 hours after antacid dosing.
- Strong or moderate CYP3A4 inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- Lactation: Advise women not to breastfeed.

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Please see [Full Prescribing Information](#) for additional safety information.

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

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and healthcare providers with reimbursement support and referrals to resources that can help with financial assistance. More information on the Puma Patient Lynx program can be found at www.NERLYNX.com or 1-855-816-5421.

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. NERLYNX® (neratinib) is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

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

About CANbridge Life Sciences

CANbridge Life Sciences, Ltd. is a clinical-staged bio-pharmaceutical company accelerating development and commercialization of specialty healthcare products for serious and critical medical conditions in China and North Asia (Korea and Taiwan). CANbridge develops partnerships with Western bio-pharmaceutical companies with clinical-stage pharmaceutical, medical device or diagnostic products that are either unavailable in China/North Asia or address medical needs that are underserved in the region. CANbridge also licenses, or obtains exclusive rights to commercialize, drug and device products that are approved in their home markets for commercialization in China and North Asia. Led and backed by a highly-seasoned executive team, with extensive Chinese drug development experience, CANbridge has the capability to select, acquire, develop and commercialize future therapeutics and diagnostics targeting the unmet medical needs of Chinese and East Asian patients with serious or critical conditions. CANbridge is privately-held and headquartered in Beijing, China.

Additional information can be found at <http://www.canbridgepharma.com/>.

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Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the commercialization and commercial availability of NERLYNX® in Greater China; the registration of, and regulatory approval of, NERLYNX in the region; the expected milestone payments and royalties payable under the agreement with CANbridge Pharma Ltd.; the benefits of NERLYNX and neratinib; the Company's clinical trials; and the announcement of data relative to those trials.

All forward-looking statements included in this press release involve risks and uncertainties that could cause the Company's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the fact that the Company has only recently commenced commercialization and shipment of its only FDA approved product; the Company's dependence upon the commercial success of NERLYNX (neratinib); the Company's history of operating losses and its expectation that it will continue to incur losses for the foreseeable future; risks and uncertainties related to the Company's ability to achieve or sustain profitability; the Company's ability to predict its future prospects and forecast its financial performance and growth; failure to obtain sufficient capital to fund the Company's operations; the effectiveness of sales and marketing efforts; the Company's ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support the Company's drug candidate claims; even if approved, the risk that physicians and patients may not accept or use the Company's products; the Company's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates; risks pertaining to securities class action, derivative and defamation lawsuits; the Company's dependence on licensed intellectual property; and the other risk factors disclosed in the periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

Contact:

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

David Schull or Amiad Finkelthal, Russo Partners, +1-212-845-4271 david.schull@russopartnersllc.com
amiad.finkelthal@russopartnersllc.com

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Confidential Treatment Requested by Puma Biotechnology, Inc.

Schedule 9.2.1

Licensed Patents

A. Hong Kong, Macau & Taiwan

[***]

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B. China

[***]

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Schedule 9.2.2

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LICENSE AGREEMENT

By and between

Puma Biotechnology, Inc.

and

Pint Pharma International SA

March 30, 2018

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LICENSE AGREEMENT

Puma Biotechnology, Inc., a corporation organized and existing under the laws of Delaware with offices at 10880 Wilshire Blvd Suite 2150, Los Angeles, CA 90024 (“**Puma**”) and Pint Pharma International SA, a company organised and existing under the laws of Switzerland and having its principal place of business at Route de Chenaux 9, 1091 Bourg-en-Lavaux, Switzerland (“**Pint**”) have entered into this License Agreement as of March 30, 2018 (the “**Effective Date**”).

Background

Whereas, prior to the Effective Date, Puma has entered into a License Agreement with Pfizer (as defined below) dated August 18, 2011, as amended (the “**Pfizer License Agreement**”), pursuant to which Puma receive an exclusive, worldwide license, with the right to grant sublicenses, to develop and commercialize neratinib;

Whereas, Puma is developing and commercializing the pharmaceutical product known as Nerlynx™ (neratinib) (as more specifically described below, the “**Product**”);

Whereas, Puma has obtained regulatory approval of neratinib in the United States;

Whereas, Pint has expertise in obtaining regulatory approval for and commercializing pharmaceutical products in the Territory (as defined below);

Whereas, Pint wishes to obtain from Puma, and Puma wishes to grant to Pint, certain rights and licenses under intellectual property controlled by Puma to commercialize neratinib in the Territory on the terms and conditions of this Agreement;

Whereas, Pint wishes to have Puma supply, and Puma wishes to supply to Pint, the Product to Pint for use and sale in the Territory, on the terms and conditions of this Agreement.

Now, therefore, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

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Agreement

1 Overview . Under this Agreement, as more specifically provided in the body of the Agreement:

1.1 Definitions . Defined terms have the meanings given to them in **Section 3**.

1.2 License Grant and Related Matters .

1.2.1 Puma grants an exclusive license to Pint in the Territory under the Puma Patent Rights and Puma Know-How as provided in **Section 3.1** and under the Product Trademarks as provided in **Section 3.2**. Puma also agrees to make certain related technology transfers to allow Pint to practice its licensed rights, as provided in **Section 3.4** .

1.2.2 **Section 3.5** defines Pint's diligence obligations in regard to exercising the rights granted to Pint under the licenses.

1.2.3 The Parties agree to certain exclusivity obligations, including agreement by Pint to obtain all Product for sale in the Territory exclusively from Puma, as provided in **Section 3.6** .

1.3 Regulatory Approvals, Data Sharing and Related Matters .

1.3.1 The Parties agree to cooperate to allow Pint to obtain and maintain Regulatory Approvals for the Product in the Territory, as provided in **Sections 4.1 through 4.6**

1.3.2 The Parties agree to share data and to handle adverse event reporting as provided in **Section 4.7 and 4.8**.

1.3.3 **Sections 4.9** provides for regulatory inspections and **Section 4.10** for recalls and withdrawals.

1.4 Product Manufacture and Supply

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Puma agrees to Manufacture Products as provided in **Section 5.1** and to supply Products to Pint pursuant to a Supply Agreement to be entered into by the Parties as provided in **Section 5.2**.

- 1.5 Upfront, Milestone and Royalty Payments. Pint will pay to Puma an upfront payment, milestone payments and royalty payments, as provided in **Section 6**.
- 1.6 Intellectual Property Matters, including ownership of inventions, patent prosecution, enforcement against infringement and defence against claims of infringement, are provided for in **Section 7**.
- 1.7 Confidentiality and Related Obligations are provided for in **Section 8**.
- 1.8 Representations and Warranties. The Parties' representations and warranties are provided in **Section 9**.
- 1.9 **Section 10** covers Indemnification, Limitation of Liability and Insurance.
- 1.10 Term and Termination provisions are defined in **Section 11**.
- 1.11 **Section 12** covers Publicity and Publications.
- 1.12 **Section 13** provides for the creation of a Joint Steering Committee and Alliance Managers.
- 1.13 **Section 14** defines Dispute Resolution.
- 1.14 **Section 15** covers a number of miscellaneous provisions, including assignment, force majeure and choice of law.

2 DEFINITIONS

- 2.1 “ **Affiliate** ” means, 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,

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or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity.

- 2.2 “ **Anti-Corruption Laws** ” means (a) the U.S. Foreign Corrupt Practices Act of 1977 (the “FCPA”), the U.K. Bribery Act 2010, (b) the criminal code of each Region in the Territory, and (c) the domestic laws of the Territory.
- 2.3 “ **Applicable Laws** ” means all applicable laws, statutes, rules, regulations and guidelines, including, without limitation, all good manufacturing practices and all applicable standards or guidelines promulgated by the appropriate Regulatory Authority and the rules and regulations of a securities exchange.
- 2.4 “ **Business Day** ” means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, New York or in any of the Major Market Countries are authorized or required by law to remain closed.
- 2.5 “ **Calendar Quarter** ” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, provided, however: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the Calendar Quarter in which the Effective Date occurs; and (b) the last Calendar Quarter shall extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.
- 2.6 “ **Calendar Year** ” means for the first Calendar Year, the period beginning on the Effective Date and ending on December 31, 2018, and for each Calendar Year thereafter, any twelve (12) month period commencing on January 1, except that the last Calendar Year shall commence on January 1 of the year in which this Agreement expires or terminates and end on the effective date of such expiration or termination.
- 2.7 “ **cGMP** ” means current good manufacturing practices, and compliance with the applicable regulations, guidance and practices in force in the country(ies) of Manufacture of the Product and the Territory relating to the Manufacture of the Compound and the Product, as amended from time to time.
- 2.8 “ **Commercialize** ”, “ **Commercializing** ” or “ **Commercialization** ” means any and all activities related to the pre-marketing, launching, marketing, promotion (including advertising and detailing), labelling, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, importing and exporting for sale, distribution, customer service and support,

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and post-marketing safety surveillance and reporting of a product (including a Product), but not including Manufacturing.

- 2.9 " **Commercially Reasonable Efforts** " means, with respect to the Development or Commercialization of a Product by any company in any jurisdiction, that level of efforts and resources commonly dedicated in the pharmaceutical industry by a company of similar size and financial and scientific resources to the Development or Commercialization, as the case may be, in such jurisdiction 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 of the product in such jurisdiction, the then current and likely future competitive environment for such product in such jurisdiction and the likely timing of such product's entry into the market in such jurisdiction, the regulatory environment (including any applicable pricing and reimbursement requirements) and status of such product in such jurisdiction, and other relevant scientific, technical and commercial factors.
- 2.10 " **Compound** " means (a) the therapeutically active pharmaceutical ingredient in the Product designated by Puma as Nerlynx TM , which ingredient is also known as "neratinib," "WAY 179272" or "HKI-272" (the " **Neratinib Compound** "), (b) the compound designated by Puma as PF-05208766, also known as "WAY 178357" or "HKI-357" (the " **HKI-357 Compound** "), (c) any other compound covered by the claims of U.S. Patent No. 7,399,865 (the " '865 Patent") or any issued foreign counterpart thereof having claims equivalent to the claims of the '865 Patent, (d) any compound listed on Schedule 2.10, (e) all [***], and (f) all [***].
- 2.11 " **Control** " or " **Controlled** " means, with respect to any Intellectual Property Right, 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 Right, 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.
- 2.12 " **Data Base** " and " **Data Base Plan** " are defined in **Section 4.7**.
- 2.13 " **Develop** " or " **Development** " means non-clinical and clinical drug research and development activities, whether before or after Regulatory Approval, including drug metabolism and pharmacokinetics, translational research,

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toxicology, pharmacology, test method development and stability testing, process and packaging development and improvement, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, conduct of clinical studies, regulatory affairs, the preparation and submission of Regulatory Filings, clinical study regulatory activities, and any other activities directed towards obtaining Regulatory Approval of any Product. Development includes use and importation of the relevant Compound or Product to conduct such Development activities. Development will not include Commercialization activities.

- 2.14 “ **Dollars** ” or “ **\$** ” shall mean the legal tender of the United States of America.
- 2.15 “ **EMA** ” means the European Medicines Agency, or a successor agency thereto.
- 2.16 “ **EMA Approval** ” means, with respect to any Product and any specific indication, Marketing Authorization by the EMA for such Product in such indication.
- 2.17 “ **FDA** ” means the United States Food and Drug Administration, or a successor federal agency thereto.
- 2.18 “ **FDA Approval** ” means, with respect to any Product and any specific indication, Marketing Authorization by the FDA for such Product in such indication.
- 2.19 “ **First Commercial Sale** ” means with respect to a Product in any country or regulatory jurisdiction, the first sale for use or consumption by an end user of the Product in such country or jurisdiction following receipt of Marketing Authorization for such Product in such country or jurisdiction.
- 2.20 “ **Force Majeure Event** ” means any event reasonably beyond the control of a Party including wars, hostilities, revolutions, riots, civil disturbances, national emergencies, strikes or lockouts, unavailability of supplies, epidemics, fires, floods, earthquakes, other forces of nature, explosions, embargoes, or any other acts of nature, in each case to the extent reasonably beyond the control of the Party.

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- 2.21 “ **GAAP** ” means the generally accepted accounting principles in the United States, consistently applied.
- 2.22 “ **GHC License Agreement** ” means the License Agreement between The General Hospital Corporation d/b/a Massachusetts General Hospital (“ **MGH** ”) and Wyeth, an Affiliate of Pfizer, acting through its Wyeth Pharmaceuticals Division dated as of December 21, 2006.
- 2.23 “ **Governmental Authority** ” means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.
- 2.24 “ **IND** ” means: (a) an investigational new drug application filed with the FDA for authorization for the investigation of a Product, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.
- 2.25 “ **Initial Indication** ” means the use of the Product for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.
- 2.26 “ **Intellectual Property Rights** ” means all trade secrets, copyrights, patents and other patent rights, Trademarks, moral rights, Know-How and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.
- 2.27 “ **Joint Steering Committee** ” has the meaning set forth in Section 13.1.
- 2.28 “**Know-How**” means 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.
- 2.29 “ **Knowledge** ” means first hand and actual knowledge of the officers of Puma and is not meant to require or imply that any particular inquiry or investigation has been undertaken including, without limitation, obtaining any type of search or opinion of counsel.

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- 2.30 “ **Letter** ” means that letter agreement by and between Pint and Puma dated as of the Effective Date.
- 2.31 “ **Licensed Technology** ” means collectively, the Puma Patent Rights, the Puma Know-How and the Product Trademarks.
- 2.32 “ **Major Market Country** ” means each of Colombia, Brazil, Argentina, Peru and Mexico.
- 2.33 “ **Manufacture** ” or “ **Manufacturing** ” means all activities related to the production of a Product, including the production of any of the following to the extent used in a Product: 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, including but not limited to the following activities: reference standard preparation, cell bank preparation, mammalian cell production, 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. References to a Person engaging in Manufacturing activities will include having any or all of the foregoing activities performed by a Third Party.
- 2.34 “ **Marketing Authorization** ” means, with respect to a Product in any country or jurisdiction, all required approvals, registrations, licenses and authorizations required by the applicable Regulatory Authority to market and sell such Product in such country or jurisdiction.
- 2.35 “ **Milestone** ” means each milestone as set forth in Sections 6.2 and 6.3.
- 2.36 “ **Nerlynx** ” means the product known as Nerlynx™ (neratinib), whose FDA New Drug Application number is 208051.
- 2.37 “ **Net Sales** ” means the gross amount invoiced by or on behalf of Pint, its Affiliates and their respective sublicensees for sales of any Product in the Territory (other than sales among Pint, 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 (a) included in the gross invoiced

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sales price of the Product or otherwise directly incurred by Pint, its Affiliates and their respective sublicensees with respect to the sale of the Product, (b) normal and customary, and (c) not otherwise deducted in computing other amounts hereunder: (i) rebates, quantity and cash discounts, and other discounts to customers, (ii) taxes (except income taxes) and tariffs or duties paid, absorbed or allowed which are directly related to the sale of the Product, (iii) credits, allowances, discounts and rebates to, and chargebacks for, spoiled, damaged, outdated, rejected or returned Product (including in connection with Product withdrawals, expired Product and Product recalls), (iv) 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, (v) discounts or rebates or other payments required by Applicable Law, including any governmental special medical assistance programs, (vi) customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of the Product, and (vii) bad debts actually written off in connection with such Products.

Subsections (i) through (vii) shall be collectively referred to as “Deductions”. The following principles shall apply in the calculation of Net Sales:

In the case of any sale of 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 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 Product provided as free samples or as charitable donations shall not give rise to any Net Sales.

Net Sales shall be determined in accordance with GAAP.

- 2.38 “ **Other Active Ingredient** ” means any therapeutically active pharmaceutical ingredient other than a Compound.
- 2.39 “ **Parties** ” means Pint and Puma.

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- 2.40 “ **Patents** ” means (a) unexpired letters patent (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 letters patent, 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.
- 2.41 “ **Person** ” means 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.
- 2.42 “ **Pfizer** ” means Pfizer Inc., a corporation organized and existing under the laws of Delaware with offices at 235 East 42nd Street, New York, NY 10017.
- 2.43 “ **Pfizer License Agreement** ” has the meaning set forth in the Background hereto.
- 2.44 “ **Product** ” means a Compound or any product that contains a Compound.
- 2.45 “ **Public Official or Entity** ” means any individual or entity acting in an official or public capacity on behalf of (a) Governmental Authority (including physicians, hospital administrators, and other healthcare professionals working for or on behalf of state-controlled healthcare organization), (b) any official or employee of a quasi-public or non-governmental international organization, (c) any employee or other Person acting for or on behalf of any entity that is wholly or partially government owned or controlled by a Governmental Authority, (d) any Person exercising legislative, administrative, judicial, executive, or regulatory functions for or pertaining to a Governmental Authority (including any independent regulator), (e) any political party official, officer, employee, or other Person acting for or on behalf of a political party and (f) any candidate for public office.
- 2.46 “**Puma IP**” means the Puma Know-How and the Puma Patent Rights.
- 2.47 “**Puma Know-How** ” means any Know-How Controlled by Puma or any of its Affiliates at the Effective Date or during the Term that relates to the

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composition of any Compound or Product or to the Use or Manufacture of any Compound or Product.

2.48 “ **Puma Patent Right** ” means any Patent that (a) is Controlled by Puma or any of its Affiliates as of the Effective Date or during the Term and (b) claims the composition of matter, method of Using or Manufacturing, formulation or any other attribute of any Compound or Product. For the avoidance of doubt, “Puma Patent Rights” shall:

2.48.1 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 (x) any one or more Compounds together with any one or more Other Active Ingredients as a Combination Product or (y) two or more Compounds;

2.48.2 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

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

For the further avoidance of doubt, Puma Patent Rights include any Joint Patent Right that claims the composition of matter, method of Using or Manufacturing, formulation or any other attribute of any Compound or Product.

2.49 “**Quality Agreement**” means the quality agreement regarding the assembly, packaging, quality control and release issues relating to the Product, including the quality tasks related to the transfer of the Product between the Parties, and to be negotiated in good faith and executed within [***].

2.50 “ **Redacted Pfizer License Agreement** ” means the terms and conditions of the Pfizer License Agreement to the extent that the same appear in the redacted version of the Pfizer License Agreement attached to the Letter.

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- 2.51 “ **Regulatory Approval** ” means, with respect to a Product in any country or jurisdiction, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization that is required by the applicable Regulatory Authority to Develop or Commercialize the Product in such country or jurisdiction.
- 2.52 “ **Regulatory Authority** ” means any Governmental Authority responsible for granting any Regulatory Approval for a Product in the Territory.
- 2.53 “ **Regulatory Filing** ” means, with respect to a Product, any submission to a Regulatory Authority of any appropriate regulatory application, any submission to a regulatory advisory board, any Marketing Authorization application, and any supplement or amendment thereto.
- 2.54 “**Required Documents**” means those documents specified in the initial Regulatory Approval Plan as Required Documents to be delivered by the Required Document Deadline, (as defined therein).
- 2.55 “ **Required Documents Deadline** ” means the date that is [***].
- 2.56 “ **Royalty Term** ” means, on a Product-by-Product and country-by-country basis, the period commencing on 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 Puma Patent Rights which covers Use of the Product in such country, or (b) the earlier of (x) the time when Generic Competitors to the Product have achieved [***] or more market share in such country based on unit volume, or (y) ten (10) years following the date of First Commercial Sale of the Product in such country. “Generic Competitors” means, with respect to any Product being sold in any country, [***].
- 2.57 “ **Second Indication** ” means the use of Product for the treatment of metastatic breast cancer.
- 2.58 “ **Specification**” means, with respect to any Product to be sold for use in an indication in any regulatory jurisdiction in the Territory, the finished product specification of the Product as approved by the applicable Regulatory Authority in such jurisdiction in the Marketing Authorization for such Product in such indication in such jurisdiction, as notified by Pint to Puma. If Pint requires Puma to supply any Product for sale in any indication in any regulatory jurisdiction in the Territory prior to Marketing Authorization of such

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Product for sale in such indication in such jurisdiction, the Specification for such Product shall be those specifications for the Product specified by Pint to Puma based on the specifications Pint anticipates being approved by the Regulatory Authority for such indication in such jurisdiction or in the case of any Product supplied for Named Patient Sales, the specification for the Product as approved by the FDA in the FDA's authorization for the sale of such Product in such indication.

- 2.59 “ **Supply Agreement** ” means the agreement, contemplated by the Parties as of the date of this Agreement, between Pint and Puma, pursuant to which Puma shall supply the Product to Pint for purposes of Pint performing its responsibilities under this Agreement, as the same shall be executed and may be amended from time-to-time during the Term of this Agreement.
- 2.60 “ **Technology Transfer Plan**” is defined in **Section 3.4.1** .
- 2.61 “ **Term** ” means the term of this Agreement, as defined in **Section 11** .
- 2.62 “ **Territory** ” means Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama, Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Suriname, Uruguay, and Venezuela, French Guiana, the Falkland Islands, and Mexico.
- 2.63 “ **Third Party** ” means any Person other than a Party or an Affiliate of a Party.
- 2.64 “ **Trademarks** ” has the meaning as set forth in Section 3.2.1.
- 2.65 “ **Use** ” means to Develop, Commercialize, use, sell, have sold, offer for sale, have offered for sale, import, and export.
- 2.66 “ **Valid Claim** ” means either: (a) a claim of an issued and unexpired patent included within the Puma Patent Rights, 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 (b) a claim of a pending patent application included within the Puma Patent Rights, which claim was filed in good faith, has not been pending for more than [***] from its priority date, and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

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3 License Grant and Technology Transfer ; Pint's Diligence Obligation ; Exclusivity

- 3.1 License Grant. Subject to the terms and conditions of this Agreement, Puma hereby grants to Pint an exclusive, sublicensable (subject to Section 3.3), royalty-bearing license, under Puma's interest in the Puma IP, (i) to Use the Product in the Territory and (ii) to Manufacture or have Manufactured Product anywhere in the world, solely for Use in the Territory, such license to Manufacture only to be exercisable when and as provided in the Supply Agreement.
- 3.1.1 For clarity, Puma IP includes all intellectual property rights licensed to Puma under the Pfizer License Agreement, including any rights licensed to Puma through the Pfizer License Agreement as a result of the sub-license provided for therein to Puma of Pfizer's rights under the GHC License Agreement, subject to Section 3.1.2.
- 3.1.2 Pint acknowledges that the rights granted by Puma to Pint under any Puma IP that is Controlled by Puma pursuant to the Pfizer License Agreement are, in addition to being subject to the terms and conditions of this Agreement, subject to the terms and conditions the Redacted Pfizer License Agreement regarding the rights granted to Puma thereunder. For the avoidance of doubt, Puma shall be solely responsible for any amounts payable to Pfizer or any other obligations to Pfizer under the Pfizer License Agreement and Pint shall have no obligation under this Agreement to make any payment to Pfizer under the Pfizer License Agreement. Notwithstanding Article 8, pursuant to the Pfizer License Agreement, Pint acknowledges that Puma will furnish to Pfizer a true and complete copy of this Agreement and any current and future amendments thereto, which Agreement may be redacted to omit information not directly relevant to the performance of Puma's obligations under the Pfizer License Agreement, within thirty (30) days after the Effective Date of this Agreement or any amendments hereto have been executed. To the extent reasonably requested by Puma from time-to-time, Pint will take reasonable steps to support Puma's compliance with obligations under the Pfizer License Agreement that have been disclosed to Puma prior

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to execution of this Agreement and provided that Pint shall not be required to incur any material internal or out of pocket expenses to do so.

3.1.3 Direct License. At Pint's request at any time during the Term Puma shall exercise Puma's rights under the Pfizer License Agreement (or any other license agreement with a Third Party licensor providing Puma with Control over any material Puma Patent Right or Puma Know-How), if such rights exist under such agreements, to request that Pfizer (or such other licensor) grant to Pint a direct license from Pfizer (or such other licensor) that would become effective on, or survive, termination of such agreement. Pint acknowledges and agrees that Pfizer shall have no obligation to enter into any such direct license and that any other such licensor may have no obligation to consider such request or to enter into such a direct license.

3.2 Trademark License. Subject to the terms and conditions of this Agreement, Puma hereby grants to Pint an exclusive, sublicensable (subject to **Section 3.3**) license under Puma's interest in any and all Product Trademarks (as defined below) Controlled by Puma to use such Product Trademarks for the purpose of Manufacturing, marketing, distributing, selling, or otherwise Developing and Commercializing, such Product in the Territory during the Term pursuant to the terms and conditions of this Agreement.

3.2.1 As used herein, "**Trademark**" means any registered or unregistered trademark, service mark, trade dress, trade name, logo, insignia, domain name, symbol, design, or combinations thereof.

3.2.2 A **Product Trademark** is any Trademark specifically identifying any Product, as used by Puma or any Affiliate of Puma or any of Puma's licensees or sublicensees outside of the Territory.

For the sake of clarity, Product Trademarks do not include any Trademark that is also used generally by Puma, its Affiliate or its licensee or sublicensee, as the case may be, rather than specifically with the Product.

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- 3.3 Sublicense Rights. Pint may sublicense the rights granted to it by Puma under this Agreement to any of its Affiliates (with prompt written notice to Puma but without any requirement for Puma's consent) or to any Third Party solely with the prior written consent of Puma, which consent shall not be unreasonably withheld; 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, Pint shall provide prompt written notice to Puma 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 Puma, such approval not to be unreasonably withheld. Any such permitted sublicensee shall have the necessary financial, regulatory and technical capacity to carry out the portion of Pint's obligations under this Agreement sublicensed to such party. Any and all sublicenses shall be subject to the following requirements:
- 3.3.1 All sublicenses shall be subject to and consistent with the terms and conditions of this Agreement.
 - 3.3.2 In no event shall any sublicense relieve Pint of any of its obligations under this Agreement.
 - 3.3.3 Pint shall furnish to Puma a true and complete copy of each sublicense agreement and each amendment thereto, which sublicense agreement may be redacted to omit information not directly relevant to the performance of Pint's obligations under this Agreement, within [***] after the sublicense or amendment has been executed.
- 3.4 Technology Transfer. Puma will provide to Pint such technology transfer as Pint may reasonably request, from time to time, to exercise the license rights granted to Pint under the Agreement.
- 3.4.1 The initial technology transfer will be made pursuant to the **Technology Transfer Plan** attached as **Exhibit 3.4.1**, at [***] expense except as otherwise provided in such Plan.

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- 3.4.2 Pint shall reimburse Puma for any costs, including both any out-of-pocket costs and Puma's internal costs, reasonably incurred by Puma in connection with any further technology transfer.
 - 3.4.3 Notwithstanding anything to the contrary in this Section 3.4, Puma shall not be obligated to provide Pint such technology transfer relating to the Manufacture of the Product until such time as Pint may exercise its right to Manufacture the Product, as provided in the Supply Agreement.
- 3.5 Pint's Diligence Obligation . Pint itself, or through its Affiliates or sublicensees, shall use Commercially Reasonable Efforts (a) to seek Marketing Authorization for Nerlynx in each Major Market Country in the Territory in the Initial Indication and (b) to seek Marketing Authorization for any other Product for which Puma obtains Marketing Authorization from the FDA or the EMA in each Major Market Country in the Territory in each indication for which such Product was approved by the FDA or the EMA. When Pint obtains Marketing Authorization for any Product in any indication in any country in the Territory (whether or not such country is a Major Market Country), Pint itself, or through its Affiliates or sublicensees, shall use Commercially Reasonable Efforts to Commercialize such Product in such indication in such country.
- 3.5.1 Pint will have no obligation to seek Marketing Authorization for any Product in any indication in any jurisdiction unless and until Puma has achieved FDA Approval or EMA Approval for such Product in such indication.
 - 3.5.2 The Parties acknowledge that under appropriate circumstances it may fall within Commercially Reasonable Efforts not to seek or not to continue to seek Marketing Authorization for a specific Product in a specific indication in a specific jurisdiction or not to Commercialize or continue to Commercialize a specific Product in a specific indication in a specific jurisdiction.
 - 3.5.3 Effect of Sublicensing on Diligence Obligations . Sublicensing will not relieve Pint of its diligence obligations. However, activity by any

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sublicensee(s) under any sublicense will count toward satisfaction of Pint's diligence obligations.

3.6 Exclusivity and Related Restrictions.

- 3.6.1 Pint to Obtain Supply of Products Exclusively from Puma. Except as provided in the Supply Agreement, Pint and Pint's Affiliates shall not Manufacture or have Manufactured, or license or sublicense any Third Party to Manufacture or have Manufactured, any Product for Use in the Territory but shall rather have the obligation to obtain supplies of such Product exclusively from Puma under the provisions of this Agreement.
- 3.6.2 Pint to Sell Products Exclusively for Use in the Territory. Pint and Pint's Affiliates shall use Commercially Reasonable Efforts to require, and to have any licensee or sublicensee require, that any Third Party to whom any of them sells Product in the Territory not sell or distribute such Product for Use outside of the Territory and, at the request of Puma, cease to sell such Product to any such Third Party if such Third Party continues to make material sales of such Product for Use outside of the Territory.
- 3.6.3 Puma and Puma's Affiliates and Sublicensees Not to Sell Into Territory. During the Term, Puma and Puma's Affiliates:
 - 3.6.3.1 shall not Develop or Commercialize, or license or sublicense any Third Party to Develop or Commercialize any Product in the Territory except through Pint pursuant to this Agreement;
 - 3.6.3.2 shall not Manufacture or supply any Product to any Third Party that Puma or its Affiliate or sublicensee knows will use supplied Product for Development or Commercialization in the Territory; and
 - 3.6.3.3 shall not grant rights to, and shall require any licensee or sublicensee not to grant rights to, any Third Party to whom

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any of them sells Product outside of the Territory, to sell or distribute such Product for Use in the Territory.

3.6.4 Exclusivity.

3.6.4.1 Each Party. During the Term, Puma, Puma's Affiliates, Pint, and Pint's Affiliates shall each not Develop or Commercialize itself in the Territory, or license any Third Party to Develop or Commercialize in the Territory, any product that [***], other than a Product for Use in the Territory in the Initial Indication or any other FDA Approved additional indication, or supply any Third Party with any such product for such Use in the Territory.

3.7 No Implied License. No rights, other than those expressly set forth in this Agreement, are granted to either Party under this Agreement, and no additional rights will be deemed granted to either Party by implication, estoppel or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party or its Affiliates to the other under this Agreement are reserved.

4 **Regulatory Approvals**

4.1 Regulatory Filings and Approvals. Any and all applications for Regulatory Approval for or related to any Product in the Territory will be filed in Pint's name. Pint will be responsible for obtaining and maintaining any Marketing Authorization for Product in the Territory.

4.2 Right of Cross Reference. Puma hereby grants to Pint, its Affiliates and sublicensees the right to cross reference, in connection with any Regulatory Filing regarding Product in the Territory during the Term, any Regulatory Filing or Regulatory Approval regarding Product outside the Territory. Pint hereby grants Puma, its Affiliates and sublicensees the right to cross reference any Regulatory Filing or Regulatory Approval filed by Pint regarding Product to Develop and Commercialize Products outside the Territory and to Manufacture Products. The foregoing rights include without limitation the right for each Party and, to the extent permitted under this Agreement, its Affiliates and sublicensees, to access and make copies of

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and reproduce such documentation and information for the purposes set forth in this Section 4.2. Upon termination of this Agreement by Puma for cause pursuant to Section 11.3 (cause) or 11.4 (bankruptcy) or by Pint pursuant to Section 11.2 (at will), Puma's rights under this Section 4.2 shall apply on a worldwide basis.

4.3 Development; Regulatory Approval Plan.

- 4.3.1 Subject to the terms and conditions of this Agreement, Pint will have sole authority to, at its own expense, Develop Product for the purpose of obtaining Regulatory Approval in the Initial Indication and in the Territory subject to (a) the prior written consent of Puma to conduct such Development, and (b) Puma's written approval of all protocols and study designs for any clinical studies to be conducted by or on behalf of Pint for the Product in the Initial Indication in the Territory. Pint will be responsible for the day-to-day implementation of any Development activities for which it (or any of its Affiliates) so obtains Puma's prior written consent, and will keep Puma reasonably informed as to the progress of such activities.
- 4.3.2 The Parties have agreed on the Regulatory Approval Plan attached hereto as **Exhibit 4.3** and incorporated herein (the "**Regulatory Approval Plan**"). Pint may revise and update the Regulatory Approval Plan from time to time, provided that any change to the Regulatory Approval Plan which affects Puma's obligations under the Regulatory Approval Plan shall be subject to Puma's written consent, not to be unreasonably withheld or delayed.
- 4.3.3 The Regulatory Plan provides, among other things, for the delivery by Puma to Pint of the **Required Documents** (as defined therein) by the Required Documents Deadline.
- 4.3.4 Pint acknowledges and agrees that, as of the Effective Date, Puma has not Developed [***] or obtained Regulatory Approval for [***]. Nothing in this Agreement shall be construed to impose on Puma an obligation to conduct such Development of or obtain such Regulatory Approval for [***]. Notwithstanding anything to the

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contrary in this Agreement, Pint shall not Develop or Commercialize [***] without the written consent of Puma, which consent Puma may withhold in its sole discretion.

- 4.4 Filings and Communications with Regulatory Authorities. Except as otherwise provided in this Agreement (including the Regulatory Approval Plan), Pint will be responsible for all Regulatory Filings made to obtain or maintain any Regulatory Approval for Product in the Territory and for all other written or oral communications made in connection with obtaining or maintaining any such Regulatory Approval.
- 4.5 Cooperation by Puma. Puma will reasonably cooperate with Pint in preparing any such Regulatory Filing and, upon Pint's reasonable request, provide Pint with any information in Puma's possession or control which Pint reasonably deems to be relevant to any such filing. More specifically, Puma will take the specific actions provided for Puma to take in the Regulatory Approval Plan, including [***].
- 4.6 Pint to Keep Puma Informed. Pint will promptly keep Puma informed of any material communication or correspondence to or from any Regulatory Authority in the Territory regarding any Product and consider in good faith any advice on such communication Puma may provide. Until such time as Pint obtains Regulatory Approval for a Product in the Territory, to the extent legally permissible and practicable, Pint shall provide Puma with prior written notice of all material meetings with Regulatory Authorities in the Territory (including advisory committee meetings and any other meeting of experts convened by a Regulatory Authority) regarding the Product, such notice to be provided within [***] after Pint receives notice of the scheduling of such meeting. Puma shall have the right to request to be present at (but not to participate in, unless requested by Pint or the Regulatory Authority) all such meetings with such Regulatory Authorities to the extent permitted under Applicable Laws, at Puma's sole cost and expense, and Pint shall consider any such request in good faith.
- 4.7 Data Sharing. The Parties will create a shared data base (the "**Data Base**") containing information that may be used by either Party in regard to any Regulatory Filing or Regulatory Approval or for Development or

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Commercialization of Products, according the **Data Base Plan** attached as **Exhibit 4.7** .

- 4.8 Pharmacovigilance and Adverse Event Reporting. The Parties shall execute, within [***], a separate pharmacovigilance agreement (the “ **Pharmacovigilance Agreement** ”) to specify details of the Parties’ obligations with respect to reporting any adverse events associated with any Product, exchanging adverse event and other safety information relating to the Products, and any other pharmacovigilance obligations.
- 4.9 Inspections. Puma will cooperate in good faith with respect to the conduct of any inspection by any Regulatory Authority in the Territory of any site or facility of Puma or any Third Party contract manufacturer supplying Compound or Product to Puma, will allow Pint to attend the summary, or wrap up, meeting with such Regulatory Authority at the conclusion of any such site inspection and will keep Pint informed as to any material regulatory actions or communications resulting from such inspection that are related to Product.
- 4.10 Withdrawals and Recalls .
- 4.10.1 In the event that any Regulatory Authority in the Territory threatens or initiates any action to remove a Product from the market (in whole or in part), the Party receiving notice thereof shall notify the other Party of such communication promptly, but in no event later than [***], after receipt thereof.
- 4.10.2 If Pint, Puma or any Regulatory Authority in the Territory determines that a Product recall or withdrawal in the Territory is necessary, then Pint will take all actions appropriate, following standard operating procedures, in order to recall or withdraw the Product as promptly as possible after notice to do so by Puma or the Regulatory Authority or as Pint itself may determine.
- 4.10.3 To the extent that any recall or withdrawal is due to the negligence or breach of this Agreement by Puma or the failure to meet Specifications of Product that is Manufactured by Puma prior to delivery to Pint as provided in the Supply Agreement, [***].

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5 Product Manufacture and Supply

- 5.1 Puma shall have the sole right and responsibility to Manufacture or have Manufactured and supply to Pint the Product for Development, Commercialization and Use in the Territory.
- 5.2 The Parties shall execute a Supply Agreement within [***] in relation to the Product. The Supply Agreement will contain terms consistent with those terms included in **Exhibit 5.2** and other commercially reasonable terms mutually agreed to by the Parties.
- 5.3 Quality Agreement. The Parties shall enter into a Quality Agreement within [***].

6 Upfront, Milestone and Royalty Payments

6.1 **Upfront Payment.** Within [***], Pint shall pay to Puma a non-refundable, non-creditable payment in the amount of Ten Million Dollars (\$10,000,000) (the “ **Upfront Payment** ”).

6.2 Development Milestone Payments

6.2.1 In partial consideration of the licenses and rights granted to Pint, within [***] after achievement of each Milestone set forth below, Pint shall pay to Puma the corresponding non-creditable and non-refundable development milestone payment:

Milestone	Payment
[***]	[\$***]
[***]	[\$***]
[***]	[\$***]
Total Development Milestone Payments	\$9,500,000

Within [***] after a Party becomes aware that a Milestone under this Section 6.2.1 was achieved, it will notify the other Party thereof in writing.

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6.3 Commercial Milestone Payments

6.3.1 In partial consideration of the licenses and rights granted to Pint, within [***] after achievement of each Milestone set forth below, Pint shall pay to Puma the corresponding non-creditable and non-refundable commercial milestone payment:

Annual Net Sales of a Product in the Territory in any Calendar Year equal to or greater than:	Payment
\$[***]	\$[***]
\$[***]	\$[***]
\$[***]	\$[***]
Total commercial Milestone Payments	\$15.0

Each commercial Milestone payment is payable one time only; [***].

Net Sales of Product in the Territory by any sublicensee(s) or Affiliate(s) of Pint will count toward Net Sales of Product for the purpose of determining achievement of any commercial Milestone in this Section 6.3.1.

Within [***] after a Party becomes aware that a Milestone event under this Section 6.3.1 was achieved, it will notify the other Party thereof in writing.

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6.4 **Royalty Payments**

6.4.1 **Royalty Rates** . In further consideration of the licenses and rights granted to Pint hereunder, on a country-by-country and Product-by-Product basis, Pint shall pay to Puma a royalty on Net Sales of Products (including those Products supplied for Named Patient Sales) in the Territory during the Royalty Term at the rates specified below (collectively, “ **Royalties** ”):

[***]	Royalty Rate
[***]	[***]%
[***]	[***]%

6.4.2 Pint shall pay to Puma the applicable Royalties within [***] following the end of each Calendar Quarter in which there are any Net Sales on which Royalties are payable.

6.4.3 **Reports to be Made with Payment.** All Royalties payments shall be accompanied by a report that includes reasonably detailed information regarding a total monthly sales calculation, on a country-by-country and Product-by-Product basis, of Net Sales of each Product (including gross sales and all Deductions) and all Royalties payable to Puma for the applicable Calendar Quarter (including any foreign exchange rates employed and conversion calculations).

6.4.4 **Third Party Royalties** . The Royalties payable with respect to Net Sales of any Product in any country will be reduced by [***] by Pint to any Third Party with respect to such Net Sales of such Product in order to obtain rights to any Patents that, in the absence of a license under such Patents, Pint could not Use the Product without infringing such Patents; provided that in no event shall such reduction reduce the Royalties payable to Puma to lower than [***] of the royalty rate that would otherwise have been payable to Puma.

6.4.5 [***] and [***] during a Calendar Year in such country or regulatory jurisdiction are [***].

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6.4.6 **Payment Method.**

6.4.6.1 **Currency Conversion** . With respect to Net Sales invoiced in Dollars, the Net Sales and the amounts due for Royalties hereunder will be expressed in Dollars. With respect to Net Sales invoiced in a currency other than Dollars, such Net Sales will be converted to Dollars using the average of the applicable daily foreign exchange rates published in the Wall Street Journal (or any other qualified source that is acceptable to both Parties) for the last day of each month of the Calendar Quarter in which such Net Sales occurred, and the amounts due for Royalties hereunder will be expressed in Dollars. For purposes of calculating the Net Sales thresholds set forth in Section 6.3, the aggregate Net Sales with respect to each Calendar Quarter within a Calendar Year will be calculated based on the currency exchange rates for the Calendar Quarter in which such Net Sales occurred, in a manner consistent with the exchange rate procedures set forth in the immediately preceding sentence.

6.4.6.2 **Payment by Wire Transfer.** All payments from Pint to Puma shall be made by wire transfer in Dollars to the credit of such bank account as may be designated by Puma in writing to Pint. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

6.4.7 **Taxes.**

6.4.7.1 **VAT.** It is understood and agreed between the Parties that any amounts payable by Pint to Puma hereunder are exclusive of any and all applicable sales, use, VAT, GST, excise, property, and other taxes, levies, duties or fees (collectively, "Taxes"), which shall be added thereon as applicable.

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- 6.4.7.2 **Withholding Taxes.** If Pint is required to make a payment to Puma subject to a deduction of tax or withholding tax, the sum payable by Pint (in respect of which such deduction or withholding is required to be made) shall be made to Puma after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with Applicable Law, provided, however, that if such withholding or deduction obligation arises solely as a result of Pint changing its domicile or place of incorporation (a "Pint Withholding Tax Action"), then [the sum payable by Pint (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Puma receives a sum equal to the sum which it would have received had no such Pint Withholding Tax Action occurred. Any amounts deducted, withheld and remitted in accordance with the provisions of this Section 6.4.7.2 shall be treated as having been paid by Pint to Puma for all purposes of this Agreement.
- 6.4.7.3 **Tax Cooperation.** To the extent Pint is required to deduct and withhold taxes on any payments to Puma, Pint shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and, upon Puma's request, shall promptly transmit to Puma an official tax certificate or other evidence of such withholding sufficient to enable Puma to claim such payments of taxes. Puma shall provide to Pint any tax forms that may be reasonably necessary in order for Pint not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.
- 6.4.7.4 **Tax Forms.** The Parties agree to cooperate and produce on a timely basis any tax forms or reports, reasonably

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requested by the other Party in connection with any payment made by Pint to Puma under this Agreement.

6.4.8 **Records**

6.4.8.1 **Relevant Records.** Pint shall keep, and shall cause its Affiliates and sublicensee to keep accurate financial books and records pertaining to Pint's and its Affiliates' and sublicensees' sale of Products, including any and all calculations of payments due to Puma hereunder.

6.4.8.1.1 Pint, its Affiliates and sublicensees shall maintain the Relevant Records for the longer of: (a) the period of time required by Applicable Law, or (b) [***] following expiration or termination of this Agreement.

6.4.8.1.2 Pint shall require its sublicensees to provide to Pint (so that Puma may provide the same to Pfizer) copies of all Relevant Records relating to such sublicensees' sale of Products as necessary to allow Puma or, if applicable, Pfizer (under the Pfizer License Agreement) to review such Relevant Records when conducting an audit of Pint or Puma, as applicable, pursuant to Section 6.4.9. Notwithstanding Article 8, pursuant to the Pfizer License Agreement, Pfizer will be allowed to review such Relevant Records.

6.4.9 **Audit Rights**

6.4.9.1 **Audit Request** . Puma shall have the right during the term and for [***] thereafter to engage, at its own expense, an independent auditor reasonably acceptable to Pint to examine the Relevant Records in Pint's or its Affiliates' possession from time-to-time, but no more frequently than [***], as may be necessary to verify compliance with the terms of this Agreement. Such audit shall be requested in writing at least [***] in advance, and shall be conducted

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during Pint's (or its Affiliate's, as applicable) normal business hours and otherwise in manner that minimizes any interference to Pint's (or its Affiliate's, as applicable) business operations.

6.4.9.2 **Audit Fees and Expenses** . Puma shall bear any and all fees and expenses it may incur in connection with any such audit of the Relevant Records; provided, however, in the event an audit reveals an underpayment by Pint of more than [***] as to the period subject to the audit, Pint shall reimburse Puma for any [***] costs and expenses of the audit within [***] after receiving invoices thereof.

6.4.9.3 **Payment of Deficiency** . If any audit establishes that Pint underpaid any amounts due to Puma under this Agreement, then Pint shall pay Puma any such deficiency within [***] after receipt of written notice thereof. For the avoidance of doubt, such payment will be considered a late payment, subject to Section 6.5. If any audit establishes that Pint overpaid any amounts due to Puma under this Agreement, then Pint shall be entitled to take a credit against future amounts becoming due to Puma equal to the overpaid amount.

6.5 **Late Payments.** Any late payments shall bear interest, to the extent permitted by law, at [***] above the Prime Rate of interest as reported in the Wall Street Journal on the date payment is due.

7 Intellectual Property Rights.

7.1 Ownership

7.1.1 **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 or independent of this Agreement.

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7.1.2 Ownership of Inventions and Intellectual Property Rights .

- 7.1.2.1 “ **Inventions** ” means any and all inventions (whether or not patentable), that are conceived during the Term and in the course of activities conducted pursuant to this Agreement by one or more employees, Affiliates, sublicensees or independent contractors of Puma and/or Pint.
- 7.1.2.2 Inventorship of Inventions shall be determined in accordance with the rules and regulations of the U.S. Patent and Trademark Office.
- 7.1.2.3 Except as otherwise expressly set forth below, all Inventions made solely by employees, agents and independent contractors of Puma or its Affiliates and all Intellectual Property Rights therein, shall be owned, as between the Parties, solely by Puma (“ **Puma Inventions** ”).
- 7.1.2.4 Except as otherwise expressly set forth below, all Inventions made solely by employees, agents and independent contractors of Pint or its Affiliates or sublicensees, and all Intellectual Property Rights therein, shall be owned, as between the Parties, solely by Pint (“ **Pint Inventions** ”).
- 7.1.2.5 Except as otherwise expressly set forth below, all Inventions made jointly by employees, agents and independent contractors of each Party or its Affiliates or sublicensees (as applicable), 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** ”), and all Intellectual Property Rights in such Joint Inventions.
- 7.1.2.6 Notwithstanding anything to the contrary in this Section 7.1.2, Puma shall solely own all Inventions that cover or are directly related to the composition, Use, administration, or Manufacture of the Compound or Product regardless of the inventorship of such Invention, and all Intellectual Property Rights therein. Such Inventions shall be included in Puma

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Inventions. Pint shall, and shall cause its sublicensees and Affiliates, and all independent contractors, employees, and agents, to cooperate with Puma and take all reasonable actions and execute such agreements, declarations, assignments, legal instruments and documents as may be reasonably required to perfect Puma's right, title and interest in and to all Puma Inventions and Intellectual Property Rights therein.

7.1.2.7 All Patents claiming patentable, jointly owned Joint Inventions (excluding for clarity those inventions assigned to Puma pursuant to Section 7.1.2.6) 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: (a) 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, (b) execute documents as reasonably necessary to accomplish the foregoing, and (c) reasonably cooperate with the other Party to transfer to such other Party physical embodiments (or copies thereof) of any Joint Inventions, at such other Party's request and expense.

7.1.3 **Further Actions** . 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 Section 7.1.2. Each Party shall also include provisions in its

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relevant agreements with Third Parties that affect the intent of this Section 7.1.3.

7.2 **Patent Prosecution and Maintenance .**

7.2.1 The Parties' rights and obligations with respect to rights licensed to Puma pursuant to the Pfizer License Agreement that are sublicensed to Pint under this Agreement are expressly subject to the terms of the Redacted Pfizer License Agreement. The Parties agree to cooperate reasonably with Pfizer with respect to matters described under this Agreement to the extent required by the Redacted Pfizer License Agreement.

7.2.2 **Prosecution and Maintenance of Puma Patent Rights .**

7.2.2.1 Puma Patent Rights Outside the Territory . Puma shall have the sole right to file, prosecute and maintain the Puma Patent Rights outside the Territory, as Puma determines in its sole discretion, at Puma's sole expense. As used in this Agreement, prosecuting or to prosecute includes acting in connection with any re-examinations, oppositions and the like.

7.2.2.2 Puma Patent Rights Inside the Territory . Puma shall have the first right, but not the obligation, to prepare, file, prosecute and maintain any Puma Patent Right (including any Joint Patent Rights) in each country in the Territory, using patent counsel that is reasonably acceptable to Pint. Puma shall be responsible for [***] in connection with such filing, prosecution and maintenance; provided that if Puma intends to abandon, or not to file a patent application covering, any such Puma Patent Right that is not sublicensed to Pint under the Pfizer License Agreement in any country in the Territory (a "Non-Pfizer Puma Patent Right"), Puma shall provide Pint with a written notice of such intent at least [***] in advance of the relevant deadline. In such case: (a) Pint will provide a written response to Puma at [***] in advance of the relevant deadline if Pint wishes, or

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wishes to allow a Third Party to, file, prosecute and maintain (in its sole discretion) such Non-Pfizer Puma Patent Right in such country; (b) if Pint provides the affirmative notice under clause (a) above, Puma shall promptly provide all files related to filing, prosecuting and maintaining such Non-Pfizer Puma Patent Right to counsel designated by Pint; (c) upon completion of the transfer of such files under clause (b), Puma shall no longer be responsible for [***] 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 any Product, the term "Puma Patent Right" automatically shall be modified to exclude such Non-Pfizer Puma Patent Right in such country as of the date Pint provides such written request to Puma.

- 7.2.2.3 Information Sharing Regarding Puma's Prosecution and Maintenance of Puma Patent Rights in the Territory. The provisions of this Section 7.2.2.3 apply in regard to any Puma Patent Right that Puma is prosecuting or maintaining in any country in the Territory in accordance with the provisions of this Agreement. Puma shall provide Pint with copies of any material correspondence with the patent office in such country pertaining to Puma's prosecution or maintenance of such Puma Patent Right. Upon the written request of Pint, Puma shall provide Pint with draft copies of all filings and relevant documentation (to the extent not previously submitted to and reviewed by Pint) relating to such Puma Patent Right in such country at least [***] prior to the required submission date and shall not file or submit any such filing or documentation until Puma has received comments on such filing and documentation from Pint and considered any proposed comments to such filings and documentation in good faith, provided that Puma may file or submit such filings or documentation without considering Pint's comments if Puma has not received any comments from Pint at least [***] prior to the required submission date. Puma is not required to incorporate Pint's comments and,

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subject to the provisions of this Agreement, retains final decision-making authority with respect to prosecution and maintenance of such Puma Patent Right.

7.3 **Actual or Threatened Infringement, Disclosure or Misappropriation; Defense Actions; Orange Book Listings; And Patent Term Extension**

7.3.1 **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 Technology in the Territory of which it becomes aware (“ **Third Party Infringement** ”) and (b) any allegation by a Third Party that any Intellectual Property Right owned by it is infringed, misappropriated, or otherwise violated by the Development, Commercialization, and/or Use of any Product in the Territory which it becomes aware (“ **Defense Action** ”).

7.3.2 **Pint Control of Action Against Third Party Infringement** . Pint shall have the first right (but not the obligation), [***], to control enforcement of the Licensed Technology against any Third Party Infringement. Prior to commencing involvement in any such suit, action or proceeding, Pint shall consult with Puma and shall consider Puma'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 Pint or Puma. Pint shall give Puma timely notice of any proposed settlement of any such suit, action or proceeding that Pint controls and Pint shall not settle, stipulate to any facts or make any admission with respect to any Third Party Infringement without Puma's prior written consent (not to be unreasonably withheld) if such settlement, stipulation or admission would: (a) adversely affect the validity, enforceability or scope, or admit non-infringement, of any of the Licensed Technology; (b) give rise to liability of Puma or its Affiliates; (c) grant to a Third Party a license or covenant not to sue under, or with respect to, any Intellectual Property Rights Controlled by Puma or its Affiliates (other than as expressly provided for in this Agreement with respect to Pint's rights to sublicense the Licensed Technology); or (d) otherwise impair

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Puma's or any of its Affiliates' rights in any Licensed Technology or Puma's or any of its Affiliates' rights in this Agreement.

- 7.3.3 **Puma Control of Action Against Third Party Infringement** . Puma shall have the right (but not the obligation) to control enforcement of the Licensed Technology against any Third Party Infringement if Pint provides Puma with written notice that it is not exercising its right to control such enforcement, or if Pint fails to initiate or file the relevant response to (as applicable), a suit, action or proceeding with respect to such Third Party Infringement prior to or upon the earlier of: (a) expiration of the [***] period following first receipt by either Party of notice from the other Party of such Third Party Infringement or (b) [***] prior to the deadline for filing, or filing the applicable response to (as applicable), such suit, action or proceeding (including suits, actions or proceedings based on a Third Party's filing of a Paragraph IV Certification under 21 CFR §314.94(a)(12)(i)(A)(4)).
- 7.3.4 **Rights of Non-Controlling Party in Actions Against Third Party Infringement** . Notwithstanding anything to the contrary herein, the Party that is not controlling the suit, action or proceeding pertaining to enforcement of the Licensed Technology against Third Party Infringement as described in this Section 7 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 at its own expense (subject to Section 7.3.5) in any such suit, action or proceeding.
- 7.3.5 **Recoveries in Actions Against Third Party Infringement** . Any and all recoveries resulting from a suit, action or proceeding relating to a claim of Third Party Infringement shall first be applied to reimburse each Party's costs and expenses in connection with such suit, action or proceeding, with any remaining recoveries (the "**Remaining Recoveries**") allocated as follows: (a) if Puma is the

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enforcing Party, first to pay any amounts payable to Pfizer with respect to such Third Party Infringement, and then [***] to Puma and [***] to Pint or (b) if Pint is the enforcing Party, first to pay any amounts payable to Pfizer with respect to such Third Party Infringement, and then [***] to Pint and [***] to Puma.

- 7.3.6 **Defense Actions** . Upon Pint's request, Puma will reasonably cooperate with Pint, at Pint's expense, to the extent necessary to defend Pint or any Affiliate or sublicensee of Pint in a Defense Action in which the claim of infringement, misappropriation or other violation is directed at Pint's or its Affiliate's or sublicensee's Use of any Licensed Technology in accordance with the terms of this Agreement. Pint shall have all authority with respect to any Defense Action, 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 Pint shall keep Puma timely informed of the proceedings and filings, and provide Puma with copies of all communications pertaining to each Defense Action and Pint shall not settle, stipulate to any facts or make any admission with respect to any Defense Action without Puma's prior written consent if such settlement, stipulation or admission would: (a) adversely affect the validity, enforceability or scope, or admit non-infringement, of any of the Licensed Technology; (b) give rise to liability of Puma or its Affiliates; (c) grant to a Third Party a license or covenant not to sue under, or with respect to, any Intellectual Property Rights Controlled by Puma or its Affiliates, other than as expressly provided for in this Agreement with respect to Pint's rights to sublicense the Licensed Technology; or (d) otherwise impair Puma's or any of its Affiliates' rights in any Licensed Technology or Puma's or any of its Affiliates' rights in this Agreement.
- 7.3.7 **Rights of Pfizer** . All rights of Puma and Pint under this Section 7.3 are expressly subject to the terms of the Redacted Pfizer License Agreement with respect to rights sublicensed to Pint under the Pfizer License Agreement, with the terms and conditions of the Redacted Pfizer License Agreement being given effect prior to the

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terms and conditions of this Section 7.3. The Parties agree to cooperate reasonably with Pfizer with respect to matters described in this Section 7.3 to the extent required by the Redacted Pfizer License Agreement.

- 7.3.8 **Orange Book Listings** . To the extent required by or permitted by Applicable Law, Pint will have the right to decide whether to list with the applicable Regulatory Authorities in the Territory during the term of this Agreement any applicable Patents for a Compound or Product that has become the subject of an application for Regulatory Approval submitted to such Regulatory Authorities. Such listings may include without limitation any equivalents in the Territory of the so-called “Orange Book” listings required under the Hatch-Waxman Act and all so-called “Patent Register” listings as required in Canada. Puma will reasonably cooperate, at Pint’s request and expense, in preparing and/or filing such listings within the time frames available or required for such listings to be submitted in connection with such Compound and/or Product.
- 7.3.9 **Patent Term Extension** . Pint shall notify Puma of the date of Regulatory Approval of a Product by the relevant Regulatory Authority. Pint shall have the right to prepare and file, or to cause Puma to prepare and file (at Pint’s request and expense), a patent term extension or supplementary protection certificate application upon Regulatory Approval of such Product. At Pint’s request and expense, Puma shall provide to Pint for inclusion in such filing any information not in Pint’s possession relating to the regulatory timeline, diligence and regulatory period calculations required as part of the application to complete such application(s), and otherwise reasonably cooperate in any other matters related to preparation or filing of the application(s) therefor to make such filing within the applicable time period.
- 7.3.10 **Enforcement of Licensed Technology against Third Parties Manufacturing Products for Use in the Territory** . Each Party will promptly notify the other Party in writing of any Third Party who is Manufacturing Product(s) for Use in the Territory (a “ **Manufacturing Infringement** ”).

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- 7.3.10.1 Prior to the time Pint may exercise its right to Manufacture Products as provided in Section 3.1 and the Supply Agreement, Puma shall have the sole right to enforce the Licensed Technology against such Manufacturing Infringement, but shall use Commercially Reasonable Efforts to prevent such Third Party from continuing to Manufacture Product(s) for Use in the Territory.
- 7.3.10.2 During the time Pint has the right to Manufacture Products as provided in Section 3.1 and the Supply Agreement, any Manufacturing Infringement shall be treated as a Third Party Infringement and shall be subject to the provisions of this Section 7.3.

8 Confidentiality.

- 8.1 **Definition** . “ **Confidential Information** ” means 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 has supplied or otherwise made available to the other Party or its Affiliates, which are disclosed, whether orally, visually or in writing. All Puma Know-How shall be considered Puma’s Confidential Information.
- 8.2 **Obligations** . During the Term and for [***] thereafter, the receiving Party will (a) protect all Confidential Information of the disclosing Party against unauthorized disclosure to Third Parties, and (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). 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

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confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

8.3 **Exceptions** .

- 8.3.1 The obligations under this Section 8 shall not apply to any information to the extent the receiving Party can demonstrate by competent evidence that such information:
 - 8.3.1.1 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;
 - 8.3.1.2 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;
 - 8.3.1.3 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 to the disclosing Party; or
 - 8.3.1.4 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.
- 8.3.2 The restrictions set forth in this Section 8 shall not prohibit the receiving Party from disclosing or using (as specified below) any Confidential Information of the disclosing Party (a) that the receiving Party is required to disclose under Applicable 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, (b) that the receiving Party needs to disclose or use to file, prosecute or enforce any Patent Rights under this Agreement, or (c) that Pint, as receiving Party, needs to disclose or use for purposes of obtaining or maintaining any

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Regulatory Approval of any Product; provided that the receiving Party (i) as to subsection (a), provides the disclosing Party at least [***] prior written notice of such disclosure (and the right to review and comment on the proposed disclosure), to the extent practicable, (ii) as to subsection (a), affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure or, for submissions or disclosures required by the SEC or national securities exchange, itself uses reasonable efforts to secure confidential treatment for such required disclosure, (iii) as to subsection (a) discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose as advised by the receiving Party's legal counsel and (iv) as to subsections (a) and (c), 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.

8.3.3 In the event that Puma wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Milestone Payments and Royalties payable hereunder, Puma may disclose to a Third Party Confidential Information of Pint in connection with any such proposed assignment, pledge or transfer, provided that Puma shall hold such Third Parties to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement. To the extent that any such assignment would affect Pint's performance of its obligations hereunder, Puma shall notify Pint promptly if it enters into any agreement under which it has assigned its rights to receive some or all of the Milestone Payments and Royalties payable hereunder.

8.4 **Right to Injunctive Relief** . Each Party agrees that breaches of this Section 8 may cause irreparable harm to the disclosing Party and may entitle the disclosing Party, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action.

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- 8.5 **Ongoing Obligation for Confidentiality** . Upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy, delete, or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party, except for one copy which may be retained in its confidential files for archive purposes.

9 **Representations, Warranties and Covenants.**

- 9.1 **Representations and Warranties by Each Party** . Each Party represents and warrants to the other Party as of the Effective Date that:
- 9.1.1 it is duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;
 - 9.1.2 it has full power and authority to execute, deliver, and perform under this Agreement, and has taken all action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;
 - 9.1.3 this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;
 - 9.1.4 all consents, approvals and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and
 - 9.1.5 the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (a) conflict with or result in a breach of any provision of its organizational documents, (b) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (c) violate any Applicable Law.
- 9.2 **Representations and Warranties by Puma** . Puma represents and warrants to Pint that:

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- 9.2.1 to Puma's Knowledge, as of the Effective Date, the Use of Nerlynx within both the Territory and the United States will not infringe, misappropriate or otherwise violate the Intellectual Property Rights of a Third Party or breach any obligation of confidentiality or non-use owed by Puma to any Third Party;
- 9.2.2 to Puma's Knowledge, the Use of Nerlynx by Puma on or prior to the Effective Date did not, and the contemplated Use by Puma of Nerlynx in the United States in the Initial Indication will not, infringe, misappropriate or otherwise violate the Intellectual Property Rights of any Third Party;
- 9.2.3 to Puma's Knowledge, as of the Effective Date, (a) no claim has been made against Puma asserting the invalidity, misuse, unregistrability, unenforceability or non-infringement of any Puma Patent Right and (b) Puma is not aware of any claim made against it challenging Puma's Control of any Puma Patent Right or making any adverse claim of ownership of or other rights to any Puma Patent Right;
- 9.2.4 to Puma's Knowledge, as of the Effective Date, no Third Party is infringing, misappropriating or otherwise violating the Licensed Technology within the Territory or the United States, or has done so;
- 9.2.5 to Puma's Knowledge, as of the Effective Date, neither Puma nor its Affiliates or any Third Party manufacturer has received any notice on Form 483 or any other notice of material noncompliance with Applicable Laws relevant to the Manufacture of Nerlynx, and no such entity has entered into a consent decree or similar arrangement with respect to the Manufacture of Nerlynx;
- 9.2.6 to Puma's Knowledge, as of the Effective Date, no Third Party has any right, title or interest in or to any Puma Patent Right existing as of the Effective Date, other than Pfizer under the Pfizer License Agreement and MGH under the GHC License Agreement;
- 9.2.7 to Puma's Knowledge, the Puma Patent Rights and the Puma Know-how are not subject to any funding agreement with any

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government or government agency which is inconsistent with the rights granted to Pint under this Agreement;

- 9.2.8 Puma has not utilized, directly or, to Puma's Knowledge, through any contract manufacturer or other contractor, in connection with the Development or Commercialization of Nerlynx any Person or entities that have been or are debarred by FDA pursuant to the provisions of the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335)];
- 9.2.9 Puma has not received any notice of any violation of Applicable Law from the FDA or any other Regulatory Authority with respect to the Development or Use of Nerlynx that could reasonably be deemed to adversely affect the Development or Use of Nerlynx;
- 9.2.10 to Puma's Knowledge, all employees and officers of Puma or its Affiliates conducting activities with respect to any Compound or Product have executed or will execute agreements requiring assignment to Puma or its Affiliate, as applicable, of all right, title and interest in and to any inventions and discoveries invented or otherwise discovered or generated in connection with such activities, whether or not patentable, to Puma or its Affiliate, as applicable, as the sole owner thereof;
- 9.2.11 Puma is not a party to any litigation in which any Third Party has alleged that the Use of a Product within the Territory (a) to treat a human patient has resulted in an injury, harm or death of such patient or (b) infringes, misappropriates or otherwise violates the Intellectual Property Rights of such Third Party;
- 9.2.12 to Puma's Knowledge, to the extent material to the Development of Nerlynx, all activities conducted by or on behalf of Puma or its Affiliates prior to the Effective Date in the course of developing the Compounds or Nerlynx have been in material compliance with all Applicable Laws;
- 9.2.13 Puma has the right to grant the license and rights herein to Pint and it has not granted to any Third Party any license, right or interest in, to or under, or with respect to, the Puma Patent Rights or Puma

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Know-How that would interfere with the exercise of the licenses granted under this Agreement;

- 9.2.14 to Puma's Knowledge, as of the Effective Date, there are no claims, judgments or settlements against or owed by Puma and there are no pending or threatened claims or litigation, in each case relating to the Puma Patents or Puma Know-How;
- 9.2.15 **Schedule 9.2.15** contains a complete and correct list of all Puma Patents Rights existing as of the Effective Date in the United States and the Territory, indicating in the case of each Puma Patent Right the source of Puma's Control over such Puma Patent Right, which list shall be updated from time to time, [***], to identify any new such Puma Patents Rights or any change in the status of any such Puma Patent Right; and
- 9.2.16 Puma has provided to Pint a copy of the Redacted Pfizer License Agreement, including all amendments or modifications thereto; the Pfizer License Agreement remains in full force and effect; to its Knowledge, Puma is not in breach of any provision of the Pfizer License Agreement and has not received any notice or claim of any such breach; to Puma's Knowledge, as of the Effective Date, the GHC License remains in full force and effect and Puma continues to have rights under the GHC License as sublicensee under the Pfizer License Agreement, as and to the extent contemplated by the Pfizer License Agreement; Puma will promptly notify Pint of any breach by Puma or claim of such breach by Pfizer of Puma's obligations under the Pfizer License Agreement.

9.3 **Representations, Warranties and Covenants by Pint** . Pint represents and warrants to Puma that:

- 9.3.1 to the extent material to Use of the Compounds and the Products in the Territory, it shall, and shall ensure all Third Parties that it engages with respect to activities directed to the Compounds and the Products in the Territory shall, comply in all material respects with all Applicable Laws with respect to its activities and the performance of its obligations hereunder.

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- 9.3.2 Pint will not knowingly utilize, in conducting Development or Commercialization of Product, any Person or entities that at such time are debarred by FDA, or that, at such time, are, to Pint'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) , and Pint will check the FDA Debarment List (as made available on the FDA website) at least once a month during the Term .
- 9.3.3 all employees, officers, contractors, and consultants of Pint or its Affiliates working under this Agreement shall execute agreements requiring assignment to Pint 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 their association with Pint, whether or not patentable, if any, to Pint as the sole owner thereof prior to commencing any such work;
- 9.3.4 Pint currently has, and will maintain during the Term, directly or through Affiliates or Third Party subcontractors (a) sufficient qualified and trained personnel and resources, and (b) necessary financial and technical capacity to effectively fulfil its obligations related to the Products as contemplated in this Agreement;
- 9.3.5 as of the Effective Date, Pint and its Affiliates do not, and are not contractually obligated to, develop, promote, offer for sale, sell or distribute any pharmaceutical product for use in any Initial Indication or Second Indication in the Territory;
- 9.3.6 all due diligence materials that Pint has provided to Puma are and shall be accurate, truthful and complete and do not omit any material facts as requested by Puma;
- 9.3.7 without limiting the generality of Section 9.3.1 , Pint shall comply with Anti-Corruption Laws. Pint represents and warranties that Pint and its Affiliates and sublicensees and their respective employees and contractors (each a "Pint Party" and, collectively, the "Pint Parties") have not violated, and will not violate any such Anti-Corruption Law;

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- 9.3.8 neither the Pint Parties nor any Person or entity acting any Pint Party's behalf has offered, given, authorized, or promised, or will offer, give, authorize, or promise, anything of value, either directly or indirectly, to any Person, including to any Public Official or Entity, for the purpose of (a) improperly influencing any official act or decision; (b) inducing performance or non-performance of any act in violation of a lawful duty; or (c) securing an improper benefit or business advantage;
- 9.3.9 the Pint Parties have thoroughly investigated all allegations of violations of such Anti-Corruption Laws known to them, and all facts and circumstances known to the Pint Parties that reasonably could suggest violations of Anti-Corruption Laws, and these investigations have not confirmed any violations of such Anti-Corruption Laws, and no additional investigations of such Anti-Corruption Laws are ongoing. Further, no Pint Party is aware of any notice, request, citation, investigation, or prosecution by any Governmental Authority, with respect to any alleged or suspected violation of Anti-Corruption Laws;
- 9.3.10 the Pint Parties shall not cause any Puma Indemnitees to be in violation of (a) such Anti-Corruption Laws; (b) Export Control Laws; or (b) any other Applicable Laws applicable to either Party with respect to the matters provided for in this Agreement;
- 9.3.11 the Pint Parties shall fully cooperate with the Puma Indemnitees in ensuring compliance with the Anti-Corruption Laws, Export Control Laws and all other Applicable Laws applicable to either Party with respect to the matters provided for in this Agreement;
- 9.3.12 Pint shall immediately notify Puma if Pint has a reasonable basis to believe that there has been or will be a violation of (a) any Anti-Corruption Law or (b) other Applicable Law adopted by any country in the Territory in each case in connection with the performance of this Agreement or the sale of the Product in the Territory;

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- 9.3.13 to Pint's Knowledge, no officer, director, employee of a Pint Party or other contractors, or any immediate family relation of any such person (collectively, "Interested Persons"), is a Public Official or Entity or Governmental Authority. Pint shall notify Puma immediately if during the Term (a) any Interested Person becomes a Public Official or Entity or Governmental Authority or (b) any Public Official or Entity or Governmental Authority acquires a legal or beneficial interest in any Pint Party or other subcontractors;
- 9.3.14 Pint has in place and shall maintain an anti-corruption compliance program, including policies and procedures reasonably designed to ensure that it and its Affiliates and sublicensees comply with all Anti-Corruption Laws. As part of its anti-corruption compliance program, Pint shall ensure that its employees, and the employees of any other Pint Party, receive appropriate, risk-based anti-corruption compliance training; and
- 9.3.15 upon request, and at least [***], the Pint Parties shall provide Puma with certifications regarding compliance with Anti-Corruption Laws relating to this Agreement.

9.4 **No Other Warranties** . EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. ANY INFORMATION PROVIDED BY EITHER PARTY OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS, REGULATIONS OR APPLICABLE LAW OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

10 **Indemnification; Limitation of Liability; Insurance.**

- 10.1 **Indemnification by Pint** . Pint agrees to indemnify, hold harmless and defend Puma and its Affiliates, and their respective officers, directors,

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employees, contractors, agents and assigns (collectively, “ **Puma Indemnitees** ”), from and against any Claims to the extent arising or resulting from: (a) the Development, Commercialization and other Use of Products by Pint, its Affiliates, subcontractors or sublicensees (b) the gross negligence or wrongful intentional acts or omissions of Pint, its Affiliates, subcontractors or sublicensees, (c) breach by Pint of any representation, warranty, obligation or covenant as set forth in this Agreement, or (d) breach by Pint of the scope of the licenses set forth in Section 3.1 or 3.2. As used herein, “ **Claims** ” means collectively, any and all Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys’ fees).

- 10.2 **Indemnification by Puma** . Puma agrees to indemnify, hold harmless and defend Pint and its Affiliates and sublicensees, and their respective officers, directors, employees, contractors, agents and assigns (collectively, “ **Pint Indemnitees** ”), from and against any Claims to the extent arising or resulting from (a) the Development and other Use of Compounds and Products by Puma, its Affiliates, subcontractors or sublicensees, (b) the gross negligence or wrongful intentional acts or omissions of Puma, its Affiliates, or subcontractors or (c) breach by Puma of any representation, warranty, obligation or covenant as set forth in this Agreement, in each case except for those Claims for which Pint has an obligation to indemnify Puma Indemnitees pursuant to Section 10.1.
- 10.3 **Indemnification Procedure** . In connection with any Claim for which a Party (the “Indemnified Party”) seeks indemnification from the other Party (the “Indemnifying Party”) pursuant to this Agreement, the Indemnified Party shall: (a) give the Indemnifying Party prompt written notice of the Claim; provided, however, that failure to provide such notice shall not relieve the Indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnifying Party, at the Indemnifying Party’s expense, in connection with the defense and settlement of the Claim; and (c) permit the Indemnifying Party to control the defense and settlement of the Claim only if the Indemnifying Party confirms in writing that it is liable to indemnify the Puma Indemnitees or the Pint Indemnitees, as applicable, in connection with the relevant matter and provides reasonable substantiation that the

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Indemnifying Party has the financial resources to pay for the defense and settlement of the Claim (including any settlement thereof or judgment thereon); provided, however, that the Indemnifying Party may not settle the Claim without the Indemnified Party's prior written consent, which shall not be unreasonably withheld or delayed, in the event such settlement materially adversely impacts the Indemnified Party's rights or obligations. Further, the Indemnified Party shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

10.4 **LIMITATION OF LIABILITY**

10.4.1 **No Consequential Damages** . EXCEPT FOR A BREACH OF SECTION 3.1 OR SECTION 8 OR OBLIGATIONS ARISING UNDER SECTION 10, NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

11 **Term and Termination**

11.1 **Term** . The term (the "Term") of this Agreement shall commence as of the Effective Date and unless earlier terminated as expressly provided herein, shall expire upon the expiration of the last-to-expire Royalty Term.

11.2 **Termination by Pint** .

11.2.1 **Termination at Will** . Pint may terminate this Agreement in its entirety at will, in its sole discretion, at any time upon one (1) year's prior written notice to Puma.

11.2.2 **Termination for Safety Concerns** . Pint may terminate this Agreement in its entirety on not less than sixty (60) days prior written notice to Puma if Pint has evidence of safety issues on the basis of which a reasonable investigator would conclude that such

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issues will prevent the successful Development and Commercialization of Products hereunder. Pint shall provide such evidence to Puma together with such notice and shall discuss such evidence as reasonably requested by Puma.

- 11.3 **Termination by Either Party for Cause** . Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in the event the other Party breaches any of its material obligations hereunder and fails to cure such breach within thirty (30) days of receiving notice thereof; provided, however, if such breach is capable of being cured, but cannot be cured within such thirty (30) day period, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed sixty (60) days unless otherwise agreed in writing by the Parties. Any termination by a Party under this Section 11.3 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party.
- 11.3.1 For the avoidance of doubt, Pint's failure, or the failure of Pint's Affiliate and/or sublicensees, as applicable, to use Commercially Reasonable Efforts to Develop and Commercialize Products as provided in Section 3.5 shall constitute a breach of a material obligation by Pint under this Agreement.
- 11.3.2 Any uncured material breach by either Party of the Supply Agreement, as further defined therein, that entitles the other Party to terminate the Supply Agreement for cause shall be treated as a material breach by the breaching Party of a material obligation under this Agreement.

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11.3.3 In the event that Pint is entitled to terminate this Agreement due to Puma's breach of a material obligation under this Section 11.3, and Pint determines not to terminate this Agreement:

11.3.3.1 Pint may reduce the Royalties otherwise payable to Puma under the Agreement by [***] of the royalties otherwise payable to Puma until [***]; provided that [***].

11.4 **Termination by Either Party for a Bankruptcy Event** . Either Party shall have the right to terminate this Agreement by written notice to the other Party in the event of a Bankruptcy Event of the other Party. "Bankruptcy Event" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against such Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof or any other country or state thereof (the "Bankruptcy Code"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within ninety (90) days after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by such Party of any involuntary debts as they mature, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of Pint not involving the Bankruptcy Code, (d) appointment of a receiver for all or substantially all of such Party's assets, or (e) any corporate action taken by the board of directors of such Party in furtherance of any of the foregoing actions.

11.5 **No Partial Termination** . This Agreement may not be terminated by Pint under Section 11.2 or by either Party for cause under Section 11.3 or for a Bankruptcy Event under Section 11.4 on a Compound-by-Compound or country-by-country or other partial basis.

11.6 **Termination for Failure to Deliver Required Documents**. If the Required Documents are not delivered to Pint in all material respects within [***], Pint may terminate this Agreement by written notice to Puma, with such notice to be provided no later than [***], and such termination to be effective [***] after the other Party receives such notice. Such termination shall be treated as a termination by Pint for Cause under Section 11.3.

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11.7 Effect of Termination or Expiration .

- 11.7.1 Upon termination of this Agreement in its entirety pursuant to Sections 11.2-11.4 and 11.6, the Parties' rights and obligations under this Agreement will terminate and neither Party will have any further rights or obligations under this Agreement from and after the effective date of termination, except as set forth in this Section 11.7.
- 11.7.2 Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability which, on the effective date 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. Each Party will cause its Affiliates and sublicensees to comply with the obligations in this Section 11.7.
- 11.7.3 Within [***] after the effective date of termination of this Agreement in its entirety, each Party will, and will cause its Affiliates to (a) destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or Control, and provide written certification of such destruction, or (b) prepare such tangible items of the other Party's Confidential Information for shipment to such other Party, as such other Party may direct, at the first Party's expense; provided, however, that, in any event, (i) each Party may retain one (1) copy of the Confidential Information of the other Party to the extent necessary to perform its obligations that survive expiration or termination of this Agreement; and (ii) such first Party may retain one copy of such Confidential Information of the other Party for its legal archives.
- 11.7.4 Upon termination or expiration of this Agreement, Pint shall pay to Puma all amounts due to Puma as of the effective date of termination or expiration, within [***] following the effective date of termination or expiration.

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- 11.7.5 Upon termination of this Agreement for any reason, Pint (and its Affiliates and sublicensees) shall have the right to sell any remaining inventory of Products in the Territory following the termination of this Agreement so long as Pint has fully paid, and continues to fully pay when due, any and all Royalties and Milestone Payments owed to Puma.
- 11.7.6 Subject to Section 11.7.5, upon termination of this Agreement all licenses granted by Puma to Pint shall terminate.
- 11.7.7 Upon termination of this Agreement:
- 11.7.7.1 Pint hereby grants to Puma a non-exclusive, fully paid-up, royalty-free (except as provided in the last sentence of this Section 11.7.8.1), worldwide, transferable, perpetual and irrevocable license, with the right to sublicense through multiple tiers, under any Intellectual Property Rights Controlled by Pint claiming Inventions that are necessary or reasonably useful for the Development, Commercialization or other Use of Products as they exist at the time of such termination of this Agreement to Develop, Commercialize and otherwise Use the Products. If the applicable termination giving rise to Puma's rights under this Section 11.7.8.1 was for Puma's material breach of this Agreement pursuant to Section 11.3 or 11.6, the licenses granted to Puma under this Section 11.7.8.1 shall become effective as of the date of such termination as provided above, but Puma shall pay Pint [***], not to exceed [***].
- 11.7.7.2 To the extent permitted by applicable Regulatory Authorities and as promptly as practicable after requested by Puma, Pint, at Pint's sole cost and expense (unless the applicable termination was for Puma's material breach pursuant to Section 11.3 or 11.6, in which case such transfer shall be at Puma's sole cost and expense), shall: (a) transfer to Puma all Regulatory Filings and Regulatory Approvals held by Pint or its Affiliates or sublicensees with

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respect to Products in the Territory and will take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under such Regulatory Filings and Regulatory Approvals, including Marketing Authorizations, and (b) to the extent subsection (a) is not permitted by the applicable Regulatory Authority, grant and hereby does grant to Puma an exclusive and irrevocable right of access and right of reference to such Regulatory Approvals, including Marketing Authorizations, and Regulatory Filings filed by Pint or its Affiliates or sublicensees with respect to Products in the Territory and will reasonably cooperate to make the benefits of such Regulatory Approval and Regulatory Filings available to Puma or its designee(s).

- 11.7.7.3 Pint, if requested in writing by Puma, shall, at Pint's sole cost and expense (unless the applicable termination was for Puma's material breach pursuant to Section 11.3 or 11.6, in which case such provision shall be at Puma's sole cost and expense), provide any and all (a) material correspondence with the relevant patent offices pertaining to Pint's prosecution of the Patent Rights to the extent not previously provided to Puma during the course of the Agreement, and (b) a report detailing the status of all Patent Rights at the time of termination or expiration.
- 11.7.7.4 Pint hereby grants to Puma a non-exclusive, fully paid-up, royalty-free, worldwide, transferable, sublicensable, perpetual and irrevocable license under Pint's interest in any Product Trademark for use for the purpose of Manufacturing, marketing, distributing, selling, or otherwise Developing and Commercializing Products.
- 11.7.7.5 At Puma's option on a study-by-study basis for any study then on-going, and to the extent permitted under applicable agreements, Pint will take such actions as Puma may reasonably request, at Puma's expense, to allow Puma or its CRO to complete the applicable study and to assign all

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related Regulatory Filings and Regulatory Approvals and investigator and other agreements relating to such study to Puma.

11.7.7.6 Within [***] after the effective date of termination of this Agreement, at Puma's written request, Pint shall and shall cause its Affiliates to assign all of its right, title and interest in and to any Third Party agreements that solely relate to the Product and not to another product (“ **Third Party Agreement** ”) to Puma [***].

11.7.7.7 Promptly following the effective date of termination of this Agreement, Pint shall provide copies to Puma or its designee of any Know-How in Pint's possession or control that is (a) reasonably useful or necessary to make, use, sell, offer for sale, or import the Products and (b) developed by Pint in the course of performing its obligations and exercising its rights under this Agreement. Such Know-How shall include without limitation customer lists, but only to the extent such customer lists relate solely to the Product and not another product.

11.8 **Survival.** Any expiration or termination of this Agreement shall not preclude the terminating Party from exercising any other of those remedies to which it may be entitled under this Agreement or Applicable Law, or terminate any right to obtain performance of any obligation provided for in this Agreement that shall survive termination. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 2, Sections 3.1 and 3.2 (but only, in the case of Sections 3.1 and 3.2, to the extent required to allow Pint to exercise the rights granted to Pint to continue to sell remaining inventory under Section 11.7.5), Sections 6.4.6 through 6.4.9, Section 6.5, and Sections 7, 8, 9, 10, 11, 12, 14 and 15 shall survive expiration or termination of this Agreement.

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12 Publicity and Publications

12.1 Publicity .

12.1.1 Each Party agrees not to issue any press release or other public statement, whether written, electronic, oral or otherwise, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other Party, provided however, that (a) on or after the Effective Date, each Party may, at its option, issue a global press release (collectively, the "Global Press Releases"), and (b) neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Laws or the rules and regulations of the SEC or any national securities exchange so long as the disclosing Party provides the other Party at least [***] prior written notice (and the right to review and comment on the proposed disclosure), to the extent practicable, and only discloses information to the extent required by Applicable Law or the rules and regulations of the SEC or national securities exchange, as set forth in Section 8.3. The content of the Global Press Releases shall be reasonably agreed-upon by the Parties prior to the Effective Date.

12.2 **Publications** . The restrictions imposed by this Section shall apply only to publication of the results of any activities conducted under this Agreement and shall not apply to publication by Puma or Pint of any other results, including publication by Puma of any such other results related to Compounds or Products. Each Party acknowledges that the other Party's personnel may desire to publish in scientific journals or present at scientific conferences results of activities conducted hereunder. Both Parties understand that a reasonable commercial strategy may require delay of publication of information or filing of patent applications. Accordingly, from and after the Effective Date, no publication of such results will be submitted, and no such presentation shall be made without the prior written consent of the other Party. Any such publication or presentation shall be submitted in writing to the other Party for review by the other Party reasonably in advance of the proposed publication or presentation date. The reviewing Party will reasonably consider such publication or presentation request, but shall not

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be obligated to consent thereto, and such reviewing Party shall provide its consent to or denial of such request within [***] of its receipt of such proposed publication or presentation. The Parties will reasonably agree upon appropriate authorship of any such publication to which the other Party consents. The Parties acknowledge that Pfizer has certain rights with respect to publications relating to the Development of Products under the Pfizer License Agreement, and the Parties agree that such rights shall apply to any such publications under this Agreement.

13 Joint Steering Committee and Alliance Managers .

- 13.1 **Formation** . The Parties will establish a Joint Steering Committee (the “ **Joint Steering Committee** ” or “ **JSC** ”).
- 13.2 **Structure** . The JSC will be composed of a total of [***] representatives, [***] of which will be appointed by each of Puma and Pint, with the [***]. Each individual appointed by a Party as a representative to the JSC will be an employee of such Party, or an employee of such Party’s Affiliate. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party’s co-chairperson. The JSC will be co-chaired by one designated representative of each Party. The co-chairperson of the JSC will cast its Party’s vote on the JSC and such designee will have the authority to make decisions on behalf of such Party. Each co-chairperson will alternate being responsible for each meeting for (a) calling meetings, and (b) preparing and circulating an agenda in advance of each meeting; provided, however, that the applicable co-chairperson will include any agenda items proposed by either Party on such agenda. Each JSC representative will be subject to confidentiality obligations no less stringent than those in Article 8 .
- 13.3 **Time and Location of Meetings** . The JSC shall meet at such times and in such manner (either in person or remotely) as the JSC shall determine. The JSC will hold meetings [***] during the Term for so long as the JSC exists. Other representatives of the Parties, their Affiliates and Third Parties involved in the Development or Commercialization of Products may be invited by the members of the JSC to attend meetings as non-voting observers; provided, however, that such representatives are subject to confidentiality obligations no less stringent than those set forth in Article 8;

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and, provided further, that each representative appointed by a Party to take action at a meeting will have sufficient authority to execute such action on behalf of such Party. No action taken at a meeting will be effective unless at least one representative of each Party is present or participating. Neither Party will unreasonably withhold attendance of at least one (1) representative of such Party at any meeting of the JSC for which reasonable advance notice was provided.

13.4 **Minutes** . Each co-chairperson will alternate being responsible for drafting and issuing minutes of the meeting reflecting all material items discussed and any agreements of the JSC, which minutes shall be distributed to all JSC members for review and approval. Such minutes shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, or determinations arising out of the meeting. Minutes of each JSC meeting shall be distributed to all JSC members within [***] of such meeting and shall be finalized and approved within [***] after each such meeting. Approval of minutes may be indicated by email and by signature by one (1) JSC member from each Party; provided that if a Party's JSC members have not notified the JSC of such members' disapproval of such minutes prior to [***] after the meeting, such minutes shall be deemed approved by, and binding on, such Party's JSC members. Final minutes of each meeting shall be distributed to the members of the JSC by the chairperson.

13.5 **Scope of Authority; Responsibilities** .

13.5.1 The JSC shall perform the functions and assume the responsibilities and have such authority only as set forth in this Agreement. The JSC shall perform only an informal oversight and collaboration role, reviewing the activities performed by the Parties under the Agreement and facilitating the sharing of information and reporting of activities between the Parties.

13.5.2 For the avoidance of doubt, the JSC shall have no authority to: (a) amend any of the terms of this Agreement, including by means of JSC minutes or otherwise; (b) waive any rights that either Party may otherwise have pursuant to this Agreement or otherwise; (c) allocate the ownership of any intellectual property right; (d) interpret this Agreement, or (e) determine whether or not a Party has met its

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diligence or other obligations under the Agreement or whether or not a breach of this Agreement has occurred.

- 13.6 **Costs and Expenses of JSC** . Each Party shall be responsible for all travel costs, labor costs and out-of-pocket expenses incurred by its respective representatives in connection with attending the meetings and otherwise being part of the JSC.
- 13.7 **Term of the JSC and Sub-Committees** . The JSC shall, unless otherwise mutually agreed by the Parties, continue through the Term.
- 13.8 **Alliance Managers** .
- 13.8.1 **Appointment** . Each of the Parties shall appoint an Alliance Manager. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party.
- 13.8.2 **Responsibilities** . The Alliance Managers shall be appointed members of the JSC and shall attend all JSC meetings and support the other members of JSC in the discharge of their responsibilities. In addition to the Alliance Managers' duties as members of the JSC, each Alliance Manager: (a) will be the point of first referral for routine communications between the Parties; (b) will be a point of contact for coordinating activities between the Parties and attempting to resolve any conflicts; (c) will identify and bring disputes to the attention of the JSC in a timely manner; and (iii) will take responsibility for ensuring that activities, such as the conduct of required JSC and Sub-Committee meetings and production of meeting minutes, occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.
- 13.8.3 **Coordination re Promotion of the Product; Marketing and Promotional Materials**
- 13.8.3.1 Among other activities, the Alliance Managers will work to coordinate promotion of Nerlynx and other Products in the Territory with the promotion of Products outside the Territory.

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- 13.8.3.2 Working through their Alliance Managers, the Parties will use Commercially Reasonable Efforts to develop and share marketing and promotional materials and to generally share information regarding marketing and promotion of the Products.

14 Dispute Resolution

- 14.1 **Dispute Resolution; Escalation** . The Parties recognize that disputes as to certain matters arising out of or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedited manner by mutual cooperation. To accomplish this objective, any and all disputes between the Parties arising out of or in connection with this Agreement will first be referred to the JSC for resolution. Should the JSC not be able to reach agreement at a duly called meeting of the JSC within [***] after the date on which the matter is referred to the JSC, then either Party may refer such matter to the CEO of Pint and CEO of Puma (collectively, the “ **DR Executives** ”) for resolution and the DR Executives will attempt to resolve the matter in good faith. If the DR Executives fail to resolve such matter within [***] after the date on which the matter is referred to the DR Executives (unless a longer period is agreed to by the Parties in writing), then either Party may submit the dispute to the [***] for final resolution by binding arbitration in accordance with Section 14.2 .
- 14.2 **Arbitration** . Except as set forth in this Section 14.2 , each dispute, difference, controversy or claim arising in connection with or related or incidental to, or question occurring under, this Agreement or the subject matter hereof will be referred to and finally resolved by arbitration in accordance with the Rules of Arbitration (the “ **Rules** ”) of the [***], by an arbitral tribunal composed of three (3) arbitrators, all of whom will have previous judicial experience, with each Party appointing one (1) arbitrator and the third arbitrator to be selected by mutual agreement of the two (2) arbitrators appointed by the Parties. The foregoing arbitration proceedings may be commenced by either Party by notice to the other Party. Unless otherwise agreed by the Parties hereto, all such arbitration proceedings will be held in [***]; provided, however , that proceedings may be conducted by telephone conference call with the consent of the Parties and the

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arbitrator(s). All arbitration proceedings will be conducted in the English language. The arbitrator(s) will consider grants of equitable relief and orders for specific performance as co-equal remedies along with awards of monetary damages. The arbitrator(s) will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney's fees, will be [***]. The Parties hereby agree that the arbitrator(s) has authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. All rulings by the arbitrator(s) will be final. Notwithstanding any contrary provision of this Agreement, any Party may seek equitable measures of protection in the form of attachment of assets or injunctive relief (including, without limitation, specific performance and injunctive relief) in any matter relating to the proprietary rights and interests of either Party from any court of competent jurisdiction, pending a decision by the arbitral tribunal in accordance with this Section 14.2. The Parties hereby exclude any right of appeal to any court on the merits of such matter. The provisions of this Section 14.2 may be enforced and judgment on the award (including without limitation equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Except to the extent necessary to confirm an award or as may be required by Applicable Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. Nothing in this Section 14.2 will preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, scope, validity, enforceability or infringement of, Intellectual Property Rights shall not be subject to arbitration under this Agreement, and the Parties may pursue

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whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.

15 General Provisions

- 15.1 **Assignment** . Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) Puma may assign to a Third Party its rights to receive some or all of the Milestone Payments and Royalties payable hereunder, provided that doing so does not adversely affect in any material respect the payment or other obligations of Pint hereunder; (b) each Party may assign its rights and obligations under this Agreement to one or more of its Affiliates without the consent of the other Party, provided that such assignment does not increase materially the other Party's payment obligations (including without limitation such other Party's tax payment obligations); and (c) either Party may assign this Agreement to the successor entity in the event it undergoes a Change in Control. As used herein, "Change in Control" means the acquisition of a Party by a Third Party or the sale of all or substantially all of its business to which this Agreement relates. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee pursuant to clauses (b) and (c) above shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. Any attempted assignment in contravention of the foregoing shall be void.
- 15.2 **Severability** . Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such invalidity or unenforceability, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.
- 15.3 **Governing Law; Exclusive Jurisdiction** .
- 15.3.1 This Agreement shall be governed by and construed under the laws in effect in the State of New York, US, without giving effect to any

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conflicts of laws provision thereof or of any other jurisdiction that would produce a contrary result.

15.3.2 The courts of the State of New York, US, shall have exclusive jurisdiction over any action brought to enforce this Agreement, and each of the Parties hereto irrevocably: (a) submits to such exclusive jurisdiction for such purpose; (b) waives any objection which it may have at any time to the laying of venue of any proceedings brought in such courts; (c) waives any claim that such proceedings have been brought in an inconvenient forum, and (d) further waives the right to object with respect to such proceedings that any such court does not have jurisdiction over such Party. Notwithstanding the foregoing, application may be made to any court of competent jurisdiction with respect to the enforcement of any judgment or award, or the pursuit of injunctive or other equitable relief described in Article 14.

15.4 **Force Majeure** . Except with respect to delays or non-performance caused by the negligent or intentional act or omission of a Party, any delay or non-performance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or non-performance is caused by acts of God, natural disasters, acts of the government or civil or military authority, fire, floods, epidemics, quarantine, energy crises, war or riots or other similar cause outside of the reasonable control of such Party (each, a “ **Force Majeure Event** ”), provided that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for [***], then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

15.5 **Waivers and Amendments** . The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be

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amended or modified other than by a written document signed by authorized representatives of each Party.

- 15.6 **Relationship of the Parties** . Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Puma and Pint, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.
- 15.7 **Successors and Assigns** . This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.
- 15.8 **Notices** . All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt), (b) sent by fax (with written confirmation of receipt), provided that a copy is sent by an internationally recognized overnight delivery service (receipt requested), or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

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

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

Latham & Watkins
140 Scott Drive
Menlo Park CA 94025-1008
Fax: [***]
Attention: [***]

If to Pint:
Pint Pharma GmbH
Wipplingerstrasse 34 Top 112 – 119
Vienna- Austria
Attention: [***]
Email: [***]
Telephone: [***]
Fax: [***]

With copies to:
Legal Department
Pint Pharma GmbH
Wipplingerstrasse 34 Top 112 – 119
Vienna- Austria
Email: [***]
Telephone: [***]
Fax: [***]

Barker Davis
10 Greene Street
Providence, RI 02903
Telephone: [***]
Fax: [***]
Email: [***]
Attention: [***]

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- 15.9 **Further Assurances** . Pint and Puma hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.
- 15.10 **No Third Party Beneficiary Rights** . This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.
- 15.11 **Entire Agreement; Confidentiality Agreement** .
- 15.11.1 This Agreement, together with its Exhibits and Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including, without limitation, that certain Confidentiality Agreement by and between the Parties, dated as of January 24, 2017 (the “**CDA**”). The Parties acknowledge and agree that, as of the Effective Date, all Confidential Information (as defined in the CDA) disclosed by a Party pursuant to the CDA shall be considered such Party’s Confidential Information and subject to the terms set forth in this Agreement.
- 15.11.2 In the event of any conflict between a material provision of this Agreement and any Exhibit or Schedule hereto, the Agreement shall control.
- 15.12 **Counterparts; Facsimile Signatures** . This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 15.13 **Cumulative Remedies** . Unless otherwise expressly set forth herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under applicable law.
- 15.14 **Waiver of Rule of Construction** . Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.
- 15.15 **Construction** . For purposes of this Agreement: (a) words in the singular shall be held to include the plural and vice versa as the context requires; (b) the words "including" and "include" shall mean "including, without limitation," unless otherwise specified; (c) the terms "hereof," "herein," "herewith," and "hereunder," and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; and (d) all references to "Section", "Schedule" and "Exhibit," unless otherwise specified, are intended to refer to a Section, Schedule or Exhibit of or to this Agreement.
- 15.16 **Export Control**. This Agreement is made subject to any restrictions concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to the Parties from time to time (" **Export Control Laws** "). Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other Governmental Authority.

(Signatures appear on following page.)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Other Compounds

[**]

]

[**] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Technology Transfer Plan

*To be mutually agreed by Parties and added within [***].*

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Regulatory Approval Plan

*The Provisions of the Regulatory Approval Plan regarding the Required Documents are complete and effective as provided below. The remainder of the Regulatory Approval Plan will be added within [***]. Pint will draft the remainder of the Plan, for approval by Puma, not to be unreasonably withheld or delayed.*

The following **Required Documents** must to be provided by Puma to Pint on or before the **Required Document Deadline** (except as expressly provided below), for use by Pint in obtaining Regulatory Approvals, including Marketing Authorizations, for Nerlynx in the Initial Indication in each of the following countries: [***].

All Required Documents will be delivered in the form Pint reasonably determines is appropriate for obtaining Regulatory Approval, including Marketing Authorization, for Nerlynx in the Initial Indication in each of the seven countries.

[***]

In addition, Puma agrees to use Commercially Reasonable Efforts to provide to Pint any additional documents that the Parties reasonably agree in good faith are required by any Regulatory Authority in any of the seven countries, (with Puma having reasonable time, not to exceed [***] from notice from Pint that such documents are required, to obtain such additional documents); provided that such additional documents shall not be deemed to be Required Documents hereunder. Examples of such additional documents might include:

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Data Base Plan

*To be added within [***]. Pint to draft, Puma to review and approve, such approval not to be unreasonably withheld or delayed.*

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Supply Agreement Terms

1 Packaging and Labeling.

- 1.1 Puma will supply each Product with labels and packaging as specified by Pint, provided that Puma shall not be obligated to supply more than [***] distinct labelling and packaging configurations unless Puma otherwise agrees, in its sole discretion.
- 1.2 Pint will specify secondary packaging as required by each applicable authority.
- 1.3 Product will be delivered by Puma to Pint on a “release for supply” basis for export by Pint or its designee to markets in the Territory.
- 1.4 Subject to the foregoing, Puma will supply the Product to Pint in [***] form, including [***].
- 1.5 Any Product supplied for named patient or similar sales will be supplied with [***] labelling.

2 Samples for regulatory purposes (including any testing required for regulatory purposes).

- 2.1 Reasonable quantities to be supplied [***].

3 Forecasts and Orders. [***]

4 Batch size. Products ordered for commercial sales to be ordered in batches of at least [*to be added by agreement of the Parties in definitive Supply Agreement*] units. [***]

5 Lead times for Product orders.

- 5.1 **For NPP sales:** to be supplied on approximately on [***] notice .
- 5.2 **For Commercial Sales:** [*to be added by agreement of the Parties in definitive Supply Agreement; may vary based on whether new packaging or labelling is required*]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

5.3 **Time for Puma to confirm commercial orders after Pint has placed a PO: [***]**

6 **Shelf life on Delivery:** at least [***].

7 **Delivery.** Deliveries will be [***] (Incoterms 2010) at [***] and title and risk of loss will pass to Pint upon [***].

8 **Purchase Price .** Transfer price will be all inclusive, including payment for all labor, labelling, packaging, Product and any other costs. The transfer price will be Puma's per unit allocable cost of goods sold for the Product plus an additional [***] thereof, as more fully defined in Supply Agreement.

9 **Payment Terms :** [***] from delivery

10 **Country of Origin:** [***]

11 **Production Allocation.** Puma shall allocate its production capacity for the production of Product to be supplied to Pint on a basis that [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

All Puma Patents Rights existing as of the Effective Date in the United States and the Territory, indicating in the case of each Puma Patent Right the source of Puma's Control over such Puma Patent Right

*To be added by Puma within [***]*

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**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, 2018;
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, 2018

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

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

I, Charles R. Eyler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2018;
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, 2018

/s/ Charles R. Eyler

Charles R. Eyler

Principal Financial and Accounting Officer

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

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2018, 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, 2018, 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, 2018

/s/ Alan H. Auerbach

Alan H. Auerbach
Principal Executive Officer

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

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

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2018, 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, Charles R. Eyler, 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, 2018, 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, 2018

/s/ Charles R. Eyler

Charles R. Eyler

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.